The State of Research Integrity and Misconduct Policies in Canada

Prepared for:

Canadian Research Integrity Committee

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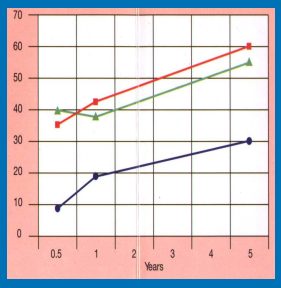

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INNOVATION POLICY ECONOMICS

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Images on Cover: Cartoon from S. Titus, J. Wells and L. Rhoades. 2008. “Repairing Research Integrity”. *Nature*, Vol 453,19; and painted mice from W. Summerlin, MD falsified skin graft study, 1973.

This report was prepared by a team of HAL consultants led by Tijs Creutzberg, PhD. HAL is Canada's premier consulting company specializing in innovation, policy, and economics for organizations using, promoting, or supporting science and technology.

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Executive Summary

Objective and Scope

The purpose of this study is to develop a comprehensive understanding of the organizations and policies that define how allegations of research misconduct are addressed in Canada and in other selected countries. The study is to inform a discussion to be led by the Canadian Research Integrity Committee about how best to strengthen Canada's research integrity system.

To this end, the study analyzes both the policies and organizations that define how the Canadian system works and individual research integrity policies at Canadian research organizations that set out how allegations of misconduct are responded to. In addition, the study provides insight into the prevalence of research misconduct in Canada and concludes with a discussion of options for strengthening the country's research integrity system.

The focus of this report is on policies related to *research integrity*, which emphasize such principles as honesty, carefulness, and fair recognition, and to its converse, *research misconduct*, which refers to the unacceptable behaviors related to the scientific process, including fabrication of data, falsification of data and plagiarism. Though conceptually related, research integrity and misconduct policies are, in practice, distinct and separate from those addressing *research ethics*, which are concerned with ensuring that the scientific methodology (i.e. how one carries out the research) is in line with accepted ethical norms and practices. Research ethics policies are outside the scope of this study.

The Issue

Though Canada's system for addressing research integrity and misconduct, is, as this study finds, generally well regarded, it is not without shortcomings. Indeed, there is a wide perception within the broader research community that much more needs to be done to strengthen Canada's approach for addressing research integrity and misconduct lest there be more damaging impacts following any future revelations of gross research misconduct.

Canada is by no means alone in looking to improve its system. This study examines research integrity systems in eight other countries and finds that all are in a conversation about how best to improve their respective approaches.

The global concerns over research misconduct stem from a number of negative impacts that each public case can bring to science as a whole. These include the damage to science as a result of the wasted time, effort and resources of the researchers and institutions who follow up on fraudulent findings; the potential harm to individuals and to society should fraudulent research

lead to the commercialization of unsafe products or processes, or if falsehoods become widely known and accepted as truths; and its consequences for the public's trust in science, a trust that ultimately underwrites much of the financial support for a country's public research system.

A Complex Policy Landscape for Research Integrity

The Canadian policy landscape governing research integrity is multi-faceted and multi-levelled, comprising a mix of policies, codes of conducts, and guidelines directly and indirectly influencing how actors within the research community respond to issues of research integrity and misconduct. Collectively, these policies have jurisdiction over nearly all publicly funded research conducted in Canada. Private sector research is generally outside the reach of Canada's current system.

Despite its decentralized character, Canada's research integrity system has an influential locus of policy coordination and leadership that resides with the three federal granting councils, and in particular, through their *Tri-Council Policy Statement on Integrity in Research and Scholarship* (TCPS-IRS) and related documents which are enforced through a Memorandum of Understanding between the granting councils and eligible institutions that receive funding and is signed by institution presidents. The TCPS-IRS has been the most influential mechanism for achieving a degree of policy coordination and compliance across the research system in Canada, despite only having formal jurisdiction over academic and medical research institutions that receive council funding.

How the System Works

The various policies, codes and guidelines that shape the core of the Canadian oversight system explicitly and implicitly recognize that the responsibility for responding to allegations of misconduct resides with the institutions where the research misconduct is alleged to have occurred. Institutions respond to allegations in accordance with their own policies for addressing research integrity and misconduct, which have been developed within the framework of the TCPS-IRS, and other institutional, international and, or, provincial policies.

As a passive 'fire alarm' system, however, institutions and their policies for responding to allegations are only one part of the system. Analogous to the use of an actual fire alarm system, triggering the alarm depends on individuals who are aware of the policies, have a sense of professional responsibility, and have assurances that there would be no serious repercussions for speaking up.

Institutional Policies

Of the 42 institutions analyzed in this study, all non-government research institutes and close to half of the major government science-based departments and agencies contacted have policies in place that provide guidelines and standards for addressing research misconduct. These policies generally have jurisdiction over all research and scholarly activity at respective institutions; for

universities and colleges, they also apply to students involved in research activities which are not related to their course work.

The majority of these policies are similar in structure and scope owing to the fact that most publicly funded research in Canada is influenced directly or indirectly by the TCPS-IRS. Institutions that are compliant with this policy are required to develop and observe a number of general principles related to research integrity and misconduct, and outline procedures for processing allegations and reporting to the councils.

There are nonetheless notable differences in policy content among research organizations due to the flexibility inherent to the TCPS guidelines that allow policies to be tailored to respective institutional environments. One of the areas where policies differ is in the definition of research integrity and misconduct. While nearly all policies explicitly recognize falsification, fabrication and plagiarism in their definitions of what constitutes misconduct, there is far less consensus on what other misconduct behaviors and practices to include.

This study suggests that Canada consider adopting an explicit national definition of research misconduct that identifies sanctionable behaviors in addition to the current definition of research integrity. This step would help reduce variation in research integrity policies at the institutional level.

The State of Canada's Research Integrity System

This study finds a research integrity system in Canada that, despite a number of inherent shortcomings, is generally viewed as functioning reasonably well among those with experience working with the system. Canada's system also compares relatively well internationally. Its decentralized approach that gives primary responsibility to research institutions for addressing allegations is widely viewed in a positive light, as is the role that the granting councils play in instituting policy requirements. It is accommodating of the complexity of many misconduct allegations and allows for discretion in dealing with cases, many of which, it is noted, are based on misunderstanding or due to poor oversight.

Moreover, Canada's system, not having been legislated, has maintained a degree of flexibility that has allowed for improvements as a result of learning from experiences. The granting councils have been introducing new requirements over the years by way of new schedules and frameworks, while many research institutions have been updating their policies both in response to the granting councils, and to their own experiences in dealing with allegations.

Because of these strengths, this report suggests that any changes to Canada's research integrity system should be in keeping with Canada's current non-legislated approach which defers to the granting councils for leadership on policy issues. As is revealed in the comparative analysis, the Canadian approach holds up relatively well in an international context and that there is no one best model that Canada could adopt which does not have drawbacks.

Canada's system is not, however, functioning equally well for all actors and for all areas of research. The greatest concerns come from the actors in the health sciences - medical research organizations, universities, and journal editors. This group not only has more experience with research misconduct, but also heightened understanding of what is at stake should research misconduct be left unaddressed.

While this group does recognize the basic strengths of the system, it also recognizes the need for Canada to address its shortcomings, including: a weakness in formal oversight; inadequate reporting requirements; inconsistent educational efforts; differing definitions as to what constitutes research misconduct; and poor whistleblower assistance.

To adequately address key issues related to oversight, education and training and whistleblower assistance, this report suggests that Canada consider a national system that gives well-meaning individuals with concerns a place to go for information and assistance that is independent from their employer. Canadian researchers have no such place, leaving those frustrated by existing processes in dealing with legitimate complaints and issues to become dismissive of the system. As a central node of the system, such a place can attend to a number of shortcomings in Canada's current system by providing:

- visibility and a focal point to the system that is important if Canada is to improve awareness of research integrity issues and to respond effectively to related international issues;
- a degree of oversight, however informal, that can encourage institutional compliance with research integrity policies;
- a logical point for collecting and sharing experiences and other data; and
- support for education and the dissemination of training guidelines and information.

Prevalence of Research Misconduct in Canada

The 29 institutions that provided data on research misconduct for this study collectively acknowledge dealing with some 39 cases per year. Together, these institutions account for approximately 60 percent of publicly funded research conducted in Canada.

This estimate should be treated with the appropriate caution given the challenges associated with collecting this information. In addition to research institutions having little incentive to share this information, there is a strong likelihood that misconduct cases go unreported by researchers due to an unwillingness to risk one's own reputation or sour relationships with colleagues, or simply an unwillingness to engage a process that can lead to frustration and additional work stress. Under-reporting also comes about when allegations are reported but are then 'swept under the carpet' at some level of the institution. Anecdotes from interviews conducted for this study attest to all of these instances.

Another complicating factor is related to the definition of research misconduct itself. Allegations can only be made in a consistent manner if there is a national consensus - and awareness of this consensus - on what constitutes research misconduct. While no one disputes the more serious breaches of falsification and fabrication, there is far more scope for under-reporting more minor violations, some of which may occur frequently in a particular research community, unbeknownst to those perpetuating the misconduct, that a certain practice is elsewhere viewed as entirely unacceptable. Nonetheless, as many have noted, it takes only one major case to damage the integrity and reputation of the research system.

Opportunities for Strengthening Canada's Research Integrity System

There are a number of compelling reasons why Canada should strengthen its system. Foremost is the need to ensure that future research misconduct, for which there will always be a risk, does not continue to damage Canada's scientific endeavors, as have past scandals. And related to this is the need to mitigate damage that research misconduct brings to the public trust in science, which is important both for the funding of science and for accepting the role of scientific evidence in public policy making. Finally, in recognition of the fact that science is now very much a global activity, Canada must be seen to be a leader in maintaining the principles of research integrity by way of a system that can engender the confidence of, and engage with, the international science community. To this end the following options are put forth for discussion.

Option A – An Evolving Current System: The first option is to maintain the current system, while recognizing that it continues to be strengthened by the Tri-Councils. Indeed, the Tri-Councils are, at present, completing a review of the TCPS-IRS and related documents with the goal of improving existing policies and bolstering the effectiveness of the system as a whole.

Among the possible changes that should be explored and which would have a positive impact on the current system with limited disruption are:

- An explicit national definition of research misconduct that identifies sanctionable behaviors in addition to the current definition of research integrity. This step would help reduce variation in research integrity policies at the institutional level.
- Strengthened reporting requirements that necessitate the public reporting on an annual basis of all cases where research misconduct is found.
- An elaboration of timelines within the *Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research* that set out the number of days to complete each stage of the process for addressing misconduct allegations. This step would support fairness and accountability.

Any considerations to enhance the role that the Tri-Councils play in Canada's research integrity system must accommodate two realities. First is that the granting councils are only able to institute changes within their jurisdiction of influence and mandate for promoting and supporting research, knowledge acquisition and training. Second, an enhanced role can aggravate the

problem identified in this study of competing obligations and interests. While the councils are well positioned to develop policies related to research misconduct, they are not so well situated for being directly involved in specific cases, cases which can tarnish the reputations of all involved.

Option B - Office of an Ombudsperson: Establishing an office of an ombudsperson whose primary role is as a trusted intermediary as opposed to an investigator of allegations, offers a number of benefits that cannot be readily achieved through Option A. First, it would provide an official, centralized point of contact that is independent of the research institutions, and which could carry the label of, and be recognized as, the focal point of Canada's research integrity system. Until such a visible node is created, the wide spread perception that Canada 'has no national research integrity system' will continue.

If the German model is to be followed, the office of an Ombudsman need not be a costly institution. If established under the umbrella of the Tri-Councils, as in the German system, it could be limited to only one individual appointed by the Tri-Councils on a full or part time basis for a limited period of time, with assistance of secretariat support.

Its role as a trusted intermediary, committed to the highest standards of research, would include providing advice and guidance to researchers and research institutions addressing allegations of research misconduct. The Office would not be called on to undertake investigations.

Option C - Canadian Office of Research Integrity: The third option is to establish a Canadian Office of Research Integrity that would take on the role of ombudsman as per Option B but with expanded responsibilities in the area of education and training, in advising institutions undertaking investigations, and with compiling statistics on misconduct and best practices for addressing allegations. As with an Office of the Ombudsman, a Canadian Office of Research Integrity would serve as a central focal and contact point to Canada research integrity system but would broadcast a stronger message internationally that Canada is committed to upholding research integrity.

If modelled on the UK Research Integrity Office, a Canadian equivalent would be hosted by the Association of Universities and Colleges of Canada with support from government and major funders of research. Such an office could develop a number of relevant services made available to all research organizations and institutions in Canada including:

- a research integrity helpline;
- a register of advisers and experts who would be available to advise on or be involved in an institution's investigation;
- provision of a handbook that outlines in-depth all the necessary steps and procedures for investigating various types of research misconduct allegations; and
- Education and training services including the development of courses.

In summary, though each has advantages, no option on its own can adequately address all of the system gaps identified in Chapter 5. Furthermore, none of the three options proposed adequately address the fact that neither government nor private sector fall within the jurisdiction of the main system. However, should either an Office of the Ombudsman or an Office of Research Integrity be considered, its influence need not be limited to universities and colleges for it would be a logical focal point for fielding calls from, and disseminating information to, both government and private sector researchers.

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Key to Abbreviations

42CFR93	42 Code of Federal Regulations Part 93 (US)
APEGGA	Association of Professional Engineers, Geologists, and Geophysicists of Alberta
AUCC	Association of Universities and Colleges of Canada
CALJ	Canadian Association of Learned Journals
CAP	Commission administrative paritaire (France)
CFHSS	Canadian Federation of Humanities and Social Sciences
CIHR	Canadian Institutes of Health Research
CNRS	Centre national de la recherche scientifique
COI	Conflict of Interest
COPE	Committee on Publication Ethics
CRIC	Canadian Research Integrity Committee
DCSD	Danish Committees on Scientific Dishonesty
FFP	Falsification, fabrication and plagiarism
FRSQ	Fonds de la recherche en santé
ICMJE	International Committee of Medical Journal Editors
MOU	Memorandum of Understanding
NIH	National Institutes of Health (US)
NSERC	Natural Sciences and Engineering Research Council
ORI	Office of Research Integrity (US)
QRP	Questionable research practices
REB	Research Ethics Board
RI	research integrity
SBDA	Science Based Departments and Agencies
SPPA	Ontario Statutory Powers Procedures Act
SSHRC	Social Sciences and Humanities Research Council
TCPS-IRS	Tri-Council Policy Statement – Statement on Integrity in Research and Scholarship
VPR	Vice President of Research

1. Introduction

1.1 Study Background

In January 2007, Health Canada, together with the Canadian Research Integrity Committee (CRIC)[1], hosted a workshop that brought together key research stakeholders to launch the development of a Canadian position and plan of action on research integrity. The workshop, *Research Integrity: Towards a Canadian Approach,* had four objectives at the outset: to review and assess approaches to addressing misconduct and other research integrity issues in Canada and other countries; assess strengths and weakness; identify whether improvements should be made; and what are the appropriate next steps including, possibly, the future role of the CRIC.[2]

One of the outcomes of the workshop was a recommendation that CRIC take further steps and develop a follow-up plan from the workshop, including a review and examination of policies related to research integrity and misconduct in Canada and the international community. This study was commissioned by CRIC to address this recommendation.

Objectives

The purpose of this study is to develop a comprehensive understanding of the organizations and policies that define how allegations of research misconduct are addressed in Canada and in other selected countries so as to inform a discussion to be led by CRIC about how best to strengthen Canada's research integrity system.

To this end, the report analyzes the policies and organizations that define how the Canadian system works, as well as the research integrity policies at Canadian research organizations including universities, colleges, hospitals and science based departments and agencies. For an international perspective on Canada's system, a comparative analysis of research integrity systems in eight advanced economies is included. Selected countries are: Australia, Denmark, France, Germany, Japan, Norway, the UK and the US. In order to gauge the magnitude of the problem of research misconduct, the study is also tasked with estimating the prevalence of research misconduct in Canada.

[1] CRIC is an affiliation of 16 Canadian research and academic institutions including 3 granting councils and the Association of Faculties of Medicine of Canada (see Appendix A for membership).
[2] See Plamondon and Associates, "Research Integrity Workshop Discussion Paper" January 22-23, 2007.

Scope

The focus of this study is on policies related to *research integrity*, which emphasize such principles as honesty, carefulness, and fair recognition[3], and to its converse, *research misconduct*, which refers to the unacceptable behaviors related to the scientific process, including fabrication of data, falsification of data, and plagiarism. Though conceptually related, research integrity and misconduct policies are in practice distinct and typically separate from those addressing *research ethics*, the latter of which are outside the scope of this study.

Whereas research ethics policies are concerned with ensuring that the scientific methodology is in keeping with accepted ethical norms and practices, research integrity and misconduct policies are focused on maintaining the highest standards of research and on addressing deceitful behaviors when they arise, irrespective of whether the process by which the research was conducted was in fact ethical. To the extent that the two areas overlap, it is when one policy references the other. For example, it is common for definitions of research integrity to include as misconduct any breach of regulations pertaining to research ethics.

Another area related to research integrity but which is outside the scope of this study is that of conflict of interest in research. Though an increasing number of institutions are developing policies explicitly addressing conflict of interest - now a requirement for those receiving funding from the federal granting councils - most definitions of research integrity will also include the failure to reveal conflict of interest as research misconduct. For a more detailed discussion of definitional issues, see Chapter 4.

1.2 Research Integrity as a Canadian and Global Issue

Though examples and suspicions of research misconduct date back to earlier eras of science - to, for example, claims that Gregor Mendel falsified data in his seminal 1866 work on genetics[4] - policies for dealing with research integrity and misconduct are far more recent. Indeed, policies only began to be developed in the early 1980s, with the US leading the way, once universities began to recognize their responsibility in upholding research integrity. According to Steneck in his 1994 review of US scientific misconduct policies, continued confidence in the 'self-correction' process of science, realized primarily through the editorial and peer review process, had 'more than any other factor' delayed the adoption of policies and processes for dealing with misconduct.[5]

By the late 1980s, however, the trend was undeniable: 'most of the major and about half of the middle range research universities [in the US] had adopted scientific misconduct policies', at which time efforts to legislate processes to deal with cases at the federal level in the US were

[3] According to Resnik, there are 12 ethical and moral principles underlying the conduct of science by scientists: honesty, carefulness, openness, freedom, credit, education, social responsibility, legality, opportunity, mutual respect, efficiency, and respect for subjects. See D. Resnik. 1998. *The Ethics of Science: An Introduction*. Routledge. New York, NY.
[4] Hartl D., and D. J. Fairbanks. 2007. "Mud Sticks: On the Alleged Falsification of Mendel's Data". *Genetics* 175(3).
[5] N. Steneck 1994. "Research Universities and Scientific Misconduct", *Journal of Higher Education, Vol 65, no. 3. P. 310.*

well underway.[6] By the early 1990s, the US had set up an independent body, the Office of Research Integrity, to oversee and respond to cases that arose from the scientific community.

During the 1990s, many other countries followed the US lead including Denmark, Australia and the UK, each establishing committees and other organizations to develop policies and processes to address research integrity and misconduct.[7] Canada also took steps at this time, establishing, among other efforts, a policy statement from the three federal funding councils for medical, natural and social sciences, outlining a definition of research integrity, corresponding responsibilities and guidelines for promoting integrity and investigating allegations.[8]

However, despite having had a policy framework or institutional systems in place for some time, countries and their respective research communities continue to debate how well these systems are working. There are several reasons for this. One is that the research environment in Canada and in other advanced economies has been subject to ever increasing productivity pressures. Governments for their part have been strongly promoting partnerships with publicly funded research organizations so as to extract greater economic returns from their R&D investments. This trend has coincided with a greater dependency by industry on the public science base for its innovations[9], and with universities themselves seeking private sector sources of funding to supplement their research undertakings.

The cumulative effect has been the emergence of a research environment characterized by complex public-private relationships that has increased the potential for the corrosion of research integrity.[10] Competition among scientists and the growing importance of publication records and citation rates to career promotion has added further stress to the research environment, a manifestation of which is the erosion of collegiality.[11] This is so even in the government research sector where bibliometric indicators, such as citation rates and publication counts, now inform assessments of institutional performance.

[6] See Steneck 1994. P. 315, and C. B. Pascal (1999) "The history and future of the office of research integrity: Scientific misconduct and beyond" in Science and Engineering Ethics, Volume 5, Number 2, pp. 183-198(16)

[7] See European Science Foundation. 2008. "Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practices in Europe". Strasbourg: ESF.

[8] See "Tri-Council Policy Statement: Integrity in Research and Scholarship". http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/tpsintegrity-picintegritie_eng.asp.

[9] A 1997 study by Narin found that close to three quarters of the references to published articles in patents were to public science organizations and that the number of references to public science nearly tripled over the six-year period covered. Narin F. K. Hamilton and D. Olivastro (1997). "The Increasing linkage between US Technology Policy and Public Science", *Research Policy*, Vol. 26, p. 317-330.

[10] The phenomenon of medical ghostwriting is one manifestation of this new environment, whereby companies craft research papers in support of their drug and seek out researchers willing to be listed as authors in exchange for money and other benefits. See D. Healy, *Let Them Eat Prozac*, Lorimer: Toronto. 2003. See also J. Thompson "Academic Integrity and the Public Interest" in J. Turk (ed.) *Universities at Risk*. Lorimer: Toronto 2008, for a discussion of the factors leading to the corrosion of academic integrity.

[11] Recent research of US scientists has found that "competition contributes to strategic game-playing in science, a decline in free and open sharing of information and methods, sabotage of others' ability to use one's work, interference with peer-review processes, deformation of relationships, and carless or questionable research conduct." See Anderson M. et al. (2007) "The Pervasive Effects of Competition on Scientists' Work and Relationships" *Science and Engineering Ethics* 13: 437-461.

Yet another reason why research integrity continues to be an important issue is the globalization of science. As a worldwide endeavor, scientific knowledge is now generated by a much greater number of countries than at any time prior, some of which may or may not uphold the same standards of research. For Canada, this factor comes into play when a Canadian institution collaborates with an institute in a foreign country which may have limited or no policies in place for dealing with, or promoting, research integrity, and may not adhere to the same scientific norms. And as a country that recruits researchers and attracts graduate students from around the world, cultural differences have become an additional factor for a number of institutions in Canada, as was noted on several occasions in this study. "We are trying to get the best people [from all over the world]", noted one senior university administrator, but "you can't assume that standards of ethics and integrity are the same".

Heightened interest in the subject of research misconduct also stems from the public reactions that typically follow revelations of gross research misconduct, often which are accompanied by renewed calls for re-examining the self-regulating nature of science and the mechanisms for dealing with allegations.[12] Such re-examining does appear, however, to be having a positive effect not only in Canada but in a number of countries reviewed in this study. Drawing on their experiences in responding to allegations, several countries have introduced changes to their systems or policy frameworks first established in the 1990s. The Canadian federal granting councils, for example, have been developing their policies, adding in a review framework for institutional research integrity policies, a requirement for institutions to have a conflict of interest in research policy, and new rules around the transfer of funds between eligible institutions and non-eligible institutions.[13]

Despite these improvements, there is a wide perception within the research community that much more needs to be done in Canada to address research integrity. Capturing this sentiment is a 2007 editorial from the Canadian Medical Association Journal where the editors ask: "Why has Canada lagged so far behind its Western counterparts in establishing comprehensive mechanisms and processes to deal with scientific misconduct?" [14] A key issue for this study is how Canada's institutional system compares to other countries.

Consequences of research misconduct

Research misconduct has a number of negative impacts, as identified in a recent OECD Global Science Forum workshop.[15] First is the damage to science as a result of the wasted time, effort and resources of the researchers who follow up on fraudulent findings. In fact, research has

[12] The genesis of the Canadian Research Integrity Committee was the well publicized case of Ranjit Chandra accused of committing fraud by the British Medical Journal. See also European Science Foundation. 2008. "Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practices in Europe". Strasbourg: ES

[13] See Section 2.1 Schedule 9, part B of the MOU.

[14] Kondro W. and P. Hebert. 2007. "Research Misconduct? What Misconduct?". *Canadian Medical Association Journal* 176(7): 905.

[15] OECD Global Science Forum. 2007. "Unofficial Report on Best Practices for Ensuring Scientific Integrity and Preventing Misconduct". Fourth Draft of August 1 2007.

shown that this damage can persist long after an official retraction due to the tendency of researchers to continue to make citations of discredited work well after the retraction date.[16]

Another negative consequence identified is potential harm to individuals and to society should fraudulent research lead to the commercialization of unsafe products or processes, or if falsehoods become widely known and accepted as truths. Research misconduct can also poison a research environment of a particular institution, degrading relations among scientists, between scientists and students and between the administration and faculty.

Finally, research misconduct has consequences for the public's trust in science which ultimately underwrites much of the financial support for a country's public research system. In Canada, public funding for research is critical to the approximately 120 public research organizations in Canada, including some 50 universities, 15 federal or provincial government departments and agencies, and 30 research oriented hospitals.[17] In 2007, Canada's research institutions collectively received some $5.5 billion in federal support, of which $2.3 billion supported the government's own science based departments and agencies.[18,19] The provinces also contribute to Canada's research system providing over $1.4 billion in funding in 2007.[20]

1.3 Approach and Methodology

This study assesses research integrity and misconduct in Canada at two levels. The first is at a national level where the focus is on the various research actors and policies that shape oversight of research integrity in Canada as a whole (Chapter 2) and which determines how the system should be functioning (Chapter 3). In support of this system level assessment, interviews were conducted with key actors, experts and stakeholders, including the federal granting councils, universities and colleges, scholarly journals and societies, and higher education associations.

The second level of analysis is from the perspective of the research institution whose policies define how specific misconduct allegations are dealt with. At this level, 37 policies were analyzed, drawing on interviews with respective institutions (Chapter 4). Research integrity policies were selected from the various types of research organizations including universities and colleges, government science based departments and agencies and medical research organizations (Figure 1), and from different regions across the country (Figure 2).

[16] Articles retracted by editors often continue to be cited long after retraction. According to Redman et al. (2008), the "primary reasons for retraction were research error, inability to reproduce, research misconduct and plagiarism. In the span of 10 years, the 315 retracted articles cumulatively were cited 3942 times before retraction and 4501 times after retraction." See B K Redman, H N Yarandi and J F Merz. "Empirical developments in retraction". *Journal of Medical Ethics* 2008;34:807-809

[17] These numbers are based on institutions with over 50 publications, as recognized by Thompson Scientific, Science Citation Index. Note that in total, there are over 205 public research organizations in Canada include 197 institutions that are eligible for Tri-Council funding.

[18] See Figure 1.1. AUCC. 2008. *Momentum: the 2008 Report on University Research and Knowledge Mobilization*.

[19] Statistics Canada (2008). "Federal Scientific Activities" 2007/2008, Catalogue No. 88-204-XWE.

[20] AUCC 2008. Momentum.

Interviews with institutions were conducted primarily at the senior level - VPs of Research, Provosts or Deans of universities or colleges, Research Directors of medical research organizations and Directors or Director Generals of government departments and agencies. These were semi-structured, 60-90 minutes in length, and involved mostly open-ended questions related to the administration of research integrity policies, the effectiveness of Canada's research integrity system as a whole and to the prevalence of research misconduct.

These two levels of analysis allow for a critical examination of the effectiveness of Canada's current system (Chapter 5). To gain perspective on how Canada's national system measures up internationally, the study includes a comparative analysis of Canada's system that compares Canada against eight other countries (Chapter 6). Case studies profiling each country were developed drawing on interviews and a document and literature review (Appendix B).

As part of the system level analysis, this study also estimates how significant the problem of research misconduct is in Canada (Chapter 7). Data for this component is drawn from interviews and a literature review.

Figure 1: Canadian Institutional Research Integrity Policies, by Institution Type

Type	No. Interviews	No. of Policies Reviewed
College	4	4
Government	8	3
Medical Research Organizations	3	3
Large* Universities	21	21
Medium* Universities	4	4
Small* Universities	2	2
Journals/Learned Societies/Experts	7	N/A
Higher Education Associations	2	N/A
Federal Granting Councils	4	5
Industry	1	N/A
Other	4	N/A
Total	60	37

*These categorizes, used by Statistics Canada, reflect income from sponsored research. Small Universities are those that conduct less than $25 million in research, medium universities conduct between $25m and $79m and large conduct more than $80m (18). See C. Read 2007, "Size counts: Outcomes of intellectual property (IP) commercialization" Innovation Analysis Bulletin, Vol. 9, no. 1.

Figure 2: Canadian Institutional Research Integrity Policies, by Region

Region	Policies (Not including Federal Gov't)
Western Canada	6
Prairies	4
Ontario	15
Quebec	8
Atlantic Canada	5

2. Policy Landscape for Research Integrity Oversight in Canada

The Canadian policy landscape governing research integrity is multi-faceted and multi-levelled, comprising a mix of policies, codes of conducts, and guidelines directly and indirectly influencing how actors within the research community respond to issues of research integrity and misconduct. Collectively, these policies have jurisdiction over nearly all publicly funded research conducted in Canada, and formally define a decentralized 'fire alarm' system for responding to allegations. This fire-alarm system, in contrast to a more costly 'police-patrol system'[21], achieves monitoring and policy compliance passively, as opposed to through active surveillance, and is set in motion only by allegations of improper research conduct.

Within this system, however, no one policy, code or guideline extends its influence across all of the research community in Canada. As Figure 3 indicates, these documents have generally been developed independently around three sets of research performing actors: non-government research institutions, which include universities, colleges, research hospitals and other non-profits; government science-based departments and agencies; and some private companies. A fourth grouping integral to the research community but which does not perform research per se, comprises a number of affiliated actors such as academic journals and professional societies which may choose to adhere to national or international policies, codes and or guidelines set by organizations within or outside of Canada.

2.1 Non-Government Research Institutions

Despite its decentralized character, Canada's research integrity system has an influential locus of policy coordination and leadership that resides with the three federal granting councils, Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC) and Social Sciences and Humanities Research Council (SSHRC). Since the mid 1990s, these granting councils have required all institutions that receive their funding to develop a policy for research integrity and misconduct that complies with the principles and guidelines set out in their *Tri-Council Policy Statement on Integrity in Research and Scholarship* (TCPS-IRS). The TCPS-IRS, which is directed at the researcher and the institution, is supported by a second document, *Schedule 4: Integrity in Research and Scholarship*, which sets out the responsibilities of the institutions and the granting councils in supporting research integrity.

[21] See McCubbins, Mathew D.; Schwartz, Thomas. "Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms" *American Journal of Political Science*, Feb84, Vol. 28 Issue 1, p165, 15p; (AN 5241535)

Figure 3: Primary Policy Context for Research Integrity (RI) and Misconduct

Schedule 4 is one of 15 schedules that make up a Memorandum of Understanding between the granting councils and eligible institutions that receive funding and is signed by institution presidents.[22] To help institutions comply with the TCPS-IRS and Schedule 4, the Tri-Councils have issued a third document, *Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research*, which outlines those items that should be included in institutional research integrity and misconduct policies in order to be eligible for funding.

The TCPS-IRS[23] has been the most influential mechanism for achieving a degree of policy coordination and compliance across the research system in Canada, despite only having formal jurisdiction over academic and medical research institutions that receive council funding. This influence is achieved in several ways. First the TCPS-IRS has been used as the quasi national standard by other organizations, including a number of science-based departments and agencies (SBDAs) which have used it as a template in the development of their own policies.

Second, by requiring all institutions that receive funding to have in place a policy on research integrity, the granting councils have succeeded in ensuring that all research conducted at eligible institutions - not just council-funded research - is covered by a research integrity and misconduct policy. Finally, the granting councils have extended the reach of the TCPS-IRS to non-eligible institutions that collaborate with eligible institutions by way of a new MOU schedule (Schedule 9). This schedule, which came into force in 2009, requires non-eligible secondary institutions to administer funds received from an eligible institution in accordance with the relevant Tri-Council policies as published in their formal guides and program literature and in the MOU.

Research integrity policies developed under the TCPS-IRS framework are also subject to provincial policies, notably provincial privacy legislation, which influences how institutions communicate with others when dealing with misconduct cases. Every province and territory has privacy legislation governing the collection, use and disclosure of personal information. In a number of provinces – Ontario, Nova Scotia, New Brunswick and Manitoba - these are supplemented by whistleblower protection policies applicable to government department and agencies and, in the case of Manitoba, to all organizations governed by the *Financial Administration Act* including universities, colleges and hospitals.[24] The *Manitoba Public Interest Disclosure Act*, which came into force in 2007, outlines procedures and protection for those making allegations of eligible wrongdoings.[25] One Manitoba-based institution noted that this new legislation has led to a discussion over how best to accommodate whistleblower protection

[22] Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards, http://www.nserc.gc.ca/institution/mou_e.htm. Note that this MOU comprising 15 schedules and which as been in effect since April 1 2008, is a successor to a previous MOU with 8 schedules.

[23] TCPS-IRS shall, from this point onwards, be a reference to all Tri-Council documents relevant to research integrity.

[24] For institutional jurisdiction see: The Public Interest Disclosure (Whistleblower Protection) Act (C.C.S.M. c. P217), http://web2.gov.mb.ca/laws/regs/pdf/p217-064.07.pdf

[25] The Act applies to the following wrongdoings in or relating to the public service: (a) an act or omission constituting an offence under an Act of the Legislature or the Parliament of Canada, or a regulation made under an Act; (b) an act or omission that creates a substantial and specific danger to the life, health or safety of persons, or to the environment, other than a danger that is inherent in the performance of the duties or functions of an employee; (c) gross mismanagement, including of public funds or a public asset;(d) knowingly directing or counselling a person to commit a wrongdoing described in clauses (a) to (c). http://web2.gov.mb.ca/laws/statutes/ccsm/p217e.php

in the context of research integrity, adding that it presents a challenge because the provincial policy is designed for non-academic institutions, and as such, some of its provisions are easier to apply than others.

Though a number of provinces do fund research, they do not necessarily have research integrity policies in place and rely instead on the TCPS-IRS based system. None, for example, were identified for Ontario, whereas in Quebec, the FRSQ (Fonds de la recherche en santé), which funds health science research, only makes passing reference to research integrity as part of its policy on research ethics – despite the fact that research integrity is referenced in the policy's title.[26] The Alberta Cancer Board is one of the exceptions, which likely reflects the fact that it is both a funder and performer of research in the health sciences. It maintains a research integrity policy that is in keeping with the typical template found at Canadian research organizations (see Chapter 4) and which is complemented by separate conflict of interest policy.

2.2 Government Research Organizations

On the federal government side, there is no equivalent document to the TCPS-IRS that requires research performing departments and agencies to have policies that deal specifically with research integrity and misconduct. As a result, a number of SBDAs– five of the eight reviewed - have no policy document in place that deals directly with research integrity and misconduct. There are, however, two codes of conduct that provide the imperative for SBDAs to maintain such policies. One is *A Guide for Ministers and Secretaries of State* which specifies a number of Ministerial responsibilities that, inherent to their fulfillment, requires research carried out under their auspices be conducted to the highest standards.[27] These responsibilities are to: preserve public confidence in integrity of management and operations within departments; maintain the tradition of political neutrality of Public Service; and third, maintain the ability to provide professional, candid and frank advice.

A second framework document applicable to all public servants is the *Values and Ethics Code for the Public Service* (effective as of 2003) which sets outs three public service values that have a bearing on research integrity, and which outlines conflict of interest measures and 'avenues for resolution'.[28] With regard to values, it calls upon public servants to first maintain 'Democratic Values' by helping Ministers to serve the public interest, "giving honest and impartial advice and making all information relevant to a decision available to Ministers" as well as loyally "implementing ministerial decisions, lawfully taken." 'Professional Values' are also emphasized whereby public servants are to serve with competence, excellence, efficiency, objectivity and impartiality. The third value is that of ethics which calls upon public servants to act at all times in such a way as to uphold the public trust. Where 'wrongdoings' arise, the Code recommends that

[26] See "Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique (FRSQ, 2008)", p. 6.
[27] Government of Canada. 2002. A Guide for Ministers and Secretaries of State. Privy Council Office. http://dsp-psd.pwgsc.gc.ca/Collection/CP22-65-2002E.pdf
[28] Government of Canada. 2003. *Values and Ethics Code for Public Service*. Canadian Government Publishing. www.tbs-sct.gc.ca

any public servant with an issue related to the Code should first talk with their manager or contact the senior official designated by the Deputy Head under the provisions of this Code.

A complaint of research misconduct may also, in principle, be made under *Public Servants Disclosure Protection Act*, introduced on April 15, 2007[29], and which outlines processes and procedures for addressing allegations of 'wrongdoings'. According to the Act, wrongdoings are defined as:

- Violating any Act of Parliament or any Act of the legislatures of Canada's provinces and territories;
- Misusing public funds or a public asset;
- Gross mismanagement;
- Doing something—or failing to do something—that creates a substantial and specific danger to the health, safety, or life of persons or to the environment;
- Seriously breaching the public sector Code of Conduct or the organization's Code of Conduct; and
- Knowingly directing or counseling a person to commit wrongdoing as defined above.[30]

Under the act, departments and agencies are each required to have procedures in place for responding to allegations of wrongdoing. A complainant, however, may also direct an allegation to the Public Sector Integrity Commission, which has shared accountability for the Act and which generally investigates only the more serious breaches, where public interest is deemed to be sufficiently affected.

Among departments without any explicit research integrity policy, one representative noted that this framework, and in particular the Value and Ethics Code, was considered adequate for dealing with research integrity although they did add that they had no experience in dealing with a misconduct allegation. Another with experience in dealing with allegations noted the contrary - that in practice, the code proved difficult to apply due to its lack of specificity.

Among departments and agencies that do have research integrity policies, these are generally comprehensive, and exceed the minimum criteria established in the TCPS-IRS framework. Thus, in addition to defining research misconduct, policies outline processes and procedures for

[29] Note that the new Public Servants Disclosure Protection Act has replaced *Policy on the Internal Disclosure of Information Concerning Wrongdoing in the Workplace* Government of Canada. 2003. *Values and Ethics Code for Public Service.* Canadian Government Publishing. www.tbs-sct.gc.ca http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tb_851/vec-cve1-eng.asp#_Toc46202820

[30] Under this Act, Federal employees may make confidential allegations directly to their supervisor or their organization's designated Senior Officer for Disclosure, according to their organizations internal procedures, or they may choose to notify directly the Public Sector Integrity Commissioner. In finding acts of wrongdoing, procedures require that the Commissioner report to respective chief executives with investigation findings and recommendations for corrective action. The Commissioner may also request that chief executives report back to Public Sector Integrity Canada on the actions taken, within a specific timeframe, and may report to the Minister responsible for the related department or agency, or the board or governing council of a Crown corporation if the recommended actions have not been taken within a reasonable time frame or if the situation may constitute an imminent risk of substantial or specific danger to the life, health or safety of persons or the environment. Source: Canada Public Service Agency website. http://www.psagency-agencefp.gc.ca

dealing with research integrity that are specific to the policy and distinct from other departmental procedures that address wrongdoings.

2.3 Compliance with US Research Integrity Policy

Canadian institutions that receive funding from the US National Institutes of Health (NIH) (Department of Public Health Service (PHS)) must comply further with Policies on Research Misconduct, 42 Code of Federal Regulations Part 93 (42CFR93), which is overseen by the Office of Research Integrity (ORI), PHS.[31] In 2007, some 42 Canadian institutions received over US$45 million from the NIH including a number of research hospitals and the National Research Council.[32]

Canadian institutions that comply with 42CFR93 generally have more comprehensive research integrity policies than their non-compliant counterparts due to the more extensive requirements of the 42CFR93 as compared to Canada's TCPS-IRS. The ORI has developed a statement that outlines what is required from foreign institutions, and which is to be a permanent amendment to research integrity policies of eligible institutions. Among the differences with Canada's TCPS-IRS is the requirement to inform research employees of the designated official responsible for receiving allegations and to publish their name on the institution's website. Institutions are also required to submit an "Annual Report on Possible Research Misconduct" to ORI (via an online web form) with information on any allegation or investigation involving "receipt of or requests for PHS funding or application for PHS funding" and which falls under PHS definition of research misconduct of fabrication, falsification or plagiarism.[33]

One notable outcome which arises with institutions that comply with US policy is that the name of any Canadian accused of research misconduct involving US funds is published by the ORI. Between 1994 and 2007, the ORI has found three individuals at two Canadian institutions to have committed research misconduct.[34] Provincial and federal privacy legislation in Canada prevents Canadian institutions from disclosing such names.

2.4 The Private Sector

There is no requirement in Canada for Canadian companies conducting and publishing research to have in place policies for dealing with research integrity and misconduct issues. The extent to which companies have developed such policies is difficult to determine due to an unwillingness to disclose such information.

[31] Note that the National Science Foundation, which also provides money to Canadian institutions, currently does not require recipient institutions to have a research integrity policy in place. The relevant code, 45CFR689, states only that institutions should have such policies in place.
[32] NIH Awards Database, Foreign Institutions, 2007.
[33] See Annual Report guidelines at http://ori.dhhs.gov/assurance/documents/2005_AR_instructions.pdf.
[34] The individuals are: Jianhua (James) Xu, M.S., University of Alberta in 2003 and Catherine Kerr and Barbara Jones at St. Mary's Hospital (SMH), Montreal.

What is known, however, is that in the non-health related sectors, most R&D carried out by firms is primarily development focused, and as such does not readily lend itself to peer reviewed publications or to misconduct to the same extent as basic research. This was underscored in the response by one R&D based company that noted "the topic of [research integrity and misconduct] is mostly out of scope for the type of research that's done, or for the results that we are looking for. For the very few parts that are potentially applicable, the information would be too confidential to release."

In the health related sectors, views on research misconduct in the private sector are mixed. One respondent with experience in dealing with health science companies through collaborative research did indicate that overall the private sector, in his view, does a good job of scrutinizing their own work, adding that companies typically 'don't want to fool around'. Yet it is also evident from public cases and a number of papers and editorials in leading medical journals over the past ten years that breeches of research integrity are a problem in some parts of the private sector, notably in the pharmaceutical industry.[35] The existence of companies, including some in Canada, that "ghost write" papers for academic researchers is but one visible manifestation of research misconduct in the private sector. These companies craft research papers in support of a particular drug and seek out researchers willing to be listed as authors in exchange for money and other benefits.[36]

2.5 Non-Research Performing Organizations

The Canadian research system includes a number of organizations that are integral to the research process but which do not perform research. Most numerous among these are the academic journals, whose editors and participating peer reviewers are often the first to detect cases of research misconduct. In dealing with possible cases, editors may choose to follow guidelines from professional bodies such as the Canadian Association of Learned Journals (CALJ), the US-based Council of Science Editors, the International Committee of Medical Journal Editors (ICMJE), all of which offer advice to editors who come across potential cases of research misconduct.

CALJ, for example, which represents over 100 Canadian journal titles, updated its 'Best Practices Guide to Scholarly Journal Publishing' in 2007, making reference to the importance of scholarly integrity as well as ethical breaches that editors should be aware of.[37] In more specific terms ICMJE recommends that: "If substantial doubts arise about the honesty or integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued, usually by the authors' sponsoring institution."[38] In addition to outlining

[35] See "Just how tainted has medicine become?" *The Lancet* , Vol 359, April 6, 2002. www.thelancet.com. For information on private sector behavior in the Olivieri case, see Thompson, Baird and Downie. 2001. *The Olivieri Report*. CAUT.
[36] See D. Healy, *Let Them Eat Prozac*, Lorimer: Toronto. 2003. http://www.healyprozac.com/GhostlyData/default.htm
[37] See for example Best Practice Guide to Scholarly Journal Publishing, Canadian Association of Learned Journals
[38] ICMJE. "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication" Updated Oct. 2008., http://www.icmje.org/index.html#publish

some basic guidelines, ICMJE adds that editors who have questions related to editorial or scientific misconduct should consult the UK based Committee on Publication Ethics (COPE).

In fact, COPE has arguably become the most influential organization maintaining guidelines for dealing with research misconduct issues among editors at scholarly publications. In 2008, COPE received the backing of a number of major academic publishers notably, Elsevier, Wiley–Blackwell, Springer, Taylor & Francis and the BMJ Publishing Group, all of which have signed up their entire catalogue of journal titles as COPE members. As a result, COPE's global membership expanded to over 3800 journals, including at least 44 Canadian titles.

In addition to a code of conduct and guidelines for board of directors and editors, COPE maintains some 17 decision flow charts, each offering best practices to editors on specific issues of research misconduct, including "What to do if you suspect redundant (duplicate) publication", "What to do if you suspect plagiarism", and "What to do if you suspect fabricated data".[39] In addition to publishing best practices, COPE officials lecture widely on the subject of research integrity, and organize annual seminars in the UK, which are to be extended to North America in 2009 due to COPEs now extensive representation of US based titles.

Professional Societies

Some research organizations rely on professional associations to provide guidelines on conduct. One in Alberta, for example, encourages all employees to become members of the Association of Professional Engineers, Geologists and Geophysicists of Alberta (APEGGA), which maintains a 29 page code of conduct that outlines best practices and expected behavior for a range of professional activities.[40]

Finally, learned societies may also have guidelines relevant to research integrity as does, for example, the Canadian Federation of Humanities and Social Sciences. This organization, which represents 70 learned societies, has developed guidelines which take into account the fact that Canadian learned associations generally do not sanction members as they may do in the US.

2.6 Summary

A wide variety of organizations, both within and outside of Canada, are engaged in the governance of research integrity, each contributing to a complex and multifaceted policy landscape that has developed over time. This fact is underscored again in the following chapter's look at how the system functions when an allegation is made.

[39] See Committee on Publication Ethics. http://publicationethics.org/flowcharts.
[40] APEGGA, Guideline for Ethical Practice V2.1 June 2005. http://www.apegga.org/pdf/Guidelines/02.pdf

3. How Canada's Research Integrity System Works

3.1 Responding to Allegations of Misconduct

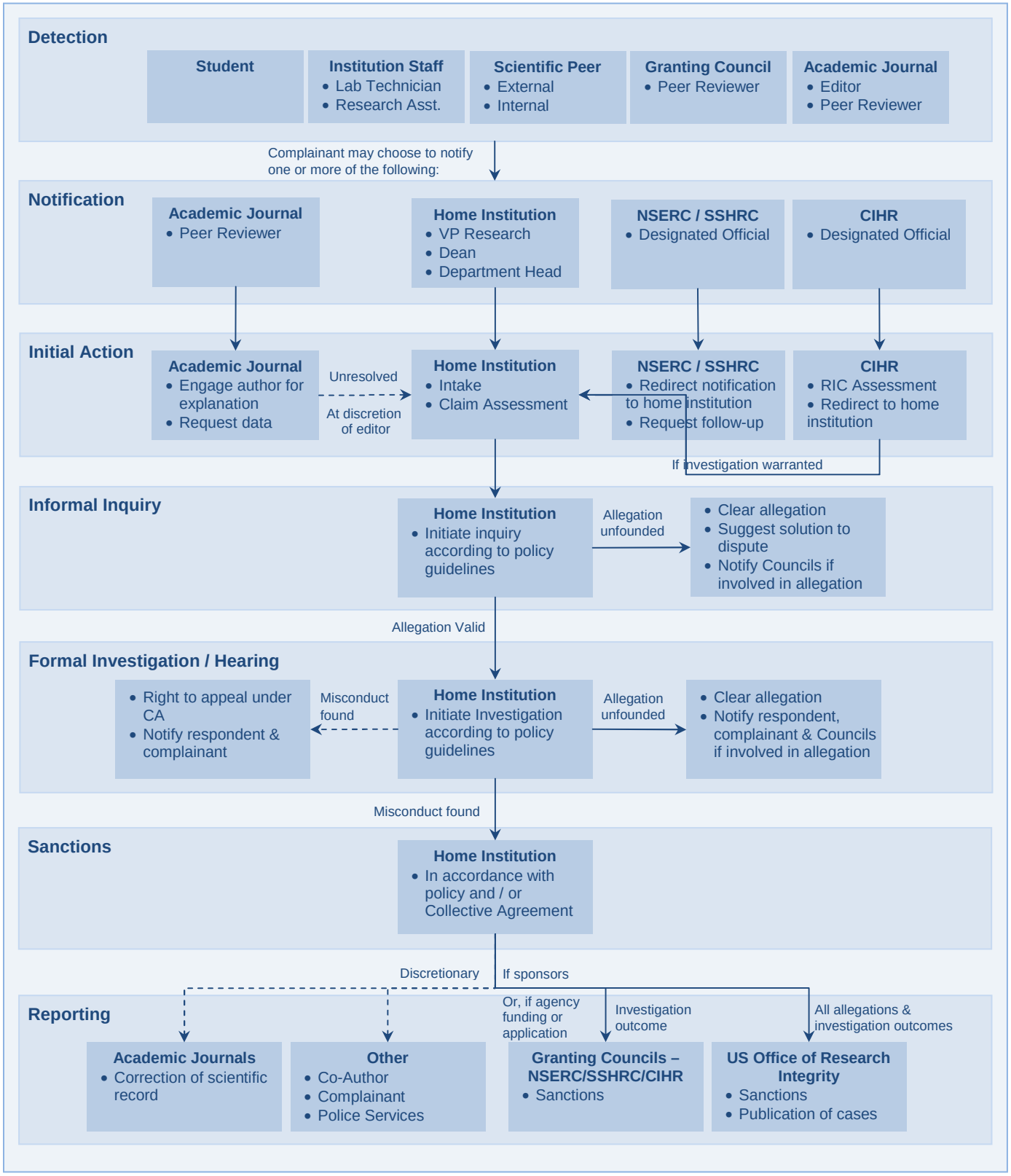
The various policies codes and guidelines that shape the core of the Canadian oversight system explicitly and implicitly recognize that the responsibility for responding to allegations of misconduct resides with the institutions where the suspected research is conducted. Institutions respond to allegations in accordance with their own policies for addressing research integrity and misconduct, which have been developed within the framework of the TCPS-IRS, the 42CFR93 or other institutional and, or, provincial policies.

At base, this approach is in keeping with academic self-governance, a tradition that is associated with the protection of academic freedom and with the capacity for institutions of higher education to continue to generate valuable knowledge. It also allows universities the flexibility to tailor external guidelines, such as those of the TCPS-IRS, to their own internal and often complex governance processes and policies. Several universities, for example, have produced research integrity policies in the context of other related policy documents, including conflict of interest policies and research ethics policies. The flexibility that this self-governance approach allows is in some cases critical to meshing new external requirements to existing and legally binding contracts such as collective agreements that govern employment. Institutions whose collective agreements stipulate employee sanctions or appeal processes will defer to these agreements in their research integrity policies.

As a passive 'fire alarm' system, however, institutions and their policies for responding to allegations are only one part of the system. Analogous to the use of an actual fire alarm system, triggering the alarm depends on individuals who are aware of the policies, have a sense of professional responsibility, and have assurances that there would be no serious repercussions for speaking up. As such, research institutions may not necessarily be involved in the early stages of an allegation.

Figure 4 provides a simplified schematic of how Canada's system currently functions when an allegation arises. The first stage of detection can involve the widest array of actors within and outside the Canadian research system, and may include students, peers or journal editors, all of whom must decide for themselves whether to pursue an allegation of misconduct and thereby invoke the research integrity policies that make up the Canadian system.

Figure 4: How allegations are addressed in Canada's Research Integrity System



Cases that are pursued generally begin with a notification to either: the journal, where suspected research was or is being considered for publication; to granting councils, which are deemed by some in the research community as a first point of contact for such cases; or, to the home institution where the researcher suspected of misconduct resides.

The initial response to an allegation depends on which body is first notified. For example, a journal editor, in keeping with the Committee on Publication Ethics (COPE) guidelines for journal editors, will generally engage the author first as part of a preliminary investigation, requesting an explanation or original data sets. It is, however, at the discretion of the editor whether they choose to notify the home institution and therefore initiate a more formal process of inquiry and investigation. Notifications directed to NSERC or SSHRC are generally redirected to the home institution with a request that the institution keep the granting council informed of the process and outcome. Notifications directed to CIHR are initially assessed internally and then reviewed by its Research Integrity Committee to determine whether the allegation should be referred to the appropriate home institution for investigation. Should an investigation be deemed necessary, the institution is asked to conduct an investigation and keep CIHR informed of the process followed and outcome. Finally, if the home institution is notified directly, they are obliged to begin procedures for responding to the allegation as outlined in their policy on research integrity.

A number of institutions have appointed an official who can field confidential questions regarding allegations and offer advice to those considering a formal complaint. Such complaints, when made, are in writing and sent to senior administrative staff which may be a Vice-President of Research, a President or other designated official.[41] Once an allegation reaches the home institution, responsibility for following it up typically rests with a Vice President of Research (e.g. universities) or a Director of Research (e.g. medical research organizations). If an allegation is received and considered to meet the definition of research misconduct, institutions typically begin a two stage investigation process which begins with an initial and often informal inquiry headed up by a VP of Research or other designated official, to determine whether the case merits a full investigation. Some institutions encourage mediation to resolve allegations prior to any formal investigation. This is in recognition of the fact that, as several of those interviewed made clear, many allegations arise from interpersonal conflict among colleagues or among supervisors and students and are not in fact based on claims of actual research misconduct.

If a case merits a full investigation, institutions will invoke policy procedures for establishing a hearing or tribunal that uphold principles of fairness applicable to all parties. If misconduct is found, universities will determine what sanctions are appropriate, given the severity of the case. If, at any stage, allegations of misconduct are judged as unfounded, allegations are cleared. In cases where the granting councils were notified of the complaint, clearing an allegation also involves reporting to the councils on the outcome.

[41] For institutions compliant with 42CFR93, the name and contact information of the official designated to receive a complaint must be posted on the institution's website.

3.2 Accountability and Transparency

As a passive and largely self-governed system that relies on the willingness of complainants - be they a research colleague, a journal editor or a lab technician - to submit a complaint, and on an institution's responsibility to follow its own policies in managing an allegation, formal accountability within the overall system is limited. At this level, the system relies primarily on professional conduct, values, and a cultural norm of honesty, together with a general awareness and education of relevant institutional policies. One exception is the use of quality assurance processes in some medical laboratories that ensure all research data is double-checked and recorded properly. Such processes provide, in effect, an audit function for research, but one that is specific to a given laboratory and not obligatory.

Awareness is, however, formally enhanced in a number of ways. First, researchers who apply for granting council funding must certify by way of a signature that they agree to comply with the TCPS-IRS. Second, in addition to making the policies readily available on a website, most institutions require that all new employees participate in orientation sessions which cover all aspects of institutional policies, including research integrity. Medical research organizations have often gone further, with dedicated research training centres for staff, and workshops and seminars that address aspects of research integrity, such as best practices for running labs and maintaining primary data.

Accountability at the researcher level may also be enhanced by statements in research integrity policies regarding a researcher's obligation to report any non-compliance with its policies. For example, in one policy, the following statements have been included in the definition of research misconduct: "condoning or not reporting the performance by another University member of any of the acts noted above"; and "encouraging or facilitating another researcher to carry out scholarly misconduct; …or otherwise creating an environment that promotes misconduct by another". Such statements further augment the awareness among the research community of their responsibilities to maintain an environment that is conducive to the highest standards of research.

Institution level

More formal mechanisms for ensuring accountability within the system exist at the institutional level. The primary mechanism is the MOU signed between the federal granting councils, which are accountable to Parliament, and the presidents of eligible institutions, most of which are self-governed. This MOU binds institutions to their responsibilities for maintaining and invoking research integrity policies and allows for the imposition of sanctions on institutions that are found to be in non-compliance with the MOU and its 15 schedules. One of these schedules, 'Schedule 8: Investigation and Resolution of Breaches of Agency Policies" addresses how institutional non-compliance with Tri-Council policies is addressed, recognizing three levels of non-compliance (see Figure 5).

Figure 5: Three Levels of Institutional Non-Compliance as recognized in Schedule 8: Investigation and Resolution of Breaches of Agency Policies.[42]

Level 1

If the Agency and the Institution consider the alleged compliance issue to be minor, the Agency and the Institution will work informally to investigate and, if necessary, to correct the problem. Relevant Research Administration officials will be advised, but senior officials of the Institution will generally not be involved in the case.

Level 2

If the Institution or the Agency considers a compliance issue to be serious, either Party, as the case may be, will document the alleged infractions, the relevant evidence and options for rectification of the situation if a breach is confirmed.

In consultation with the Agency, relevant Research Administration officials will review the documentation and establish a realistic schedule for resolving the situation, which may be altered by mutual agreement. All reasonable opportunities will be provided for affected parties to comment on the situation and to participate in its resolution.

The Agencies agree to share information among themselves concerning systemic institutional non-compliance while respecting the federal Privacy Act. If the Agency is of the view that a breach has occurred, it may require that the Institution implement corrective measures, such as appointing a consultant to assist in the development and implementation of a remedial plan.

Level 3

Should the matter not be resolved at Level 2 or be particularly serious or sensitive, it will be referred to senior level officials from both the Institution and the Agency as follows:

a. relevant senior Research Administration official (Vice-president or equivalent) of the Institution; and Vice-President(s), Executive Director(s), Director(s) or Corporate Secretary of the Agency; or

b. chief Executive Head of the Institution and President of the Agency.

Together these officials will establish a realistic schedule for resolving the situation, which may be altered by mutual agreement. If one Party believes that mediation may be useful to assist in defining a mutually satisfactory solution, the Agency President will appoint a mediator that both Parties agree is appropriate. The mediator will make non-binding recommendations to the Parties.

In addition to requiring corrective and remedial measures by the Institution, the Agency may, with prior written notification, temporarily suspend funding to specific programs or projects until corrective measures, which the Agency finds satisfactory, are in place.

3.3 Reporting

Accountability within the system is supplemented by reporting requirements that provide some additional transparency to how the system is functioning. Under the TCPS-IRS, institutions are required to report on cases of research misconduct to the appropriate granting council in two situations. The first is when misconduct is found to have occurred in research that had been funded by a particular granting council; unfounded allegations are not reported. The second is where the granting councils had been informed of, or involved in, the notification or detection stage of the allegation. In such situations, the home institution is required to report on the outcome of the investigation irrespective of whether misconduct was found. For institutions that comply with 42CFR93, both investigations *and* allegations related to misconduct and which involve NIH funding are to be reported through annual reports submitted via the ORI website.

[42] Available at http://www.nserc-crsng.gc.ca/_doc/Policies-Politiques/8-Breaches-Inobservation_eng.pdf

4. Analysis of Research Integrity Policies

4.1 Overview of Research Integrity Policies

Of the 42 institutions reviewed in this study, all non-government research institutes and close to half of the major government science-based departments and agencies contacted have policies in place that provide guidelines and standards for addressing research misconduct. These policies, of which 37 are included as part of this analysis, generally have jurisdiction over all research and scholarly activity at respective institutions, and accordingly, apply to all researchers, faculty, and staff as well as to any students involved in such activities which are not related to their course work. In cases where research integrity policies are embedded within a collective agreement or employment contract, the policy reach may be limited only to those who are bound by the agreement.

The majority of these policies are similar in structure and scope owing to the fact that most publicly funded research in Canada is influenced directly or indirectly (as for government departments and agencies) by the TCPS-IRS. Institutions that are compliant with this policy and related Schedule are required to develop and observe a number of general principles related to research integrity and misconduct, and outline procedures for processing allegations and reporting to the councils. To further assist institutions, the Tri-Councils have developed a framework that outlines in greater detail the elements expected in institutional policies (see Figure 6).[43]

There are nonetheless notable differences in policy content among research organizations due to the flexibility inherent to the TCPS guidelines that allow policies to be tailored to respective institutional environments. One broad area of difference is the type of policy in which principles and guidelines are laid out. Though the majority of institutions reviewed have separate policies on research integrity and misconduct, a number have incorporated these principles and guidelines into a broader document. In such cases, research integrity may be embedded within a policy on research ethics or research conduct (8% of the 37 reviewed), or as an article within the faculty collective agreement (11%). At several institutions, relevant research integrity policies are spread across more than one policy such that the definition of research integrity may appear in a collective agreement and be supported by two or more policies on ethical behaviour, conflict of interest, research ethics, or whistleblower protection. In one case, procedures for investigating research misconduct are presented separately in an appendix of a different policy.

[43] See Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research, http://www.nserc-crsng.gc.ca/_doc/NSERC-CRSNG/frameworkintegrity-cadrereferenceintegrite_eng.pdf.

Figure 6: Components of a TCPS-IRS compliant research integrity policy

General Principles

- A general statement of research integrity principles and description of what constitutes misconduct;
- A statement confirming expectations for standards of appropriate behavior in research for the members of the institutional research community, covering such points as honesty of researchers, respect for others, scholarly competence, and stewardship of resources;
- A statement that both the policy and adjunct policies cover and identify all those involved in the research enterprise in any capacity whatsoever at the institution;
- A policy (policies) on data recording, ownership and retention;
- A policy on authorship and publication (either university-wide or by faculty);
- A policy requiring disclosure of potential conflicts of interest;
- A statement that the institution is committed to ongoing education on research integrity.

Procedures for Processing Allegations

1. Receive allegations of misconduct
2. Conduct inquiries/investigations
3. Protect privacy/confidentiality
4. Provide an opportunity for response and for due process
5. Make decisions on misconduct
6. Determine actions in response to a report
7. Report on the results of the investigation
8. Maintain records

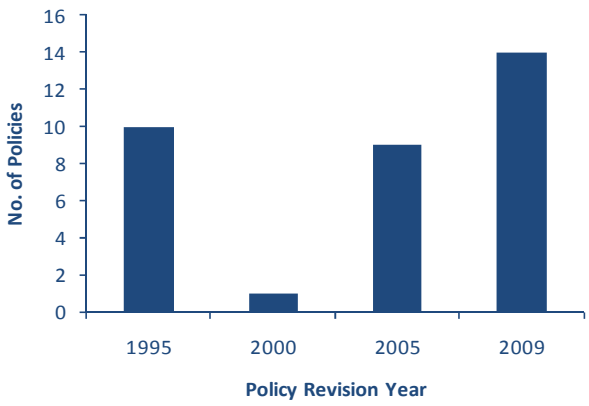
Reporting to Councils.

Finally, it should be noted that a research integrity and misconduct policy is but one of a number of institutional policies that affect research at a given institution. There can be as many as fourteen or more policies relating to some aspect of research including safety in research, research by unpaid researchers and contract research. One approach for bringing together all relevant policy statements for researchers is that of a research *conduct* policy which outlines best practices for all types of research, and which references any related policies. Such a document might include statements on research misconduct, expected practices for managing research data and collaborative research, policies on conducting secret or hazardous research and best practices for managing research funds.

2nd generation policies

A number of institutions have implemented, or are in the process of drafting, second generation policies that are both more comprehensive and more detailed than first generation policies developed in the mid 1990s after the introduction of the TCPS-IRS (Figure 7). These new policies, which may be upwards of 20 pages in length - up from the two to five page first generation policies -

Figure 7: Research integrity policies, year of most recent revision



have in some cases been revised not only as a policy document but also an educational tool to be used as part of training sessions for staff and as such are often written in a more accessible style. These revisions have also been influenced by the *Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research*, enforced by the Tri-Councils since 2006 for new institutions seeking eligibility.

4.2 Definition

4.2.1 Type of definition

Though the TCPS-IRS provides principles and guidelines for developing research integrity and misconduct policies, it does not provide an explicit definition of research misconduct. Instead it defines misconduct as any action that is inconsistent with research integrity, the principles of which are outlined positively by listing obligations and responsibilities expected of researchers. To comply with the TCPS-IRS, institutions are required not so much to *define* research integrity and misconduct, but to have a statement of research integrity principles and *describe* what constitutes research misconduct.

This approach has resulted in two broad types of definitions of research integrity and misconduct. The first type is that which follows the 'positive' style of the TCPS-IRS, that is, defining research misconduct in terms of activities and behaviours that are consistent with integrity (Figure 8). Eleven percent of the policies reviewed relied exclusively on a positive definition. A second type defines research misconduct explicitly and often negatively by listing those practices and behaviours that are sanctionable (e.g. making up data). This list may be non-exclusive with an additional statement noting that the types of misconduct are not exclusively limited to those listed in the definition. Definitions are often qualified further by acknowledging that research misconduct does not include honest errors or omissions.

4.2.2 Scope: broad versus narrow

Nearly every policy reviewed has a different definition of research misconduct and most use a definition that is broader in scope than what is expected by the TCPS-IRS (see Figure 9). Thus, in addition to recognizing what is widely acknowledged as the core of research misconduct - namely fabrication, falsification and plagiarism (FFP) - definitions also often recognize a number of 'questionable research practices' (QRP), and other types of misconduct related to research. Unlike FFPs, which are universally viewed as serious deviations from accepted standards of scientific research, QRPs are practices that deviate from accepted standards and values of scientific research but for which there is no broad consensus on their severity or acceptability. QRPs are most often related to dishonest authorship practices such as 'knowingly agreeing to publish as a co-author without reviewing the work, including the final draft of the manuscript' and giving or receiving honorary authorships. These may in one discipline be overlooked, and in another, be deemed unacceptable. Some definitions provide allowances for faculty specific

conditions to reflect the need to accommodate standards appropriate to their respective scholarly communities.

Figure 8: Two types of definitions: TCPS-IRS and the US ORI

Positive Definition: TCPS-IRS Principles and Responsibilities

1. The Councils hold researchers and scholars receiving Council funds responsible for upholding the following principles:

a) recognizing the substantive contributions of collaborators and students; using unpublished work of other researchers and scholars only with permission and with due acknowledgement; and using archival material in accordance with the rules of the archival source;

b) obtaining the permission of the author before using new information, concepts or data originally obtained through access to confidential manuscripts or applications for funds for research or training that may have been seen as a result of processes such as peer review;

c) using scholarly and scientific rigour and integrity in obtaining, recording and analyzing data, and in reporting and publishing results;

d) ensuring that authorship of published work includes all those who have materially contributed to, and share responsibility for, the contents of the publication, and only those people; and

e) revealing to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other, that might influence their decisions on whether the individual should be asked to review manuscripts or applications, test products or be permitted to undertake work sponsored from outside sources.

2. The Councils hold institutions that administer Council funds responsible for:

a) promoting integrity in research and scholarship; and

b) investigating possible instances of misconduct in research or scholarship, including:

* imposing appropriate sanctions in accordance with their own policies; and

* informing the appropriate Council(s) of conclusions reached and actions taken.

3. The Councils are responsible to the Government of Canada for ensuring that research funds administered by them are used with a high degree of integrity, accountability and responsibility.

Negative Definition: US Office of Research Integrity – Definition of Research Misconduct

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

One of the factors that determines definitional scope is the intended use or type of document of which research integrity and misconduct policy is a part. Some policies, for example, are a part of a research conduct document that outlines best practices which researchers are expected to follow in all aspects of their research. Alternatively, research misconduct may be a part of, or

combined with, a research ethics policy. The remainder of this section identifies and discusses the various elements that have been made a part of a research misconduct definition.

Figure 9 gives an indication of the degree of variability in how research misconduct is defined in the policies reviewed. All policies, except those that rely on a positive statement of research integrity principles, include FFP in their definitions.[44] These terms may or may not be clarified further with examples or qualifying definitions such as those provided by the US Office of Research Integrity.[45]

Figure 9: Defining Research Misconduct, by Definitional Element and Organization Type

Type of Research Misconduct Recognized in Definition	Total (37)	Organization Type No. of policies (% of total reviewed by type)					
		College (4 Total)	Government (3)	Medical Research Organization* (3)	University Large** (21)	University Medium (4)	University Small (2)
Falsification, fabrication & plagiarism	**97%**	4 (100%)	3 (100)	3 (100)	20 (95)	4 (100)	2 (100)
Failure to reveal conflict of interest	**73**	3 (75)	1 (33)	1 (33)	16 (76)	4 (100)	2 (100)
Dishonest authorship practices / misappropriation	**68**	3 (75)	3 (100)	2 (67)	16 (76)	1 (25)	0
Breach of any regulations on research ethics	**68**	3 (75)	1 (33)	2 (67)	8 (62)	4 (100)	2 (100)
Financial misconduct	**57**	3 (75)	1 (33)	1 (33)	9 (67)	2 (50)	0
Breach of confidentiality	**43**	2 (50)	0	1 (33)	13 (48)	2 (50)	1 (50)
Failure to reveal financial conflict of interest	**35**	0	0	0	6 (38)	3 (75)	2 (100)
Improper data management	**27**	2 (50)	1 (33)	0	14 (29)	1 (25)	0
Retaliation	**11**	1 (25)	1 (33)	0	2 (10)	0	0
Other†	**30**	100	0	0	7 (33)	0	0

* Research hospital policies typically overlap with those of the affiliated universities due to the fact that most researchers are cross appointed to a university. As such policies may therefore rely in part on the scope of the relevant university policy.
**These categorizes, used by Statistics Canada, reflect income from sponsored research. Small Universities are those that conduct less than $25 million in research, medium universities conduct between $25m, and $79m and large conduct more than $80m(18). See C. Read 2007, "Size counts: Outcomes of intellectual property (IP) commercialization" Innovation Analysis Bulletin — Vol. 9, no. 1.
† Examples include 'abuse of supervisory power affecting collaborators, assistants, students and others associated with the research'; 'use of archival material in violation of copyright act'; and breech of harassment and discrimination policy; See following discussion, p. 26.

[44] Note: institutions that rely on principles may make specific references to FFP and other types of misconduct in the principles. In such cases, this these statements are included in the analysis.

[45] The US ORI defines fabrication as making up data, results or findings and recording or reporting them; falsification as manipulating research materials, equipment or processes or changing or omitting data, findings or results such that the research is not accurately represented in the research record; and plagiarism as the appropriation of another person's ideas, processes, results or words as one's own.

Failure to reveal conflict of interests (73%) is the second most frequently referenced misconduct and applies to the relevant stakeholders when publishing work or reviewing grants and manuscripts or testing products for sale. Not all definitions recognize the same stakeholders however. Some refer just to the sponsors of research, while others include sponsors, the university, or any commissioner of work. Note that most institutions have a separate policy on conflict of interest which may be referenced directly in the research integrity policy.

Dishonest authorship practices are recognized by over two thirds of the policies reviewed. These practices, which often account for much of what is referred to in the literature and in discussion as QRPs, represent the majority of research misconduct allegations made. Many of those interviewed also noted that these are often resolved without the need for an investigation, relying instead on informal mediation among relevant parties.

There is wide variability in how these are defined. Examples include:

- "Attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for intellectual content"
- "Giving or receiving honorary authorship or inventorship"
- "Failing to provide collaborators with an opportunity to contribute as an author in a "joint publication" when they contributed to the research with the understanding and intention that they would be offered this opportunity"

Note that, in accordance with the TCPS-IRS framework document, a number of policies now include a separate statement on authorship and publication practices that may or may not be in addition to what is stated in the definition.

Breach of any regulations on research ethics refers to the federal and provincial policies and regulations that researchers must follow when carrying out research that involves human subjects or animals. As with the conflict of interest provision, all institutions that receive Tri-Council funding have a research ethics policy in place that deals in depth with these aspects of research. Including it in a definition of research misconduct, as do 68% of policies reviewed, highlights the link between research integrity and research ethics.

Financial misconduct refers to the misuse of research funds. Some 57% include financial misconduct as part of their research misconduct definition, though few define it in a similar manner. Generally, research misconduct is defined with a couple of provisions and in some cases three. These may include:

- failure to comply with terms and conditions of grants and contracts;
- misuse of equipment and facilities;
- use of institutional resources, facilities, equipment without permission;
- failure to correctly acknowledge the source of research funds;
- unauthorized purchases for personal gain;

- non-compliance with institutional rules related to research rules;
- misleading budget requests for research;
- misleading information provided for contractual purpose.

Breach of confidentiality refers to the illegitimate use or sharing of information acquired in confidence. This information may have been obtained from peer reviewing a manuscript, from a grant application, from a human research subject or from an inquiry or investigation of research misconduct. Forty-three percent of definitions reviewed made some reference to confidentiality breaches. An example includes: "Failure to obtain permission of author before using information gained through access to manuscript or grant applications during a peer-review process", and "release of confidential information without informed consent".

Failure to reveal financial conflict of interest is similar to the conflict of interest provision but with an explicit reference to undisclosed personal financial ties. The failure to disclose a financial conflict of interest when participating in research related activities is recognized in over a third of policies reviewed and is particularly prominent in policies of the small and medium universities. An example is as follows: "Failure to reveal to the University any material financial interest in a business that contracts with the University to undertake research, particularly research involving business products or to provide research related material or services. Material financial interests includes ownership, partners, substantial investment whether equity or debt, a directorship, significant honoraria or consulting fees but does not include minor share holding in public traded corporations."

Improper data management, which is included in 27% of definitions, refers to data practices such as the deliberate destruction of data that would obstruct an assessment of allegation of research misconduct. Maintaining research data is often essential for validating results and responding to allegations. The TCPS-IRS requires that policies address data recording, ownership and retention in recognition of the importance of maintaining proper research records for a period of an extended period of time, and that a separate statement be provided on this issue. An example is: "deliberate destruction of one's own research data in order to avoid the detection of wrongdoing, or tampering with or destroying the research of another person either for personal gain or out of malicious intent."

Retaliation against those who make an allegation of misconduct is recognized in about 11% of definitions. An example is: "retaliation against a person who acted in good faith and reported or provided information about alleged research misconduct".

There are a number of **other** types of misconduct recognized in definitions of research misconduct. In fact, some 30% of definitions, including all four colleges examined, recognize misconduct to include provisions other than what is discussed above. These include:

- Abuse of supervisory power affecting collaborators, assistants, students and others associated with the research;

- Use of archival material in violation of copyright act;
- Breach of harassment and discrimination policy;
- Failure to comply with government statutes e.g. Health Canada Laboratory Biosafety Guidelines;
- Disposing of intellectual property outside of university without due benefit to those entitled to some return;
- Condoning or not reporting the performance by another university member of any of the acts noted above; and
- Failure to comply with relevant federal or provincial statues or regulations applicable to the conduct and reporting of research.

4.3 Administration of Policies

The development and review of research integrity policies tends to be initiated and carried out by the same actors responsible for its day-to-day oversight and management, usually the Office of the VP Research. Most respondents indicated that all university policies were subject to Senate approval, and that it was typically the responsibility of the VP Research to initiate the development or review of the institution's Research Integrity policy. In some cases, the policy under development is informally reviewed by relevant colleagues, while in others the policy is reviewed by a formal Senate sub-committee, often referred to as some variant of a Research Advisory Committee. Either way, the policy development and review process tends to be highly collaborative, "so the VP's Office would take the lead, but there would be a lot of other people involved, like the Provost's office, the Faculty of Health Sciences, the Deans – all of the policies that are developed here are done with very broad participation". Few cases (1 or 2) reported that they consulted with university legal counsel in the policy development process.

In terms of the regular management and administration of the policy, in the majority of cases, the policy is 'housed' in and administered by the Office of the VP Research but oversight occurs in conjunction with the Office of the VP Academic (or Provost's Office), through various different governance arrangements.[46] This proved to be an important recurring theme that was evident also in investigation and disciplinary procedures (to be discussed in more detail below). For example, larger institutions will often have both a VP Research (VPR) and an Associate VP Research (AVPR), but "the two key people will be the VP Research and the Provost" who will delegate the investigation of allegations of research integrity to the AVPR. In some smaller institutions, the policy is housed in the Office of the VP Academic and Research, but is administered by the Dean of Research who reports to the VP Academic and Research. In other institutions that lack a well-established Office of VPR, the responsibility for administering and investigating research integrity policies lies with the VP Academic, who consults with the VP Research on the appropriate course of action. Generally speaking, in the division of

[46] In a few cases (2 or 3), the policy is administered and managed by the Office of the VP Research but is formally housed within the university Secretariat.

responsibility for research integrity issues, "the primary mandate to develop the policies comes through the Office of the VPR and the primary responsibility for the appeals process lies with the VP Academic". The VP Academic is involved in both the appeals and often the disciplinary process because findings of research misconduct could affect promotion and tenure, "so there is a fine balancing act between oversight for academic misconduct through the Office of the VPR and through the Office of the Provost".

In this context, it is important to note that institutions are at different points in the development of their governance arrangements to oversee research integrity issues, and the administration of research activities more broadly. About half of the colleges and universities selected for the interview sample reported having a well-developed framework for managing the institutional research activities, which include policies and protocols for research ethics, conflict of interest and research integrity all of which tend to be administered in a single unit such as the Office of the VP Research. Other institutions, however, reported that they have recently, or are in the process of, re-organizing or creating new offices for the administration of institutional research activities. Many respondents from these institutions reported being new to their position because either their position, or their office, or both, were newly created, a situation that was particularly evident in the colleges. The institutions that were in the process of developing their research administration frameworks tended to report more ambiguity and uncertainty about where to house the oversight of research integrity issues. As one noted:

> "we've been talking a lot lately about the need to develop an Office of Research Integrity, which includes ethics, misconduct and a number of other things. There really isn't a home. No body is responsible for its implementation…The responsibilities are extremely broad."

Others, particularly smaller institutions, tend to have a looser, less formal framework for managing research integrity issues. While they are required to have a research integrity policy, the procedures for dealing with allegations of misconduct may be on a "case by case" basis:

> "It's never crossed my mind. I don't think we have a very clear guideline there. Normally an allegation, which is made to somebody like the President, would go down the line to the VP Research, and the VP Research would talk to the Dean or the Chair and the researcher directly…In those situation of things for which we don't have a precedent…the executives of the university – the President, the VPs and the AVPs meet once a week for three hours and discuss whatever is important. So the VP Legal would probably tell me if I were to propose something that didn't make sense…We don't have a detailed formal policy for that."

4.4 Inquiry and Investigation Procedures

All interviewees reported that the procedures for investigating allegations of research misconduct were clearly outlined in each institution's research integrity policy. There is, however, a great deal of variation in the complexity and formalization of the procedures themselves, as well as in the distribution of responsibilities among relevant officials and adjudicators, and the degree of centralization of the investigative process. Investigation procedures can be roughly grouped into two 'procedural types', which will be referred to as 'one stage' and 'two stage' processes.

One stage process

Some institutions tend to have less layered and formalized procedures, involving fewer stages of investigation, and fewer administrators. In these institutions, there is only one stage of investigation and adjudication, the responsibility for which typically falls to the Dean of the relevant faculty, who can conduct the investigation him or herself, or can delegate it to a committee. If the allegations are found not to be substantive, or if the dispute can be mediated or resolved by the Dean in a manner satisfactory to all parties, the investigation is terminated and all parties are informed. If, however, the allegations are found to be substantive, or cannot be resolved at the Dean's level, the findings of the investigation are passed on to the VP Research (or the Dean of Research depending on the governance structure of the institution) who typically decides on the appropriate disciplinary action, with input from the institution's legal counsel where solicited. Technically, the VP Research is supposed to be informed of all allegations as they occur, but, as will be discussed in more detail below, this does not always occur. As one person described the process:

> "My first step is I send it back down to the academic unit – the Dean, Department Head or Director's Office – and submit a formal request for a departmental investigation and I trust them as part of university management to do that in a fair and open way…Under policy, I make a decision based on that information…[and] if I think there is any hint that there may be academic misconduct…I can suggest a remedy to the President that has the force of law."

Two stage process

In contrast, other institutions, both large and small, tend to have a detailed and consistent process that typically involves two formal stages of investigation usually led by a committee, with the formal involvement and oversight of the administrator(s) under whose responsibility the policy falls. In these cases, the investigative procedure involves some combination of the Chair or Dean of the relevant faculty, the Dean of Graduate Studies or the Dean of Research (where no formal Office of Research exists), the VP Research, and the VP Academic, the investigative committees they establish, and in some cases, the President of the university has final

oversight.[47] Though there are slight variations, in this procedural type, regardless of who first hears of the allegation (Department Chair, Dean), the VP Research (or Dean of Research) is informed of the complaint and will either conduct an initial investigation him or herself, or delegate the initial investigation to the faculty Dean from which the allegation originated.

The initial investigation stage varies in its degree of formality, and can be carried out by an individual or a small committee, though most institutions tend to use a formal committee according to guidelines outlined in the policy. For example, one institution convenes a "Complaint Guidance Committee" which includes the Provost, the Dean of the relevant faculty, and the VP Research, whose "only responsibility is to determine if the allegation constitutes a breach of research policy". Another institution "puts the work of looking into a complaint closest to where the activity is alleged to have taken place, so after we get an allegation, it goes to the division or faculty where it is most directly involved". This stage of the investigation is intended to determine if the allegation has enough substance to proceed, and if it falls under the jurisdiction of the research misconduct policy or is more appropriately addressed under another policy (for example, sexual harassment). If there is no substance to the allegation at this point, "the matter ends" and all parties are informed in writing.

The second stage of the process is initiated if the allegations are found to be substantive, and typically involves a formal hearing to view the evidence and make recommendations. Members of the investigative committee are typically appointed by the VPs Academic and Research, often in consultation with the Dean, and would consist of peers who are familiar with the area of research, as well as external investigators (where required or stipulated by policy). The individual(s) under investigation receive written notice, and have the opportunity to consult with their faculty association or other legal counsel, and to respond to the allegations. The committee generates a formal report outlining their findings, and if the individual is found guilty of misconduct, the investigation goes to the decision stage where academic penalty or discipline is determined by the appropriate individual, as outlined in the policy. This is typically the Provost, and less often the President, (but can also be the VP of Arts and Sciences) who determines disciplinary measures in accordance with the collective agreement or relevant academic employment contract. One interviewee described the two-stage process succinctly:

> "The allegation goes to the next person up from whomever the allegation is being made about. The first step is to try to determine whether it has substance and whether it can be reduced to writing. So it would typically be the Dean, or the Associate Dean of Research, or the Chair, depending on against whom the allegation is made. If it has substance, then the Dean strikes a committee to further look at the allegation to verify that it does have substance. If the committee says it has substance, then the Dean [of

[47] Reflecting the dynamic outlined above in the Administration of Policies section, there is variation in the relative jurisdiction of the VP Research and the VP Academic in research misconduct cases. In most institutions, primary responsibility for investigation and adjudication lies with the VP Research, and the VP Academic is responsible for imposing discipline, but in several other cases, the Office of the VP Academic has primary responsibility for investigation and adjudication, with the, often informal, input of the VP Research.

> Research] puts an investigative committee in place, and there are timelines and membership criteria on all of these things. So it goes through two committees: one to verify the allegation and the other to conduct the investigation."

It is worth noting here that there is some vagueness and inconsistency about the extent to which the VP Research is apprised of misconduct allegations. Most interviewees indicated that many allegations are not true cases of research misconduct, but rather conflicts or misunderstandings between colleagues, or between graduate students and their supervisors. As one VP Research observed:

> Sometimes it's a misunderstanding, or a dispute between two people that has nothing to do with misconduct, they just don't like each other. It comes to me when it's not easy to resolve. Department Heads are in charge of making sure that people don't do nasty things to each other so they can often mediate at the Department level. It's when they can't that it comes to me."

As a result, though the Dean or VP Research is supposed to be the first point of contact for all misconduct related matters, they may not always hear about issues because they are dealt with at the departmental level:

> "People tend to come to the Department Head first, and they may try to resolve it, so I might not hear an accusation of scholarly misconduct until somebody has been dealing with it for some time. In theory, I'm supposed to hear about it right away but they may or may not decide to get in touch with me."

4.4.1 Checks and Balances

As outlined above, there is variation in the formality of the investigation process, the number of stages it goes through, and the administrative actors involved. This also reflects variation in the relative formal emphasis on the principles of due process. Many interviewees who felt that the system of checks and balances to ensure fairness in place at their institution were sufficient, pointed out mechanisms which included: the two stage investigation process; the appeal process both under the collective agreement, and in the absence of one; that allegations are reviewed by committee rather than by a single individual; that there is a faculty association observer or legal counsel present when requested; that individuals under investigation have input into the composition of the investigative committee (in some cases); and that the policy stipulated that the allegations have to be dealt with in a 'timely' manner. Many respondents emphasized that close attention is paid to the principles of due process. A representative remark was that:

> "There should be no possible way that evidence is used that the individual doesn't know about, and there is an appeal process, and everything we do has to be defensible."

In contrast, several respondents indicated that the system of checks and balances is not sufficient to ensure fairness when allegations of misconduct are dealt with by a single administrator, such as a faculty Dean, who they felt was given too much individual discretion and judgment in the investigation and adjudication of allegations. As one respondent put it: "Any investigation is only as good as the first link in the chain", and consistency is elusive "because it is really up to the individual Deans, and one may be much more thorough than another…It depends on the quality of the Deans because it comes down to individual judgment calls" whereas "an investigative panel will produce an honest report and will outline mitigating circumstances".

4.4.2 Timelines

Having clear and consistent timelines for the various stages in the process, from responding to allegations to responding to findings, is recognized as being important to supporting fairness and accountability. "One must take action quickly, noted one observer, adding that "if the process extends over too large a period of time, magnitude of problem is diluted."

Though the Tri-Council framework now requires institutions seeking eligibility for funding to specify the timeframe for inquiries and investigations and to submit the final report within 30 days of the inquiry or investigation, currently about a third of policies reviewed make no reference to timelines. Those that do include timelines, do so to varying degree of specificity. The best examples clearly commit to timelines for each stage of the process with timelines given to, for example, nominating an inquiry assessor, appointing an inquiry panel, and for receiving objections by the respondent (see Figure 10). The time from initial receipt of an allegation to having a report from an investigation committee can range from 60 to 120 days.

A second aspect of timelines, which arises in only two of the policies reviewed, is time limits after which complaints are no longer accepted. In both cases, the time limit for filing an allegation is six months after the alleged misconduct is to have occurred.

Figure 10: Sample timelines for a research misconduct investigation

Investigation step	Days	
Preliminary assessment	20	
Nomination of an Inquiry Assessor	5	
Appointment of the Inquiry Panel	10	
Period of objection by the Respondent	10	
First meeting of the Inquiry Panel	10	
Draft Report of the Inquiry Panel	60	
Respondent's comments	10	
Final Report of the Inquiry Panel	10	
Administration/management Response	20	135
Appointment of the Investigation Committee	10	
Period of objection by the Respondent	10	
Draft Report of the Investigation Committee	120	
Respondent's comments	30	
Final Report of the Investigation Committee	20	
Administration/Management Response and Decisions	30	220
Appeal period	20	

4.5 Protection of Whistleblowers

Among policies reviewed, some twenty five percent had a statement on the importance of whistleblower protection. It should be noted, however, that institutions may have separate policies on whistleblower protection and therefore may not make reference to the issue in their policies. As noted in Chapter 2, a number of provinces now have whistleblower protection legislation, which in the case of Manitoba and potentially others[48], have jurisdiction over all publicly funded organizations in the province.

There was a particularly wide range in the level of sophistication and seriousness with which different institutions approached the issue of whistleblower protection. While some interviewees reported that their institutional policy included carefully delineated measures to protect the identity of whistleblowers, if necessary, others were vague about the provisions of the policy for whistleblower protection, or could not answer the question. Nonetheless, respondents were generally aware of the sensitive nature of this issue, and expressed the difficulty of balancing the need for privacy of the complainant with the necessity of determining the authenticity and legitimacy of their claims, as well the need to protect the privacy of people under investigation.

[48] Both Newfoundland and British Columbia are in the process of developing whistleblower legislation, though it is not yet know whether these policies will have similar jurisdiction to Manitoba's policy.

In fact, respondents expressed as much concern to protect the rights of researchers who are accused of misconduct, as to protect the privacy and security of whistleblowers, and more than one respondent reported that "we tend to stress the protection of the person against whom the allegations are made". It was not uncommon for people to mention that while the policy stipulated that there could be no reprisals for whistle blowing "in good faith", malicious allegations could be subject to disciplinary action.

Of those institutions that did have an explicit whistleblower protection mechanism stipulated in the policy, most require a formal letter from the complainant, in some cases before an initial investigation will be made, and in others, before a second stage investigation can proceed. This means that even though the allegation is kept confidential, it is rare for the complainant to be permitted to remain anonymous, because as one interviewee noted: "we need to have disclosure of the facts and it is difficult to do that in an environment that's completely anonymous". Realistically speaking, even though the identity of the complainant is often not revealed to the person under investigation, it is often "pretty obvious" who the complainant is, given the history of interactions between them.

At the same time, most institutions reported having a whistleblower protection mechanism within the Research Integrity policy, or in a few cases, a separate whistleblower policy that applies to all university policies "that could result in misconduct including conflict of interest, discrimination, harassment, fraud, etc".[49] Some of these, particularly those that had recently implemented an institution-wide whistleblower policy, expressed satisfaction with the mechanism. Others acknowledged that there needs to be more substance or "teeth" because the language in the policy is not "robust enough and shouldn't be just specific to research integrity". Explicit whistleblower protection mechanisms primarily consist of a provision for the complainant to remain anonymous if they can establish that their careers or personal safety could be compromised, or would otherwise be "subject to undue harm" if their identity were made known. In this instance, where the complainant is deemed "too vulnerable", the VP Research can name a proxy complainant from within the administration to act on the complainant's behalf.

It is worth noting however, that those who reported having an explicit whistleblower protection policy or mechanism within the integrity policy acknowledged that it is very difficult to completely protect whistleblowers from personal or professional harm if the outcome of the case is particularly conflictual or damaging. In some cases, the only person who can provide evidence to convict during formal adjudication is the whistleblower, and "we might have to tell the individual that we may not win an appeal without their testimony". In that case, in the words of one interviewee: "you try to have some separation between the whistleblower and the person who is under investigation [but] it's pretty tough to protect them".[50] At the same time, none of the interviewees in the sample reported any specific cases where the personal safety or career of

[49] For example, the province of Manitoba has recently developed provincial whistleblower legislation with which all institutions are expected to comply.

[50] Some basic interventions include ensuring that a student was no longer evaluated by the individual they have brought allegations against, or that colleagues were no longer expected to work on committees together, or be on each other's Promotion and Tenure committee.

a whistleblower was compromised, and therefore, reported little experience with actually implementing whistleblower protection mechanisms.

4.6 Enforcement

The vast majority of respondents reported that research integrity is ultimately "a trust issue", and that the best method of enforcement is education and training in the proper conduct of research. There is no reliable – or desirable – way to pre-emptively "police" research integrity, and institutions must rely instead, on the ability to respond "reactively" to allegations as they arise. Most respondents emphasized that universities operate from the assumption that people have professional integrity, and that individuals are honorable. At the same time, they acknowledged that research misconduct does occur and often mention recent examples. As one noted:

> "Do I think that every person who is engaged in an act of misconduct is caught? No, I don't, and that's a shame. It is predicated on reporting [but] I don't think anyone would self-report…you can't just say 'here's the policy'. I've been doing ethics for five years now, and I'm still shocked about faculty member's ignorance or misinterpretation of research ethics and I would assume it's the same with research integrity policies. It's not enough to have a once a year 'by the way' talk."

Many people alluded to the fact that attempting to 'police' research integrity was not only not feasible, it was not particularly desirable; "we have thousands of people out there doing research. To monitor and enforce and to know that there are no cases of misconduct, I'm not sure we have the resources to do it. And is it desirable? I'm not sure". Others put it more bluntly: "Everybody is responsible for adhering to and administering the policy. There's no academic integrity police force on campus. Instead, "we try to minimize risks by mentoring, providing opportunities for research collaboration, and research support, and we vet…research protocols through departmental committees". As a result, most people reported that they try to emphasize prevention - "the carrot rather than the stick" - through education and training about the proper conduct of research. Prevention and training initiatives will be discussed in more detail in the next section.

There were nonetheless, several other mechanisms mentioned that support the enforcement process, the most obvious of which, is having policies and procedures in place to deal with allegations of misconduct. One respondent observed that:

> "the idea of research compliance is pretty new in Canada…I think we tend to assume ethical conduct of research and we place the onus on our Chairs and Deans to create that culture. Unethical conduct is an exception to that culture, and at that point an enforcement mechanism comes into play like the investigation procedure we have here."

Others, however, commented that the existing policies were not sufficient to deal with some of the issues they had encountered, and that "I have a couple of cases that have been sitting around for a while" because "I don't think our policy has teeth".

Beyond that, however, many respondents indicated that one way to enforce research integrity is through their research ethics policy, which requires researchers to obtain approval for research on human subjects, without which research funding can be withheld. Many reported that the Research Ethics Board (REB) is a good filter that flags questionable research. Many expressed that "our biggest concerns about research integrity are the things that we can and do monitor: the use of funds and ethics". The use of research funds and research ethics "are the easiest to monitor" because "each grant that goes through has a checklist on it, so there are sign-off procedures and people who are responsible for that have to verify that these activities have been undertaken before they receive research funding".

It must be noted here, however, that these data suggest that respondents tend to conflate research ethics and research integrity. During interviews, respondents frequently needed to be re-directed to concentrate on research integrity issues as opposed to research ethics. This may reflect the fact that many institutions 'house' the administration of all of their research issues in the Office of Research, and in fact several respondents indicated that they consult regularly with the Director of Research Ethics on integrity issues.

4.7 Sanctions

The majority of institutions outline the range of sanctions for research misconduct but not generally in the research misconduct policy per se (See Figure 11). For unionized institutions, the range of disciplinary measures is outlined in the collective agreement, whereas for non-unionized institutions, they are typically outlined in the appropriate employment manual where the formal professional code of conduct (also referred to as the Faculty Handbook or Manual) is published. Moreover, where sanctions are outlined will depend on the type of faculty member. For those institutions with a collective agreement, sanctions for faculty are outlined in the faculty collective agreement, and for staff, in the staff collective agreement, and likewise for the non-unionized institutions. Sanctions for graduate students are outlined in the institution's Academic Conduct policy.

Though the range of sanctions maybe outlined clearly in the appropriate policy document, they do not specify what sanctions should be applied under each circumstance. It is normally at the discretion of the individual responsible to determine the appropriate sanction. Many respondents underscored that fact that in research misconduct cases, "things are rarely black and white", and "these environments are complex", so there is a great deal of interest in learning about how other institutions apply disciplinary measures.

Figure 11: Range of Sanctions

Institution level sanctions	Granting council level sanctions
Written warning or reprimand	Funding sanctions (for serious cases - ranging from 2 years to permanent ineligibility)
Suspension with pay	• Refuse to consider future applications for a defined time period
Suspension without pay, or a fine in lieu of	• Withdrawal of remaining instalments of the grant/award
Dismissal for cause	• Seek a refund of all or part of the funds already paid as a grant / award for the research or scholarship involved
	• Ban from participating in peer review
	• Reporting cases of possible illegal conduct to the appropriate authorities

There is some variation in the individual administrator who is responsible for determining discipline, and ranges from the Dean of the relevant department, the VP Research, the VP Academic/Provost, to the Principal or the President. In unionized institutions, the VP Research may be responsible for the investigation of allegations, but does not have the authority to sanction, which falls instead to the VP Academic to determine discipline in reference to the collective agreement, because it involves employment issues. Most people report, however, that sanctions are determined in consultation with appropriate colleagues, for example, "the Dean normally would consult with the VP Research and possibly the Provost". As one interviewee noted, if sanctions are determined according to the collective agreement, "this would always be done in consultation with other members of the administration, as well as the faculty association, because anything done under the collective agreement is grievable".

4.8 Prevention and Training

Of the 37 policies reviewed, only 35% had statements on the obligation of the institution to educate on the subject of research integrity. Though often absent in their policies, most institutions report having two primary mechanisms in place to inform the research community about research integrity. First, almost all institutions report that the policy is available on the institution's website. This tends to be only marginally effective, however, because updated policies may not be posted regularly, or different but related policies may be posted in different areas on the website, making access difficult. There is a trend in some of the larger institutions to create a 'one-stop' access that provides a formal policy manual on-line which lists all of the policies and procedures of the university in a single searchable website. Most respondents agreed, however, that this was too passive a mechanism to be effective because it relies on people to refer to the website on their own initiative, which most people do not do.

The second mechanism reported by many (though not all) institutions is the annual new faculty orientation, during which people are introduced to university policies and procedures, including those on research ethics and integrity. The problem with this approach is that new faculty are

introduced to a great deal of material in one day. In the words of one educator: "they give me 10 minutes to get all the points out about research and graduate supervision, but we don't go over the policy. We don't have time". As a result, there is no way of enforcing or knowing whether new faculty have read and understand the policy. Likewise, while many institutions require new faculty to sign a statement as part of their employment contract that they will abide by all university policies, there is no real way to ensure that they have actually read them. This also does not reach other faculty who may have been doing research at the institution for some time, but remain "blissfully unaware of university policy".

Though most institutions had these two mechanisms in place, a few typically larger institutions have implemented more extensive and concerted training and prevention activities, and tend to report that it has been worth the effort; "we've learned that you can never assume integrity…and we've definitely learned that good procedures well publicized and rigorously enforced, work". For example, some institutions have orientation sessions for new academic administrators, the Chairs and Deans, to keep them informed on research integrity protocols, particularly as they are often the first point of contact for misconduct allegations. These institutions also tended to report that requirements for education and training for research integrity are outlined in the policy itself and that "it outlines several ways in which to do that". This includes distribution to all people with campus addresses, faculty 'Research Integrity Days' to which all faculty, post-doctoral fellows and graduate students are invited, "so there is a whole series of ways it is done so nobody should be able to say 'I didn't know there was a policy.'" In the federal government, all new employees are made aware of the Code of Value and Ethics in their initiation process.

In contrast, several other institutions reported that their organized training and prevention activities are relatively weak and that they "don't have anything concrete in place right now". Several respondents underscored the difficulty of getting research integrity on the institutional agenda as "an essential item rather than a nice to have item'". They report that training for the ethical conduct of research is not "high on the priority list" because people think that "they already know". For example, one respondent reported offering an information session on the Tri-Council MOU to senior administrators that was very poorly attended.

4.9 Reporting / Communications and Transparency

More than any other area examined so far, the questions of reporting and communications, and the public disclosure of findings of research misconduct appeared to elicit the most ambivalence and confusion. It is particularly notable that none of the academic institutions in the interview sample had a formal public disclosure policy that required them to publicize findings of misconduct. Moreover, only a third of the policies make reference to reporting requirements. When asked how their particular institution handled the disclosure of misconduct cases, people either didn't know, or reported that they were disclosed on a 'need-to-know' basis, which is often outlined "explicitly" in the collective agreement.

Of the respondents who were not clear about the institution's reporting and disclosure policy, most reported that their research integrity policy was "pretty vague", or "quiet on that", and some "had never really thought about it". Beyond the general awareness that findings of misconduct must be reported to the respective granting agency, the vast majority of respondents who were knowledgeable about their institution's disclosure policy indicated that findings of misconduct were kept internal to the institution, as confidential as possible, and reported on a 'need-to-know' basis. As one noted: "we are not obliged to report it [because] it is not a matter of public record. Do we put out a press release? Most certainly not."

Typically, allegations that are not substantiated do not go beyond the individuals involved in the initial investigation stage, such as the relevant Dean, and the VP Research. Even if allegations are found to be substantive, however, the findings remain confidential to those involved in the formal investigation. This, as one interviewee added, is typically limited to a combination of "the VP Research, the AVP Research, the Provost, and the President, the members of the investigative committee if there is one, and a confidential secretary – that's it".

As was mentioned in the discussion of whistleblower policies, academic institutions tend to be as - if not more - concerned about protecting the privacy of individuals who have been accused of research misconduct, as those who bring forth allegations of misconduct. On this question more that any other, respondents expressed ambivalence over the need to balance the harm to individuals' reputations and careers, with the potential harm to the research community. Several reported that their institution was actively grappling with the question of the extent to which findings should be made public, but remain unclear as to how to proceed. On the one hand, many commented on the grave consequences of being found guilty of research misconduct. A common sentiment that was expressed was that "you don't want to ruin someone's reputation unless it's necessary". In this context, several respondents expressed the importance of conforming to provincial privacy laws, and were aware of the fact that such laws prohibit the communication of case specifics to other institutions. Distaste for the American practice of "naming and shaming" - publishing a "black list" of all researchers found guilty of misconduct – was almost universal.

On the other hand, respondents also expressed concern about harm to the institution and the larger research community. Those who mused about making findings of misconduct part of the public record reflected the current debate over whether universities should publicize cases in order to send the message that "tenure doesn't protect misconduct". In the words of one interviewee:

> "The infractions are [also] grave and what they do to confidence in the research community which largely operates on a system of good faith, the impacts are huge. This work requires a high degree of integrity. Is it really inappropriate to be expecting disclosure?"

This ambivalence was also evident in the question of what entities should be contacted in the event of a finding of misconduct. While most respondents emphasized that findings are kept confidential and internal to the institution, and should not be made public, they universally reported that "anyone affected by the research" such as academic journals or funding agencies, should be informed. Only one institution in the sample reported having a clear disclosure statement outlining the designated responsibility of the VP Research to "contact whatever external agencies need to be contacted…such as the Tri-Councils or a publication".

One administrator expressed concern about unknowingly hiring someone who had been found guilty of misconduct at another institution. Ultimately, however, several people commented that "the Canadian university system is small" so "word gets around through the grapevine". One institution reported dismissing three tenured professors in one year, one of which was identified in the press because "information was leaked".

5. Assessment of Canada's Research Integrity System

5.1 Current State of the System

Canada's research integrity system is seen by many of those involved on the front lines of allegations to be, at base, functioning reasonably well. Its decentralized approach that gives primary responsibility to research institutions for addressing allegations is widely viewed in a positive light, as is the role that the granting councils play in instituting policy requirements. It is accommodating of the complexity of many misconduct allegations and allows for discretion in dealing with cases, many of which, it is noted, are based on misunderstanding or poor oversight.

Moreover, Canada's system, not having been legislated, has maintained its flexibility that has allowed for improvements as a result of learning from experiences. The granting councils have been introducing new requirements over the years by way of new schedules and frameworks, while many research institutions have been updating their policies both in response to the granting councils, and to their own experiences in dealing with allegations. These changes have been concomitant to a growing awareness of research integrity issues over the past decade that has brought the subject out of the margins of academic discussion. In reflecting on Canada's approach, one interviewee observed that: "what were once accepted practices are no longer acceptable under current norms of research integrity". The Canadian system appears to be adapting well to what has become a global conversation about appropriate research behaviors and practices.

The system is not, however, functioning equally well for all actors and for all areas of research. For organizations that are focused on applied research and engineering, including colleges and some SBDAs, research integrity and misconduct does not generally garner much attention. In fact, there has been limited 'testing' of the system for many of those organizations involved in this area. Because research tends to be focused more on solving a client's problem than on publishing research, the opportunity and motives for carrying out research misconduct are considered to be reduced. This view was also noted in the few comments received by industry. For this group, other concerns, notably intellectual property and conflict of interest, are more pressing than research integrity and misconduct, with which few of those interviewed had much experience.

In the social sciences, views and experiences are mixed. On the one hand, while plagiarism is recognized to occur, the nature of social science research together with a peer review process that is accustomed to assessing the validity of qualitative data, has fostered, rightly or wrongly, a degree of confidence in the current system. On the other hand, some areas of social science give

rise to very difficult research integrity questions that current policies cannot resolve. Research in a fine arts context, for example, brings to the fore problems related to documentaries: if, as one interviewee noted, documentaries are taken to be research in the sense that it may further general knowledge, what artistic license does its creator have to interpret results?

The greatest concerns over the current state of Canada's research integrity system come from the actors in the health sciences - medical research organizations, universities, and journal editors. This group not only has more experience with research misconduct, but also heightened understanding of what is at stake should research misconduct be left unaddressed. As has been noted, misconduct in clinical trials has greater public implications than does misconduct in historical research. While this group does recognize the basic strengths of the system, it also recognizes the need for Canada to address its shortcomings, including a weakness in formal oversight, inadequate reporting requirements and inconsistent educational efforts. What follows is an overview of the main shortcomings as identified by all groups.

5.2 System Gaps

The current system for dealing with research integrity and misconduct has a number of gaps of various kinds that diminish its overall effectiveness. These include system elements that could be present but are not, as well as shortcomings that allow for undesirable outcomes.

5.2.1 System reach

Without an official national reach, the current system is inconsistent in its coverage of Canada's research actors. Though the TCPS-IRS has had influence beyond the universities and colleges and other non-profit organizations that receive granting council funding, it offers no assurances that all government departments and agencies, companies, or private medical practitioners conducting their own research adhere to the same standards. A notable gap is evident in government where a number of major government science-based departments and agencies have yet to develop research integrity policies.

5.2.2 Accountability and transparency

Ensuring accountability within the decentralized oversight system is made difficult by the fact that one widely used mechanism for upholding delegated responsibility in an institutional environment, namely transparency, is shrouded by a need to maintain confidentiality, which is needed at two levels. At the level of allegations and investigations, maintaining confidentiality is an essential part of the process: it is critical for whistleblower protection and ensures that a respondent's reputation is protected from frivolous allegations.

Confidentiality is also required under privacy legislation which limits the exchange and flow of information related to misconduct cases among the various actors within the system and between stakeholders. As a result, research institutions, who are bound by provincial privacy acts, do not publicly disclose details of cases where misconduct is found, such as the names of the

individuals and their home institutions. For some institutions, this privacy is interpreted as extending to all aspects of research misconduct cases, even basic facts as to whether or not allegations have been made and how many. As for the granting councils, which may be informed of investigations, federal privacy laws prevent them from disclosing this information even to each other.

These laws ultimately limit accountability that could otherwise be maintained in part by the media whose public scrutiny can help foster good governance and accountability among public self-governing institutions.

Another impact is on the granting councils which are prevented from sharing information on those found guilty of misconduct, be it financial or otherwise. As a result, it opens up the possibility for an individual found guilty of research misconduct from finding employment at another institution, which would generally not know of a new employee's past misconduct, and applying for new research funds from other sources, or from a different granting council to the one that supported their earlier research. The mechanism in place to prevent such behavior are the assurances made in signing applications for funding that attest to a researcher's status as not having "been barred from applying to NSERC, SSHRC, CIHR, or any other research funding organization, for reasons of breach of standards of ethics or integrity (including financial or scientific misconduct)". Signatures are required by both the researcher and the institution, the latter of which, in signing the application, must have the knowledge to be able to certify that the applicant has met one of the eligibility requirements of not having been barred from applying to the granting councils.[51]

Institutional non-compliance

Though Canada's research integrity system does have a mechanism through Schedule 8 of the MOU for dealing with institutions that do not comply fully with their own research integrity policies, there remain concerns not only among researchers who have experienced firsthand non-compliance by their employer, but also those on the outside in the research community as to its effectiveness.

A number of individuals engaged in peer review, including some outside of Canada, have first-hand experience with uncooperative institutions who have failed to respond to, or follow up with, allegations. Reliable evidence on institutional non-compliance is, of course, hard to come by. Instead there are anecdotes - numerous enough for one expert in Canada to suggest to those calling for advice with allegations that they should think seriously of the implications before proceeding with a formal complaint.

For a system that relies exclusively on the home institution to address complaints, such anecdotes are sufficient for several of those interviewed on the front lines, particularly in the

[51] See Frequently Asked Questions: What do the signatures on the application mean? http://www.nserc-crsng.gc.ca/Professors-Professeurs/FAQ-FAQ_eng.asp#6; and Eligibility Criteria – For Faculty, http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Eligibility-Admissibilite/faculty-corpsprof_eng.asp.

health science fields, to call for stronger national oversight, or at the very least, more education regarding what mechanisms are in place. The granting councils, which have the most influence over the policy landscape, have no mandate to pursue possible conflict of interests that may arise when institutions are left to investigate themselves. Competing obligations and interests at the institutional level, as has been noted, will always be an issue; the need to attract research funding, recruit staff and maintain reputation can too readily compromise the willingness of an institution to address a particular allegation.

5.2.3 Reporting

The Canadian system currently requires the reporting of cases only where misconduct has been found and which involve granting council funds. The number of cases where research was funded by the private sector, by institutional endowment funds, or by other government bodies, or which was performed by a government department or agency, is therefore unknown.

As a result, the Canadian system has no way of tracking whether research misconduct is decreasing or increasing, and whether efforts to improve policies and enhance awareness of research integrity issues are having an impact. Though there is little interest in 'naming and shaming' those found guilty of research misconduct, as is done in the US but not in Canada, there is considerable support for more reporting. In addition to having a better grasp of trends and extent of misconduct, improved reporting that includes case summaries (with the specifics withheld) is viewed as useful for teaching researchers as well as for administrators who may be dealing with similar issues and could benefit from the experiences and lessons that such summaries would provide. The nature of the allegation, the scope of investigation and type of sanctions meted can offer valuable lessons for those responsible for pursuing allegations and help improve uniformity in processes across the system. In the US, the ORI sends a newsletter with such summaries to research integrity officers, which is valued by some of those Canadians who receive it. Similarly in Denmark, the central body (DCSD) produces an annual report which profiles each case and or allegation (See Appendix B.1).

5.2.4 Education and training

The Canadian system needs a more unified approach to raising awareness of research integrity, both as a substantive issue in itself and also in the policies governing research integrity at an institutional level. Currently, awareness levels vary a fair amount, and depend in part on the type of research area in which one works. This is reflected in a number of interviews where research integrity, which emphasizes research*er* ethics, is often misunderstood as being synonymous with research ethics.

Support for research integrity related education and training initiatives is strong especially among those with experience in dealing with allegations. Such initiatives are increasingly recognized as being essential to improving the overall effectiveness of maintaining research integrity and for improving detection. Most institutions that recently revised, or are in the

process of revising, their research integrity policies have given emphasis to the importance of such initiatives, with some articulating new approaches for actively promoting education and training in this area. It is nonetheless an area that is subject to considerable variation among institutions and one that could benefit from guidance at the national level. Moreover, there is strong receptivity among many of those interviewed to having assistance on education.

5.2.5 Differing standards

Though the TCPS-IRS has introduced a significant degree of uniformity in how most institutions respond to allegations of misconduct, there remains considerable variation in some aspects of institutional policies, notably the definition of research misconduct. As is demonstrated in Section 4.2, the definition, which is critical to informing decisions as to whether to pursue an allegation, varies considerably across the country. While such differences reflect specific institutional policy contexts (e.g. institutions without a separate conflict of interest policy may include it in their research misconduct definition), they introduce challenges at a national level. When a researcher moves to another institution or in cases of multi-institutional collaboration, differences can open up gaps in understanding as to what constitutes research misconduct.

On the whole there is receptivity to having a national standard for a definition that goes beyond the current positive definition to include the types of behavior that are to be sanctioned. The definition, as one expert noted, should be based on the fundamental question concerning research integrity - that is: what types of behaviors are doing the most damage to publically funded research?

5.2.6 Assistance to whistleblowers

Whistleblower assistance includes both the policies that protect whistleblowers and being able to access confidential and expert advice on pursing an allegation of misconduct. Whistleblower protection, though central to encouraging detection and notification of potential misconduct, is addressed in less than a third of policies reviewed, and almost all from the large universities. This issue is complicated by the fact that institutions may have separate policies on this matter, some of which are required by provincial legislation (as is the case in Manitoba) and therefore may not include it in their research integrity policy. Similarly, federal departments and agencies are now covered by the *Public Servants Disclosure Protection Act* and therefore may not have any explicit protection procedures in their research integrity policies (see 2.2).

The Tri-Council framework document used for reviewing policies does, however, now require institutions to have procedures in place to "safeguard, as far as possible, the privacy of the complainant and respondent" and must "define actions to protect 1) person (s) who have made an allegation in good faith; 2) all persons involved (e.g., witnesses) in an inquiry/investigation." Though this framework has been in place since 1996, institutional compliance with these aspects of the framework is inconsistent. To improve compliance levels, the granting councils have been working with institutions on an on-going basis, either when institutions are updating their

policies, or following reviews of enquiry/investigation reports, at which time they examine institutional policies of those involved.

The second aspect of whistleblower assistance - having access to confidential and expert advice - is also limited in Canada. Though some institutions do have individuals who have been appointed for this purpose, there is no national service available for accessing confidential, independent and expert advice for those debating whether, and how, to make an allegation, or to discuss issues and problems related to ongoing investigations.

5.2.7 System governance

The locus of governance has thus far been at the level of the three federal granting councils which have collaborated, mostly informally by way of ad hoc committees, in developing the relevant policies such as the TCPS-IRS. Despite this collaboration and common interest, the councils themselves have each developed different internal procedures for addressing research misconduct. The result is a degree of inconsistency in how the councils, and by extension, research areas deal with research integrity. CIHR, in particular, has developed a number of procedures in addition to the MOU and related schedules to manage allegations of researcher or institutional non-compliance. One of these is an internal procedure made publically available on its website that outlines the steps CIHR follows when addressing allegations, which includes convening its Research Integrity Committee to determine whether the allegation should be referred to the appropriate home institution for investigation. [52] When sanctions are imposed, the procedure requires that its 'Applicant Status Alert System' be activated to alert appropriate staff of the institution's and, or, researcher's ineligibility, as well as the duration of this sanction. CIHR has, on a case by case basis, also suspended researcher funding during on-going investigations, and is the only granting council to publish on its website its annual statistics of research misconduct.[53]

[52] CIHR Procedure for Addressing Allegations of Non-Compliance with Research Policies, http://www.cihr-irsc.gc.ca/e/25178.html

[53] Note that statistics from NSERC and SSHRC are available on request.

6. Canada in a Comparative Context

6.1 Overview of National Research Integrity Systems

This Chapter compares Canada's research integrity system to those of eight other countries – Australia, Denmark, France, Japan, Norway, Germany, the United Kingdom, and the United States. These profiles, which are can be referenced in Appendix B, provide the basis for the analysis that follows.

Overall, the comparative analysis finds that the Canadian approach holds up well in an international context. What is clear, however, is that no system is without drawbacks and that the shortcomings inherent to Canada's approach are also shared by other countries. Furthermore there is no consensus on a best system; research integrity systems continue to be subject to revisions in most of the countries reviewed, and in all but two, these revisions are of systems that have been in use for over a decade. For the purpose of this report, these latter systems are considered to be 'established', as compared to those that are now being, or have recently been, institutionalized and are therefore 'developing'.

The instigator for these changes has typically been a serious case of research misconduct that came to public attention and which has revealed weaknesses in existing systems. Australia, for example, introduced a new national Code in 2007, Norway established a new National Commission for the Investigation of Scientific Misconduct in 2006, and in 2008, Denmark enacted new legislation to narrow the focus of the Danish Committees on Scientific Dishonesty - all changes prompted by serious public cases of misconduct.

6.2 Three Models

For all these changes, countries have yet to converge towards one best model. As Figure 12 indicates, there remains notable diversity with regard to basic system attributes, a diversity that reflects not only differences in polities but also legal and research traditions of a particular country. Despite this variation, patterns can be identified among the differences that allow for the identification of three research integrity and misconduct models.

Type 1: Type 1 systems are characterized by the fact they have been institutionalized to a degree at the national level by way of legislation. Countries that have taken this path – Denmark, Norway and the US – have research integrity and misconduct systems that share a number of attributes. These include a central research integrity body with investigatory powers; a definition

of research misconduct that is generally restricted to falsification, fabrication and plagiarism[54]; and a two tiered investigation system that gives research institutions the primary investigative role but which allows the central body to also carry out an investigation, normally at the request of institutions, and generally only for the more serious cases.

Figure 12: Attributes of Research Integrity Systems

Country		State of Development	Nationally Legislated	Central Body	Granting Council Oversight	National Policy / Code / Statement	Responsibility for Investigation	
							Investigation Levels	Investigator(s)
Type 1	Denmark	Established	Yes	Yes	No	No	2	Central Body (FFP) / Institution (FFP+QRP)
	Norway	Developing	Yes	Yes	No	No	2	Central Body (FFP) / Institution
	United States	Established	Yes	Yes	Yes	Quasi (via Granting Agency)	2	Central Body (FFP) / Institution (FFP+QRP)
Type 2	Germany	Established	No	Yes	Yes	Quasi	2	Institution / Ombudsperson
	United Kingdom	Established	No	Yes	Yes	Quasi	1	Institution
	Canada	Established	No	No	Yes	Quasi (via Granting Agencies)	1	Institution
Type 3	Japan	Developing	No	No	Yes	Yes (Code)	1	Institution
	Australia	Established	No	No	Limited	Yes-(Code)	1	Institution
	France	Developing	No	No	Limited	No	1	Institution

Type 2: Type 2 systems are non-legislated and defer to the granting councils for oversight and leadership in policy. Among the countries reviewed, the UK and Germany adhere to this model, as does Canada. In Type 2 systems, granting councils develop policies and guidelines for use by recipient institutions in establishing their own policies and procedures for addressing research integrity. Generally granting councils require that institutions have in place policies that meet its

[54] It should be noted that both Denmark and Norway define research integrity to also allow for 'other serious violations' whereas the US does not.

guidelines as a condition for funding, and as such, these policies often become a quasi national standard that is also used, or referred to, by institutions, including government organizations, that may not receive granting council funding.

Type 2 systems may have separate, or arm's length, national research integrity bodies though with varying degrees of independence, jurisdiction and authority. In Germany, the granting councils have established organizations with responsibilities to advise as well as assist in mediations or investigate allegations of misconduct. In the case of the Germany, the organization is an ombudsperson team which has a remit to oversee all cases brought to its attention, and not just those cases that have involved granting council funding. In the UK, its independent organization is hosted by the UK's university association with support from government and granting councils and acts primarily as an advisory body with no legal authority to investigate or enforce policy compliance.

Another attribute of Type 2 systems is their emphasis on research integrity as opposed to research misconduct in the key codes and policies. This reflects a positive, less legalistic approach that gives focus to good research practices as a way to prevent research misconduct from happening. And though principles of good scientific practices are stressed, most Type 2 systems will nonetheless have an agreed upon the definition of research misconduct.

Type 3: Type 3 systems are also non-legislated and are loosely characterized both by their national orientation, encompassing both government and academic research, and by the absence of any independent research integrity oversight body or compliance mechanism. Of the countries reviewed, Australia, Japan and France can be understood as having such systems though it is worth noting that there are important differences between them, not least the fact that the research integrity systems in Japan and France are still being developed.

Australia is unique among all countries reviewed in having a national 'Code for the Responsible Conduct of Research', which is a comprehensive 40 page document that is proscriptive in its detailing of all aspects of addressing research integrity and misconduct. In Japan, the Code of Conduct for Scientist Statement is written more as a loose guideline for establishing systems at individual research institutions. Though France currently has no national policy, two central research organizations are currently taking steps to develop one. CNRS, France's major public research organization, has been asked to develop a national research integrity policy while INSERM, a granting agency for health science, has been tasked with developing a national prevention and training system.

6.2.1 Model Commonalities

Despite respective differences, the three models share a number of commonalities. First, all are at base 'fire alarm' systems as opposed to 'police patrol'[55] systems, whereby monitoring and policy

[55] See McCubbins, Mathew D.; Schwartz, Thomas. "Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms" *American Journal of Political Science*, Feb84, Vol. 28 Issue 1, p165, 15p; (AN 5241535)

compliance is achieved passively, as opposed to through active surveillance, and where procedures for addressing research misconduct are set in motion only by formal allegations. To the extent that these systems are active, it is in the area of education. In this area, systems with national bodies that take on an educational role are typically more active than those that leave education to the institutions.

Second, in each system, the locus of responsibility for investigating allegations resides with the research institutions. In systems where independent bodies have been established with investigatory powers, investigations are normally done only by request from a particular institution.

Finally, according those interviewed in respective countries, each system has drawbacks, drawbacks that are often intrinsically tied to their strengths. Type 1 systems, for example, have the benefit of strong oversight by way of a legislated body, but this oversight is limited to a narrow definition of research misconduct. Moreover, as legislated systems, changes are not as easy to bring about. Type 2 systems on the other hand, may be more flexible but also are often more pluralistic by allowing for more diversity at the institutional level. It has been suggested that granting councils, though well positioned to enforce policy compliance, may not, in fact, be well positioned to effectively address research misconduct, given their own competing obligations and interests in serving their mandate to promote and finance research.

Note that no system type deals consistently with the private sector. In Type 1 systems, Norway legislation has jurisdiction over the private sector whereas in the US, the ORI can pursue cases involving companies but only if they have been recipients of federal research funding. In Type 2 systems, granting councils have influence over firms that receive their funding through funding conditions.

6.3 Model Variations and Lessons for Canada

From an international context, Canada's system compares relatively well. As a non-legislated Type 2 model led by the granting councils that hold institutions to a process for addressing research misconduct by way of an MOU, Canada's system has a number of strengths inherent to this approach. Its flexibility has allowed for continuous improvement, as demonstrated by the introduction of new schedules and frameworks related to research integrity. This flexibility has also allowed research institutions to tailor research integrity policies to their own institutional environments. Yet as Chapter 5 has pointed out, the Canadian system has a number of drawbacks, some of which have been addressed in other countries. In the following sections, the various components of Canada's research integrity system are examined in a comparative context, from which lessons for Canada's system are drawn.

6.3.1 Definition of research misconduct

Of the eight countries examined, five have an official national definition of research misconduct and all are explicit about sanctionable behaviours. Australia is unique in emphasizing a positive definition of research integrity along side a non-exclusive list of unacceptable scientific practices.

Three countries - Denmark, the US and Japan - have limited their national definitions to FFP and "other serious breaches" (although these are not defined). These three countries suggest that the definitions of misconduct may be expanded at the institutional level to include other types of behaviours. The advantage of a limited definition at the national level is twofold. For those with national oversight bodies with investigative powers, the consensus that FFP constitutes the more serious breaches of scientific values and norms legitimizes national involvement. Pursuing cases of, for example, honorary authorship, while not generally considered an acceptable practice, is not a serious enough charge to warrant a national investigation.

Second, FFP is generally considered to be the least ambiguous and most amenable to legal protocols that define Type 1 systems. Denmark, following a problematic and public case of scientific dishonesty brought to the DCSD, narrowed its definition of research misconduct to just FFP so as to prevent similar cases from again being pursued at the national level. The ambiguity of the case is recognized as the main factor for narrowing DCSD's mandate.

Though practical from an administrative and legal standpoint, limiting research misconduct to FFP potentially allows for practices to continue that may not directly damage the integrity of the research process but which ultimately erode confidence in the integrity of research, its traditions and values. In speaking to the weaknesses of the US definition, one commentator noted that a definition should be based on the fundamental question of: "What types of behaviours are in fact doing the most damage to publically funded research?" As Figure 13 indicates, Germany, the UK and Australia have all identified additional misconduct behaviours to that of FFP, though only in Australia is this official.

Figure 13: Definitions of Research Misconduct

Country	Status of Definition	Definition components	
Denmark	Official*	FFP	Other serious breaches of good scientific practices
Norway	Official	FFP	Other serious breaches
United States	Official	FFP	Institutions are encouraged to go beyond these into areas including: -improprieties in authorship -misappropriation of others ideas -violation of generally accepted research practices -material failure to comply with other federal requirements -inappropriate behaviour in relation to other misconduct -deliberate misrepresentation of qualifications for funding or advancement -misappropriation of funds
Germany	Unofficial	FFP	Infringement of IP Impairment of work of others Joint accountability of misconduct
United Kingdom	Unofficial	FFP	Misrepresentation Management and preservation of data and primary materials Breach of duty of care
Canada	Unofficial	Defines principles of integrity and states that the Councils "regard any action that is inconsistent with integrity as misconduct."	
Australia	Official	FFP	Misleading ascription of authorship Failure to declare / manage serious conflicts of interest Misuse of funds + others
Japan	Official	FFP	
France	Unofficial	N/A	
*Official definitions are those that have been defined as part of national legislation or policy			

Lessons for Canada

The TCPS-IRS has in effect established a quasi national definition that is referenced not only by the research organization that receive granting council research funding but also by other research organizations including government departments. As a national definition, however, it is one of the few that does not explicitly identify misconduct behaviours. Having an explicit definition of research misconduct is important for bringing clarity to the process and for specifying unacceptable practices that may otherwise go unacknowledged. It is also important to ensuring that all types of cases where misconduct is found are in fact reported in accordance to sponsor policies.

6.3.2 Governance and administration

For the Type 1 countries, that is, those with legislated or regulated systems, the highest level of governance is the government department or ministry designated by the law or regulation. These countries then create an Office (such as the ORI in HHS or the OIG in NSF in the US) or a Commission (such as the National Commission for the Investigation of Scientific Misconduct in Norway). These offices generally have responsibility to initiate or take over investigations from institutions. Some have the authority to impose sanctions on their own; some make recommendations back to the institutions respecting the outcome of their investigation, the seriousness of the breach and (sometimes) the nature of possible sanctions.

For all other countries, including Canada, governance and administration of the research integrity system is the responsibility of the "granting councils" as constituted in that particular country. These organizations have acted in two ways: (1) the Type 2 countries created a policy statement respecting research integrity and then required institutions receiving funding to create internal systems to implement the policy, or (2) the Type 3 countries created a national code that then applies to all institutions receiving funding.

Type 2 and Type 3 countries vary in the level of infrastructure created to develop and manage the policy or the code. For example, Australia, like Canada, has no independent or quasi-independent body specifically dedicated to the governance or administration of the nations system. The granting organizations are left to deal with these matters on a collaborative basis. On the other hand the German granting council, the DFG, created the Office of the Ombudsperson with some responsibilities respecting the oversight of the system, policy development, promotion education and limited reporting (although no investigatory powers). Under *Universities UK*, an association for the executive heads of universities, the UK has created a body called the UK Research Integrity Office. It is an advisory body only with a mandate to promote high standards of research integrity and provide advice guidance and support to employers and individuals.

As noted in Section 6.2, in all countries the day-to-day development and administration of the policies is delegated to the institutions. The administration is usually done at the level of the Vice-President, Research or the equivalent.

Lessons for Canada

In those countries that are not "legislated" there appears to be reluctance to move towards, say, the United States system. On the other hand, where those countries do not have a central body of any sort, there is support for the creation of such an organization. While the exact nature of the mandate for such a body is the subject of much debate, some areas include: education and training, data gathering and reporting (for education and training purposes), advice and support to institutions and individuals. It is generally agreed that the central body should not have an investigation role.

6.3.3 Accountability and transparency

This is a major area of concern in all of the systems examined, with an exception noted below. That is, given (1) that all the systems rely on the institutions for the implementation and administration of the policies, and (2) that there is a certain inherent conflict between maintaining research integrity and exposing the institution and the scientific enterprise to "bad publicity" (not to mention the withdrawal of funding); there is a problem with accountability and transparency in all systems. Most agree that there is a significant under-reporting of possible misconduct and at least some cases where misconduct is ignored or not dealt with adequately.

The exception is that in the Type 1 systems, at least with respect to FFP and the cases that the central body is responsible for, there is clear accountability and varying degrees of transparency. In some cases, such as the ORI in the United States, the names and institutions of "guilty" parties are published, in others they are not.

Lessons for Canada

Clearly this is a difficult issue for all countries. The solution relies on the cooperation and the commitment of the funding bodies, the professional associations and, most of all, the institutions to finding and implementing better solutions. The best evidence is that a central, independent organization with a carefully defined mandate would provide the system with, at least, its own internal transparency and the ability to ensure that the institutions are taking their "accountability" role seriously.

6.3.4 Enforcement and sanctions

As noted above in Section 6.2, one of the common features of all systems is that, at least in the first instance, the responsibility for the enforcement of the research integrity principles rests with the institutions involved in the funded research. Most have a two-stage investigation system. The first stage begins once an allegation is put forward. It involves an informal inquiry (called an "investigation" in Australia) by the person designated at the institution with responsibility for these situations. This inquiry is designed to determine if there is any substance to the allegation and to recommend to the senior management of the institution what steps, if any are required to resolve the allegation. If there is substance to the allegation, the next step is a formal investigation (called an "inquiry" in Australia). There is variation among countries (and even within a country) as to how this second step proceeds. In addition, some policies note that the investigation may take different forms based on the nature and the seriousness of the alleged misconduct. For example, it might be carried out by a senior officer of the institution, or it might be conducted by a tribunal of three people internal to the institution, or, alternatively, it might be set up as an external tribunal. In most cases, once the allegation reaches the investigation level the procedures become more formal and legalistic in order to ensure fairness and due process. It is generally at this stage that, at least internally, the name of the alleged offender and the person raising the allegation become known (formally) to each other.

The types of sanctions imposed can vary widely from country to country and from institution to institution. Generally speaking there are two types of sanctions possible: (1) employment related, and (2) science related. Employment related sanctions are usually governed by the labour laws of the relevant jurisdiction and any collective bargaining agreement that applies. They range from a reprimand to dismissal for cause. The science related sanctions include removal or repayment of funding, withdrawal of a degree, restrictions on applying for new grants, correcting the academic record, etc. The nature and scope of these types of sanctions is very broad.

Lessons for Canada

The employment related sanctions are, for the most part, regulated at the Provincial level in Canada and are a combination of legislation, collective bargaining and common and civil law principles. This aspect of the system, as it applies specifically to research misconduct would be difficult to adjust and certainly impossible to "unify".

On the other hand, the science related sanctions are to a large extent within the jurisdiction of the Councils and the institutions, especially when working in collaboration with the professional associations and the academic journals or their umbrella organizations.

This study has identified a desire to have more information about which sanction might apply in which types of cases; therefore, there is an opportunity to collect information about decided cases and provide information about the nature of the case and the sanction imposed. This might also lead to a discussion of the rationalization of the science related sanctions if and as necessary.

6.3.5 Prevention and training

In the countries reviewed, the research institutions play the primary role in prevention and training. Among countries with national research integrity bodies, this role is often supported at a high level by attending seminars and conferences and providing guidelines and other educational resources when requested by institution or when a case or series of cases suggests a need for better information and support at that institution.

Almost all of the countries studied indicated that there was a need for more and better education and training, although some were still uncertain of the ultimate value of proscribed training courses and even more uncertain about the relative merits of the many courses and programs available. All of those indicated that one major issue is the lack of resources to provide any centralized support to such programs.

Lessons for Canada

As with other countries, there is a need in Canada for more and better education and training about research integrity and misconduct. It would appear that some combination of a web-based introductory course (setting out the basic principles of research integrity and the procedures for dealing with possible cases of misconduct) and an "in-person" course using a case-study

approach would be a valuable addition to the research integrity landscape in this country. This could be a role for a central body or possibly the Councils, with advice from all stakeholders.

6.3.6 Reporting

Of the eight countries studied, four had neither any requirement nor procedure to report either allegations or findings of misconduct. For those countries with no central body, this relates in part to the fact that there is no infrastructure in place to receive the reports. The Type 1 countries (those having a legislated system) include a requirement to report cases (both allegations and the results of an inquiry or investigation) to the central authority. Even among those that do require reporting, this does not include "naming names" in two of the four cases.

Lessons for Canada

Comprehensive and accurate reporting is important to the ultimate success of the system. Reporting is important not only for understanding the extent of the problem but also for the design or redesign of the system (data and information lead to better design) and to the education and training of both existing and new researchers.

7. Prevalence of Research Misconduct in Canada

7.1 Overview

As a number of high profile cases have demonstrated, including those of Dr. Chandra at Memorial University and Dr. Poisson at St. Luc Hospital in Montreal, research misconduct is a reality in Canada's research environment, though one that is shared by any country that supports research. Indeed, a survey of several thousand US based researchers published in Nature in 2005 found a relatively significant portion of respondents acknowledging some type of research misconduct, though mostly the less severe behaviors.[56] And all eight countries reviewed in this study have experienced very public and damaging cases. The fundamental question for this country, therefore, is not whether there is a problem but how serious is the problem.

Given the state of reporting requirements in Canada as well as the complex and sensitive nature of the issue, this is by no means an easy question to answer. Of the many actors in the research system, the three granting councils are the only ones to maintain statistics, which they do only for those that they are made aware of, and which involve their research funding.[57] Research organizations, for their part, have no incentive to make public the number of allegations received, and generally view cases as a mark against their reputation.

There are several other complicating factors to determining the extent of misconduct. One is the strong likelihood of under-reporting such that any discussion of prevalence is ultimately limited only to those cases where misconduct has been reported. As has been noted, there are a number of incentives for not reporting cases, including an unwillingness to risk one's own reputation or sour relationships with colleagues, or simply an unwillingness to engage a process that can lead to frustration and additional work stress. Under reporting also comes about when allegations are reported but are then 'swept under the carpet' at some level of the institution. Anecdotes from interviews conducted for this study attest to all of these instances.

Another complicating factor is related to the definition of research misconduct itself. Allegations can only be made in a consistent manner if there is a national consensus - and awareness of this consensus - on what constitutes research misconduct. While no one disputes the more serious

[56] While only 0.3% acknowledge falsifying data, 1.4% acknowledged using another's ideas without obtaining permission or giving due credit, 6% reported failing to present data that contradict their own previous research and 12.5% acknowledge overlooking others' use of flawed data or questionable interpretation of data. A further 10% inappropriately assigned authorship credit and another 27.5% acknowledged inadequate record keeping related to research projects. See B. Martinson et al. 2005. "Scientists behaving badly". *Nature*, Vol. 435 9 June. p. 737-738.

[57] Note that while all three granting councils maintain statistics, CIHR is the only one to make the data available on its website.

breaches of falsification and fabrication, there is far more scope for underreporting more minor violations, some of which may occur frequently in a particular research community, unbeknownst to those perpetuating the misconduct, that a certain practice is elsewhere viewed as entirely unacceptable.

With these caveats, this chapter presents the study's findings of misconduct, the data for which was obtained from interviews with 37 Canadian research institutions. The data represents the first attempt in Canada to capture the prevalence of research misconduct at Canadian research institutions. For the most part, interviews were conducted with senior administrators (VPs of Research, VP of Academic, or Directors of Research), who are directly responsible for addressing misconduct allegations.

Perception of misconduct varies widely across the Canadian research system from those who believe research misconduct is not much of a problem to those who believe it happens far more than is currently acknowledged. Awareness is, however, growing, which may affect perceptions of overall prevalence of misconduct. In addition to there being more journalists on the lookout for cases, the research community as a whole is more accepting of the subject than in the past and is therefore tuning in more to the problem.

7.2 Allegations of Research Misconduct

Of the 37 institutions interviewed, 29 reported on the number of cases received either per year, or over a set period of time. From these responses, the number of allegations addressed is averaged on a per year basis, by institution type (Figure 14). Across all institutions sampled, approximately 1.4 allegations are addressed per year with no trend lines reported. The large universities report on average 2.2 a year while the three small universities reported 1.2 allegations. The colleges, which have only recently qualified for granting council research, have yet to officially register cases of misconduct. Note that within these averages, there is notable variation that makes statistical extrapolation unreliable and which results in a weak correlation between the number of research misconduct cases and institution size.

Figure 14: Reported Cases of Research Misconduct in Sample of Canadian Institutions, Per Year

Institution Type	Misconduct Cases Per Year (average)	No. of Institutions Reporting Cases
College	0.0	3
Government	0.5	3
Medical Research Organizations	1.3	3
University –Large	2.2	12
University –Medium	0.8	5
University –Small	1.2	3
Sample Average	1.4	29

In addition to the above caveats, these figures require further qualification. First, respondents have at times only given estimates of allegations that required at least a first-stage inquiry. Allegations resolved by mediation or through preliminary dialogue with the respondent may not be included in these numbers. As more than one institution noted, authorship disputes have 'tested research integrity policies many times', with another reporting double the number of cases regarding authorship or financial disagreements as compared to other types of research misconduct. This highlights an important fact about research integrity policies: that they can serve a broader purpose that just research misconduct. All allegations brought forward under the research integrity policy may be legitimate but not relevant to research misconduct. One institution commented that approximately one half of allegations made are about misunderstandings. Finally, a few respondents reported allegations of research ethics breaches as research misconduct. For those that have included breaches of research ethics policies in their research misconduct definitions, this is appropriate and underscores how differences in institutional definitions affect reporting.

Of all the allegations formally received and addressed, institutions have estimated that approximately one half have led to findings of research misconduct. This finding is consistent with the numbers of both CIHR and NSERC. On average CIHR reports dealing with five allegations a year related to TCPS-IRS, and of those that are referred to institutions for investigation, misconduct was found in 45% (See Figure 15). Similarly, NSERC, which dealt with 12 cases between 2005/06 through to 2007/08, reported that six cases (50%) were found to be warrant sanctions.

Figure 15: CIHR Research Integrity Files – April 2000- September 2008[58]

Types of Allegations

Of the 73 allegations received since 2000:

* 42 (58%) related to matters associated with the Tri-Council Policy Statement: Integrity in Research and Scholarship, such as plagiarism, falsification of research results, fraudulent data, and academic dishonesty;

* 12 (16%) related to matters associated to the Tri-Council Policy Statement: Ethical Conduct of Research involving Humans, more specifically, inadequacies in REB renewal of projects approvals;

* 12 (16%) related to matters associated with other Tri-Council Guidelines, Memoranda of Understanding (MOUs), and CIHR policies, such as the lack of adherence to CIHR's Grants and Awards Guide; and

* 7 (10%) fell outside the mandate of the RIC.

Actions Recommended by the Research Integrity Committee (CIHR)

Of the 73 allegations received since 2000,

* 50 (68%) were referred to the institution for investigation; and

* 23 (32%) were not pursued because: the information presented did not justify further action; they were outside RIC's mandate; the source of the allegation was anonymous and the facts were not publicly available nor otherwise independently verifiable, or the source refused to or was unable to provide such information; and/or there was unreasonable delay between the alleged event and the receipt of the allegation.

Results of Institutional Investigations

Of the 50 allegations that were referred to institutions for investigation,

* 23 (45%) were founded, meaning that the institution concluded that there was non-compliance with research policies;

* 19 (38%) were either not sustained, were settled before a formal investigation was undertaken, or it was not possible for the

[58] CIHR, Report on allegations of non-compliance with research policies (Fiscal 2000/01-2008/09*). http://www.cihr-irsc.gc.ca/e/29073.html

7.2.1 Summary

The 29 institutions that provided data on research misconduct for this study collectively acknowledge dealing with some 39 cases per year. Together, these institutions account for approximately 60 percent of publicly funded research conducted in Canada. Given the challenges associated with collecting this kind of information, together with the variation in the data itself, any extrapolation from this sample would be problematic. However, regardless of how many incidences of research misconduct may occur in Canada, it takes only one major case to damage the integrity and reputation of the research system.

8. Conclusions

This study finds a research integrity system in Canada that, despite a number of inherent shortcomings, is generally well-regarded among those with experience working with the system and which compares relatively well internationally. To its credit, the Canadian system has also demonstrated a capacity to adapt and improve in response to experiences and to the growing global awareness of research integrity and misconduct issues. The granting councils, which have led the development of the system, continue to introduce improvements to their policies, as do the research institutions that receive their funding.

Canada, however, cannot become complacent in bringing about such improvements given the gaps identified in this report. In truth, there are a number of compelling reasons for Canada to strengthen its system. Foremost is the need to ensure that future research misconduct, for which there will always be a risk, does not continue to damage Canada's scientific endeavors, as have past scandals. And related to this is the need to mitigate damage that research misconduct brings to the public trust in science, which is important both for the funding of science and for accepting the role of scientific evidence in public policy making. Finally, in recognition of the fact that science is now very much a global activity, Canada must be seen to be a leader in maintaining the principles of research integrity by way of a system that can engender the confidence of, and engage with, the international science community.

8.1 Principles for Strengthening Canada's Research Integrity System

Any changes to Canada's system should recognize a number of general principles that have come to light over the course of this study. First, research integrity and misconduct issues are often complex and multifaceted and need to be addressed as such. The Canadian system, by allowing research institutions to tailor policies to their own institutional and policy environment, has been effective in this respect, although at a cost of nation-wide variability in institutional research integrity policies.

Second, there is no best system that is free of shortcomings, as is clear from the country comparisons. Countries have each developed a system that responds to their unique political and social institutional context. Any changes to Canada's system should therefore build on what has thus far been established with support from the various research stakeholders.

Third, it is better to prevent inappropriate conduct and behaviors than to deal with them after the fact. A focus on prevention and training must therefore be a part of system improvements if there is to be any long term reduction of misconduct risk. The better awareness that training and

prevention initiatives bring can lead to an increase in detection and help foster a research environment that is conducive to the highest standards of research conduct.

Fourth, an improved national system should ensure clarity and consistency in defining research misconduct so as to ensure more uniform processes across the country. "You cannot deprive someone of their career or their livelihood" noted one interviewee, "unless you are precise about exactly what it is that they should not be doing." Such a definition should also correspond with government-based departments and agencies, a number of which have yet to introduce policies.

Finally, a national system should give well-meaning individuals with concerns a place to go for information and assistance that is independent from their employer. Canadian researchers have no such place, leaving those frustrated by existing processes in dealing with legitimate complaints and issues to become dismissive of the system. As a central node of the system, such a place can attend to a number of shortcomings in Canada's current system: it provides visibility and a focal point to the system that is important if Canada is to improve awareness of research integrity issues and to respond effectively to international issues; it can provide a degree of oversight, however informal, that can encourage institutional compliance with research integrity policies; and it provides a logical point for collecting and sharing experiences and other data, and disseminating training guidelines and information.

Bringing about changes in line with these principles would go a long way to improving Canada's system. It would also position Canada as a leader in addressing research integrity globally, to the benefit of the Canadian and international science communities. To this end, the following options are identified for discussion and consideration.

8.2 Options for Canada

From international comparisons, this study identifies three broad types of research integrity systems that, in principle, provide a template for options that could strengthen Canada's research integrity system. However, given the system's strengths and track record developed under the current Type 2 approach, together with the fact that no one type is without limitations, the most realistic options are to be found within the Type 2 model.

Any major shift to, say, the more legalistic and quasi-criminal approach of Type 1 systems, carries the risk of losing the number of positive attributes of the Canadian system. In addition to there being little support for a more legalistic approach among many of the stakeholders interviewed in this study, Type 1 systems also have the draw backs of requiring legislation and new public sector infrastructure, which bring forth the issue of whether that solution would be disproportionate to the size and scope of the problem. Practical options derived from Type 3 systems are also limiting but for a different reason. While national approaches hold promise, all of those reviewed are still in developing stages and have yet to demonstrate their effectiveness.

It is therefore recommended that Canada consider closely its options within the context of Type 2 systems, that is, those systems that are non-legislated and which defer to the granting councils for leadership. As is evident from the other countries that follow a Type 2 approach, Germany and the UK, there are a number of possible options for addressing the key gaps in Canada's system as identified in Chapter 5. These are: varying definitions of research integrity and misconduct across Canada; accountability and transparency; reporting; and, education and training.

Option A: An Evolving Current System

The first option is to maintain the current system, while recognizing that it continues to be strengthened by the Tri-Councils. Indeed, the Tri-Councils are, at present, completing a review of the TCPS-IRS and related documents with the goal of improving existing policies and bolstering the effectiveness of the system as a whole.

Among the possible changes that should be explored and which would have a positive impact on the current system with limited disruption are:

- An explicit national definition of research misconduct that identifies sanctionable behaviors in addition to the current definition of research integrity. This step would help reduce variation in research integrity policies at the institutional level.
- Strengthened reporting requirements that necessitate the public reporting on an annual basis of all cases where research misconduct is found.
- An elaboration of timelines within the *Framework for Tri-Council Review of Institutional Policies Dealing with Integrity in Research* that set out the number of days to complete each stage of the process for addressing misconduct allegations. This step would support fairness and accountability.

Any considerations to enhance the role that the Tri-Councils play in Canada's research integrity system must accommodate two realities. First is that the granting councils are only able to institute changes within their jurisdiction of influence and mandate for promoting and supporting research, knowledge acquisition and training. Second, an enhanced role can aggravate the problem identified in this study of competing obligations and interests. While the councils are well positioned to develop policies related to research misconduct, they are not so well situated for being directly involved in specific cases, cases which can tarnish the reputations of all involved.

Option B: Office of an Ombudsman

Establishing an office of an ombudsperson whose primary role is as a trusted intermediary as opposed to an investigator of allegations, offers a number of benefits that cannot be readily achieved through Option A. First, it would provide an official, centralized point of contact that is independent of the research institutions, and which could carry the label of, and be recognized as,

the focal point of Canada's research integrity system. Until such a visible node is created, the wide spread perception that Canada 'has no national research integrity system' will continue.

If the German model is to be followed, the office of an Ombudsman need not be a costly institution. If established under the umbrella of the Tri-Councils, as in the German system, it could be limited to only one individual appointed by the Tri-Councils on a full or part time basis for a limited period of time, with assistance of secretariat support.

Its role as a trusted intermediary, committed to the highest standards of research, would include providing advice and guidance to researchers and research institutions addressing allegations of research misconduct. The Office would not be called on to undertake investigations.

Option C: Canadian Office of Research Integrity

The third option is to establish a Canadian Office of Research Integrity that would take on the role of ombudsman as per Option B but with expanded responsibilities in the area of education and training, in advising institutions undertaking investigations, and with compiling statistics on misconduct and best practices for addressing allegations. As with an Office of the Ombudsman, a Canadian Office of Research Integrity would serve as a central focal and contact point to Canada research integrity system but would broadcast a stronger message internationally that Canada is committed to upholding research integrity.

If modelled on the UK Research Integrity Office, a Canadian equivalent would be hosted by the Association of Universities and Colleges of Canada with support from government and major funders of research. Such an office could develop a number of relevant services made available to all research organizations and institutions in Canada including:

- a research integrity helpline;
- a register of advisers and experts who would be available to advise on or be involved in an institution's investigation;
- provision of a handbook that outlines in-depth all the necessary steps and procedures for investigating various types of research misconduct allegations; and
- Education and training services including the development of courses.

In summary, though each option has advantages, no option on its own can adequately address all of the system gaps identified in Chapter 5. Furthermore, none of the three options proposed adequately address the fact that neither government nor private sector fall within the jurisdiction of the main system. However, should either an Office of the Ombudsman or an Office of Research Integrity be considered, its influence need not be limited to universities and colleges for it would be a logical focal point for fielding calls from, and disseminating information to, both government and private sector researchers.

A. CRIC Membership

Canadian Research Integrity Committee: Membership / Membres du Comité canadien sur l'intégrité de la recherche

Alberta Heritage Foundation for Medical Research

Association of Canadian Academic Healthcare Organizations / Association canadienne des institutions de santé universitaires

Association of Faculties of Medicine of Canada / L'Association des facultés de médecine du Canada

Association of Universities and Colleges of Canada / Association des universités et colleges du Canada

Canadian Association of University Research Administrators / Association canadienne d'administrateurs de recherche universitaire

Canadian Association of University Teachers / Association canadienne des professeures et professeurs d'université

Canadian Federation for the Humanities and Social Sciences / Fédération canadienne des sciences humaines

Canadian Health Services Research Foundation / La Fondation canadienne de la recherche sur les services de santé

Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Federal Government Assistant Deputy Minister Science & Technology Integration Board

Conseil des sous-ministres adjoints sur l'intégration des S.-T.

Fonds de la recherche en santé du Québec

Health Canada/ Santé Canada

Michael Smith Foundation for Health Research

National Alliance of Provincial Health Research Organizations / L'Alliance canadienne des organismes provinciaux de recherche en santé

National Council on Ethics in Human Research/ Conseil national d'éthique en recherche chez l'humain

Natural Sciences and Engineering Research Council / Conseil de recherches en sciences naturelles et en génie du Canada

Public Health Agency of Canada / Agence de santé publique du Canada

Social Sciences and Humanities Research Council of Canada / Conseil de recherches en sciences humaines du Canada

B. International Research Integrity Systems

B.1 Denmark

Research Integrity System Attributes - Highlights	
RI System:	Type 1
National Policy / Code:	Yes
Reach:	Non-government research organizations / government research
National Research Integrity Body:	Yes
Investigation Authority:	National research integrity body, home institution
Enforcement/Sanctions:	National research integrity body, home institution

B.1.1 Overview

In 1999, the Danish Ministry of Science, Technology and Innovation established the Danish Committees on Scientific Dishonesty (DCSD). The DCSD is a central body dealing with allegations of research misconduct, or to use the language of DCSD's web site, "complaints regarding dishonesty in research"[59]. Like other countries, Denmark's research integrity system grew out of the biomedical and health field. Prior to the establishment of DCSD as a central body, the DCSD was a subcommittee under the Danish Medical Research Council.[60]

The previous Executive Order (number 668 of 2005) for the DCSD was revised by the Ministry of Science, Technology and Innovation on 24 November 2008. The revised Executive Order[61] (number 1122 of 2008) narrows the definition of research misconduct to fabrication, falsification and plagiarism (FFP) and other serious violations of good scientific practice intentionally or through gross negligence. Respondents indicated that lawyers are still in the process of defining "other serious violations".

The DCSD consists of three committees, as noted in its 2006 annual report[62], which combined cover all areas of scientific research. They are:

[59] DSCD web http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty
[60] The Danish Committee on Scientific Dishonesty, Guidelines for Good Scientific Practice, Copenhagen: The Danish Committee on Scientific Dishonesty, March 1998.
[61] The revisions, according to the DCSD web site, have not yet been translated from Danish.
[62] The Danish Committees on Scientific Dishonesty, *Annual Report 2006*, Copenhagen: Danish Agency for Science, Technology and Innovation, November 2007, p. 30.

- the Committee on Scientific Dishonesty for Research in Health and Medical Science;
- the Committee on Scientific Dishonesty for Research in Natural, Technological and Production Science; and
- the Committee on Scientific Dishonesty for Research in Cultural and Social Science.

Each of the three committees comprises of one chair and six members. According to the DCSD web site, the members are recognised researchers who have been officially appointed by the Danish Minister for Science, Technology and Innovation after hearings conducted by the Danish Council for Strategic Research. The joint chair for the three committees is a high court judge who is appointed by the Minister.[63]

The Ministry of Science, Technology and Innovation, as indicated on its web site, is responsible for research, information technology (IT), innovation, telecommunications, and university education. Responsibility for carrying out the Ministry's activities in research and in innovation rests with the Danish Agency for Science, Technology and Innovation (DASTI). DASTI is also responsible for the DCSD and for providing the secretariat to the DCSD.[64]

Introduction to system

Denmark's research integrity system is formal and founded in law. The revised Executive Order of 2008 restricts the DCSD to only consider cases of serious misconduct, i.e., the responsibility for promoting good research practice rests with individual research institutions/universities and hospitals. We outline below the conditions for the DCSD to consider an allegation of misconduct. It is the understanding of this study that the 2008 Executive Order has not significantly changed the conditions for the DCSD to consider a case.

- The DCSD is mandated to consider cases brought forward by any party, provided the party filing the allegation is a researcher, e.g., a member of the general public cannot submit an allegation.
- There is no obligation by research institutes/universities to file a case with the DCSD. If the parties agree, the case is handled at a local level by the institution. A recent survey commissioned by the DCSD found the number of cases handled at the local level by individual institutions was small. However, even though the number of cases was small, there were a few cases of misconduct that stayed at the local level, and were not filed with the DCSD. Respondents noted that this is a weakness of the Danish system.
- The DCSD, as indicated in its 2007 annual report, may also consider cases brought by a party wanting to be cleared of named, anonymous or source-protected allegations of research misconduct provided that the party provides all the necessary information for use in the DCSD's consideration of the case[65].

[63] See DSCD web http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty
[64] Ministry of Science, Technology and Innovation web http://en.vtu.dk/
[65] The Danish Committees on Scientific Dishonesty, *Annual Report 2007*, Copenhagen: Danish Agency for Science, Technology and Innovation, August 2008, p. 38.

- The DCSD, like the US ORI, has the legal authority to pursue a case. As indicated in DCSD's 2007 annual report, the DCSD may choose to investigate a case that has not been filed by any party, provided the case is of interest to society or of importance to human or animal health and where there is a reasoned assumption of misconduct.[66]
- The DCSD may refuse to consider cases where (i) the case is outside the scope of the remit of the DCSD, (ii) the case is considered manifestly unfounded, or (iii) the costs of considering the case are out of proportion to its importance.[67]

As indicated in the 2007 annual report, the DCSD has three months after receipt of a case to inform the parties that the case will be heard and when a statement is expected to be made, or to indicate the case will not be considered.

Like other countries such as Australia and Germany, one famous case (the Lomborg case) has had a significant impact on shaping Denmark's system to its current formal and legal framework. As argued by Dr. Rörsch (see text box), the Lomborg case was not a case of misconduct but rather one of questionable research practice (QRP). The decision of the DCSD was appealed to the Danish Minister of Science, Technology and Innovation who asked the DCSD to review its ruling. The DCSD decided not to hear the Lomborg case again. The ambiguity of the Lomborg case, according to respondents, was the main factor for narrowing DCSD's mandate to dealing only with cases of serious misconduct, and for guidelines and procedures to be more precisely defined and grounded in law.

As noted in DCSD's 2002 annual report:

Dr. Arthur Rörsch (Prof. (em) Molecular Genetics, Leiden University, the Netherlands) describes the Lomborg affair and the complaint of misconduct to the DCSD as follows:

The book was published early 2001 with the sub title "measuring the real state of the world". It is a heavy attack on the view that mankind is heading for a catastrophe through exhaustion of natural resources, environmental pollution and climate change. Lomborg labeled the popular view of environmental collapse as the 'Litany". He did not deny there are environmental problems to be solved, but rather challenged the view we are heading for an Apocalypse. His book made a plea for a review of our priorities in making investments to address the range of environmental problems. In doing so he outraged the establishment of environmentalists. It resulted in a world wide debate whether Lomborg had used the statistical data of official organizations, such as UN, WWF, World Bank, properly and whether he had cited the scientific literature correctly. Hundreds of pages of protest were answered by Lomborg with a similar volume. He admitted mistakes in a few incidental cases but stuck to his main points in the treatise as a whole. The opponents of Lomborg were not satisfied and a number of them lodged a complaint of scientific dishonesty with DCSD.

The complaint comprised: "fabrication of data, selective citation, deliberate misuse of statistical methods, distorted interpretation of conclusions, plagiarism, deliberate misinterpretation of others results". The report of DCSD ends with the judgment 'deviation from Good Scientific Practice.' But this is not made specific by reference to the discrete accusations. The report just reproduces in very general terms the objections raised by Lomborg's opponents in Scientific American, January 2001, and made no references to any of Lomborg's responses.

Source: Arthur Rörsch, Good Scientific Practice and the Lomborg Affair In Denmark, nd. Available at: http://www.lomborg.com

[66] *Ibid.*
[67] *Ibid.*

> "DCSD published its decision concerning three complaints of scientific dishonesty in connection with Bjørn Lomborg's book "The Skeptical Environmentalist". The decision gave rise to considerable debate. This is particularly due to the fact that in this, as in so many earlier cases, DCSD applied the standard of "good scientific practice" (GSP)……The case prompted the Danish Minister of Science, Technology and Innovation to ask the Director of the Danish Research Agency to set up a working party, whose brief was to evaluate whether there is any need to adjust the regulatory basis for DCSD's future work."[68]

B.1.2 System Attributes

Definition

The definition of research misconduct, recently revised by Executive Order number 1122 of November 2008, has not yet been translated from Danish. The revised definition, as noted above, includes fabrication, falsification and plagiarism (FFP) and other serious violations of good scientific practice intentionally or through gross negligence. Under the previous Executive Order (2005) FFP was defined as:

- undisclosed fabrication and construction of data or substitution with fictitious data;
- undisclosed selective or surreptitious discarding of a person's own undesired results;
- undisclosed unusual and misleading use of statistical methods;
- undisclosed biased or distorted interpretation of a person's own results and conclusions;
- plagiarisation of other persons' results or publications.[69]

Respondents indicated that "other serious violations" have not yet been defined.

Administration of Policies

Responsibility for the administration of research integrity policies rests with the DCSD, while the responsibility for promoting good research practice and the investigation of questionable research practice (QRP) rests with individual research institutions/universities and hospitals. Respondents indicated that most universities and hospitals in Denmark have their own guidelines and codes of conduct. Larger universities in Denmark have the infrastructure to deal with research misconduct, whereas smaller universities deal with misconduct on a case by case basis, e.g., assemble a panel to investigate if an allegation is made.

[68] The Danish Committees on Scientific Dishonesty, *Annual Report 2003*, Copenhagen: Danish Agency for Science, Technology and Innovation, October 2003, preface by Hans Henrik Brydensholt.
[69] *Ibid*.

Prevention and Training

Education and training to prevent misconduct from occurring is the responsibility of individual research institutes/universities and hospitals. Under Danish Act number 658 regarding the Research Advisory System, the Ministry of Science, Technology and Innovation established the Danish Research Coordination Committee. Part of the mandate of the Committee is to provide an advisory function to individual institutes regarding research training.[70]

Inquiry and Investigation Procedures

According to the DCSD web site, the rules of procedure governing the inquiry and investigation of misconduct have not changed from the 2005 Executive Order. Once it has been determined that one of the three Committees of the DCSD shall investigate the case, the Committee procures all necessary information needed to make a decision. This can include asking the person(s) concerned to surrender all necessary information pertaining to the case, as well as written submissions and presentations from each party. The Committee concludes its consideration of the case by submitting a statement. The statement, as indicated in the DCSD's Rules of Procedure, includes: 1) particulars of the case, 2) statements from the parties to the case, 3) the Committee's deliberations, 4) the Committee's conclusions and, in the event of dissent, the number of members or alternates who have endorsed the conclusion, as well as any dissenting opinions.[71]

Respondents noted that there is no protection for whistle blowers in Denmark. If the preliminary investigation finds probable grounds for misconduct, in Denmark's tradition of transparent administration, the DCSD is required to disclose the name of the accuser to the defendant. Respondents also noted that having legislation to protect whistle blowers is one thing, but it is more important to educate people to support, rather than to punish, whistle blowers.

Enforcement and Sanctions

Under the 2005 Executive Order, in cases where research misconduct is concluded by the DCSD, the Committee is authorized to:

(i) inform the defendant's employer if the party in question is employed as a researcher;

(ii) recommend that the scientific project concerned be withdrawn;

(iii) inform the relevant public authority supervising the area;

(iv) make out a police report where a punishable offence is involved;

[70] *Ibid.*, p. 34.

[71] DCSD's Rules of Procedure are available at http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty/rules-of-procedure

(v) at the special request of an employing authority, state their views on the degree of scientific dishonesty.[72]

Reporting / Communications and Transparency

The DCSD provides the number of cases it considered each year in its annual reports. Contrary to the requirements of transparent administration, the name of the defendant and of the defendant's organization are not disclosed in DCSD's annual reports. A review of DCSD's annual reports from 2003 to 2007 indicates that DCSD considers about ten cases each year. Over the five-year period, only two cases of misconduct have been declared.

B.1.3 Strengths and Weaknesses

The strengths of the Danish research integrity system are that it is founded in law which legitimizes the system. The guidelines and codes, while written in a legalistic manner, are clear and unambiguous. The chair of all three Committees is the same, a high court judge, which ensures consistency across disciplines. The very specific focus of the DCSD at the national level leaves responsibility for matters that are more subjective in nature, e.g., QRP, at the local level to individual institutions. Academic freedom and university self-governance are respected while at the same time, the system helps to ensure that very serious cases are brought forward in front of an impartial body.

The weaknesses of the Danish system are that individual institutions/universities and hospitals are not obliged to handle and/or report cases of misconduct, or to file a case with the DCSD. This is apparently a topic of discussion in Denmark. Like Canada, the Danish system does not extend to the private sector.

B.1.4 Conclusions

There has been some discussion on the benefits of having a central body in light of the very low number of cases. However, on balance, there was a general consensus that the benefits of having a central body like the DCSD exceed its costs.

[72] The Danish Committees on Scientific Dishonesty, *Annual Report 2007*, Copenhagen: Danish Agency for Science, Technology and Innovation, August 2008, p. 42.

B.2 Norway

Research Integrity System Attributes – Highlights	
RI System:	Type 1
National Policy / Code:	Yes
Reach:	All research organizations
National Research Integrity Body:	Yes
Investigation Authority:	National Commission for the Investigation of Scientific Misconduct
Enforcement/Sanctions:	Researcher's Employer

B.2.1 Overview Overview

As with a number of other countries, Norway's recent efforts are the result of a serious case of research misconduct, that of fabrication. In January 2006 a Norwegian scientist, dentist and physician at Oslo University's Rikshospitalet-Radiumhospitalet, Jon Sudbø, admitted to research misconduct regarding one of his publications in *The Lancet*. More than 330 media reports, domestically and internationally, ensued. The basis of the misconduct was fabrication of data in his research on oral cancer, which began in his doctoral thesis work. An independent committee established to investigate the case, led by a Swedish scientist, found that variations of the fabricated data in Dr. Sudbø's doctoral thesis had been used in numerous publications. Dr. Sudbø's doctoral degree and license to practice medicine was revoked, he was fired from his position, and he is permanently forbidden from business or research activities in the US.

Though Norway has only recently introduced a national law on research misconduct in 2006, the country has been addressing the issue for nearly two decades. In 1990, a national ethics committee was established, and in 1994, the Research Council of Norway established a national Committee on Dishonesty in Health Research. Under the new law, the system has been strengthened further though it remains a "work-in-progress", amidst ongoing discussion of improvements in establishing guidelines for research organizations to advance research integrity objectives, and for addressing issues related to reporting of allegations and investigations. Thus far, Norway has established a national commission, chaired by a former Judge but as of yet has no guidelines for implementing the legislation. Initiatives are planned however to raise awareness of the new law.

There is interest in Norway in fostering a culture of openness and collaboration as opposed to focusing on policies and the rules. Also of interest is the creation of ombudsman positions with jurisdiction over multiple institutions, an approach that is considered to be less intimidating to researchers for raising questions of misconduct and which requires fewer resources than a committee.

B.2.2 Introduction to System

The legislation that established the Norwegian system is Act No. 56 on Ethics and Integrity in Research[73], enacted on June 30th 2006. The purpose of the act is "to ensure that research carried out by public and private institutions is conducted in accordance with recognized ethical standards." To this end, the Act calls for the establishment of a number of bodies, several of which pertain to ethics, and one to research misconduct. This latter body, called the National Commission for the Investigation of Scientific Misconduct, has been given a mandate to investigate and report on research misconduct involving Norwegian public or private funding.

The Norwegian system has a number of notable features. According to the new law, the main responsibility for preventing misconduct and dealing with allegations of misconduct lies at the local level. Moreover, the national law applies to all organizations that perform research, including at universities, public research institutions, and the private sector. Indeed, it is the only country to directly address research carried out in the private sector. Another feature is the link with the legal system whereby one of the seven members of the Commission must have had judicial experience. This approach is reported to be working well.

Note that the primary granting council, the Research Council of Norway, which supports most publicly funded research in Norway, uses the policies of the Committees and the Commission. As for the research institutions themselves, they are expected by the Commission to have policies, but are not required as a condition for receiving funding from the Research Council of Norway. While most organizations do have policies in place, some do not. In such cases, institutions rely on a number of different policies to address allegations including the terms of reference for the Ombudsman, if there is one, and collective agreements. It was reported that institutions without policies are in the process of developing one.

B.2.3 System Attributes

Definition

The law ethics and integrity in research defines scientific misconduct as follows:

> "Scientific misconduct is defined as falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research."[74]

There has been some debate on how broadly research misconduct should be defined. While those in the health and social sciences agree with the need for formal policies, including definitions, those in the natural sciences feel misconduct should be "self regulated" and defined by each research organization.

[73] See Act of 30 June 2006 No. 56 on ethics and integrity in research, http://www.etikkom.no/English/about/act
[74] Ibid.

Administration of Policies

The National Commission for the Investigation of Scientific Misconduct began operations in December, 2007. With one full time employee, and a seven member governing body, the Commission meets approximately four times per year, depending on the case load. Members of the Commission are appointed by the Ministry of Education, upon the recommendation of the Research Council and receive a small stipend.

The Commission staff is based in the same building as the staff for research ethics bodies of which there are three, and are funded by the Research Council.

Prevention and Training

The main responsibility for prevention and training lies at organizations that conduct research with support from the Commission. Part of the mandate of the Commission is to provide an advisory and support function to organizations, and various initiatives are planned to this end.

Overall, stakeholders are generally aware of the new national legislation. It is promoted through the Commission's website, and at various seminars at research organizations. The Commission also has plans for its staff to actively promote the legislation within research institutions.

A conference is being planned for the fall of 2009 by the Commission on the prevention of research misconduct, the program for which is not yet available. However, a member of the planning committee noted an intended emphasis on strengthening openness and collaboration among researchers.

Inquiry and Investigation Procedures

The Law that the Commission is responsible for upholding has two elements: the first deals with allegations of misconduct, and a second with ways to prevent it. While there are formal guidelines from the ethics committees (two of three have their own, and the health committee has signed onto the international Vancouver and Helsinki declarations), none have been prepared for the Commission.

Though the Commission can play an investigatory role, research institutes ultimately have the primary responsibility for investigating allegations. Indeed, as in other countries, institutions may redirect an investigation to the Commission if, for example, a case is deemed particularly complicated or has received considerable public attention. The Commission may also decide to investigate a case under authority of the law on misconduct at its own initiative.

There are currently no guidelines for inquiry or investigation of misconduct. However, the Ministry of Education does expect such guidelines to be prepared, and their development is in the planning stage.

For the one allegation that has been addressed to date, the Commission did all work through a review of documents and follow-up inquiries. There were no appearances of witnesses for the purpose of obtaining testimonials; however, this could occur in the future.

Note that should there be an international case, the appropriate policy that takes precedence is that of the nation where the majority of funding is coming from. This situation hasn't occurred yet either.

The Norwegian system supports two levels of appeals: The Commission may act as an appeal body for decisions made at the level of research institutions, and the Ministry of Education can field appeals of decisions made by the Commission. In all cases investigated by the Commission, to mitigate the likelihood of appeal, a draft written decision is prepared and provided to those concerned for comment on the facts prior to any final decision. In the event of an appeal of the Commission's decision, the Ministry sets up a second commission of seven members to receive the case. Under the law, the decision of this body is final.

There are several policies protecting the confidentiality of whistleblowers. One is a law on health and safety in the workplace, which deals with the protection of whistleblowers for all matters in the workplace. There are also guidelines for the three ethics committees pertaining to this, and research organizations may have further policies specific to misconduct. Also, at least one university has an ombudsman with jurisdiction over medical faculty.

Enforcement and Sanctions

With regard to enforcement, the Commission may only investigate with the cooperation of the institution concerned. The Commission may request information, and should this be declined, the Law stipulates that recourse is possible through the courts.

Note that under the current arrangements, there is a provision to increase resources for the Commission should a case becomes complicated. This may include resources for independent experts for example.

The responsibility for sanctions rests with the research institutions. In the event that the Commission conducts an investigation, it will defer to the appropriate institution where the incident occurred for a determination on sanctions, if any.

Reporting / Communications and Transparency

The Law states that the Commission should be informed of misconduct matters occurring among research institutions. This reporting activity, however, has not been occurring. Indeed, the Norwegian system has no formalized reporting process in place. In the single case[75] of a QRP that was brought to the Commission, at the request of a university and under appeal, the decision

[75] This case was one of a questionable research practice regarding whether data had been interpreted properly as well as a number personnel issues.

was written up and provided to a number of journalists. Note that in this case, the investigating committee was given assistance by a private law firm.

B.2.4 Strengths and Weakness

The Norwegian system's use of a national Commission is recognized as a strength and one that has thus far been working well. Having a requirement for judicial experience among the members of the Commission is considered as an important element of this approach.

While there have not been sufficient cases to test the system, there are a number of aspects that require improvements. With a lack of reporting from institutions, the Commission may lack awareness of research integrity developments. It has been expressed that what is required is a mandatory reporting system; this will be a recommendation of the Commission in its annual report to the Ministry of Education.

A further challenge - in spite of best efforts and legislation to protect whistleblowers is a concern of a continued general reluctance for concerns to be brought forward. One university interviewee believes that what is necessary is the creation of more Ombudsman positions, possibly shared over more than one institution, with the rationale that such an arrangement would be more cost effective and less intimidating for individuals to make allegations.

Finally, as a developing system, there is a lack of guidelines for individual organizations to address research integrity. To this end, Commission staff is working on establishing such guidelines that will not only advance research integrity objectives at the institutional level, but also strengthen engagement between the Commission staff and institutions.

B.2.5 Conclusions

Norway's system is in development and has yet to be adequately tested. And while Norway has followed a legislated model, there is recognition in the community that advancing research integrity objectives requires an emphasis on a culture of openness and collaboration "by leaders walking around", as opposed to the focus on the policies and rules. In such an environment, it is more difficult to engage in research misbehaviors such as data falsification or fabrication. As one interviewee noted, the solution lies in "getting away from scientists working in isolation, and protecting their data from other scientists during the research process."

B.3 United States

Research Integrity System Attributes – United States	
RI System:	Type 1
National Policy / Code:	Yes, but for "FFP" only
Reach:	Universities, Hospitals in receipt of funding and government; limited applicability to companies receiving funding (e.g. firms receiving funding under the Small Business Innovation Research SBIR) Program)
National Research Integrity Body:	Yes, but each Department has its own integrity Office (e.g. ORI at HHS; OIG at NSF; OIG at NASA and Office of the Staff Judge Advocate at DoD, etc.)
Investigation Authority:	Home institution, with ORI or OIG, for example, able to act as well
Enforcement/Sanctions:	Institutions and funding agencies

B.3.1 Overview

The US was a pioneer in institutionalizing at the national level a system for addressing research misconduct, and indeed, led the way for many other countries to develop their own systems. The original legislation addressing research misconduct was introduced under the Health Research Extension Act of 1985 as Section 493[76] to the *Public Health Service (PHS) Act*, which governed the Department of Health and Human Services (HHS). The legislation applicable to research misconduct, otherwise known as 42CFR93[77], was in fact the culmination of a discussion that began in government four years prior in 1981 when the then Representative Albert Gore, Jr., chair of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing on the emerging problem of scientific fraud and misconduct.

In 1989, the National Science Board (NSB) followed HHS's lead, and, in compliance with the Inspector General Act Amendments of 1988, established the National Science Foundation's (NSF) Office of Inspector General (OIG). The OIG, which is headed by an Inspector General (IG) who reports directly to the NSB and Congress, has among its various responsibilities, the authority for handling cases involving research misconduct.[78] The relevant NSF policy is 45CFR689.[79]

[76] Section 493 of the Public Health Service Act 42 U.S.C. §289b, as enacted by Public Law 99-158 (Nov. 20, 1985)

[77] CFR refers to The Code of Federal Regulations (CFR) which is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.

[78] In support of these responsibilities, OIG has statutory authority to subpoena or otherwise obtain all records, files, reports, documents, or materials needed to conduct audits, inspections, and investigations. The IG is independent and may not be prevented from carrying out any audit, inspection, or investigation or issuing any report.

[79] http://www.nsf.gov/oig/resmisreg.pdf

However, as policies of the Department of Health and Human Services and the NSB respectively, the research integrity system had at that time jurisdiction only over research funded by their respective granting agencies – NIH and NSF. This changed on December 6, 2000, when the Office of Science and Technology Policy in the White House published the Federal Research Misconduct Policy, requiring all federal agencies or departments supporting intramural or extramural research to implement within one year either through policies or regulations.

To comply, the HHS adopted the new legislation which included the proposed government wide definition of research misconduct developed by the National Science and Technology Council that was published in the Federal Register on October 13, 1999.

Currently therefore, at its core, the US system comprises of the Federal Policy of Research Misconduct, two oversight bodies with investigatory powers, and the multitude of research institutions that are responsible for developing policies that meet the requirements of the Policy. Of the two oversight bodies - the Office of Research Integrity, situated with the Department of Health and Human Services, and the OIG at the National Science Foundation – the former oversees the greatest number of cases owing to the fact that it is responsible for all research funded by the National Institutes of Health (NIH), which is the single largest granting agency in the US.

B.3.2 System Attributes

Overview of the Federal Policy on Research Misconduct[80]

The US system is based on a definition of research misconduct that is restricted to FFP, a definition that sets a narrow standard for the types of behavior that can be reviewed. Institutions are directed to go beyond this basic definition for the purposes of their institutional policies which most do often augmenting the definition by acknowledging "other practices that seriously deviate from those that are commonly accepted within the scientific community". These other practices are often referred to as "Questionable Research Practices" (QRPs)

According to the policy, for there to be a finding of research misconduct there must be a significant departure from accepted practices of the relevant research community and that any misconduct committed was done so intentionally, knowingly, or recklessly. Finally the policy asserts that the allegation must be proven by a preponderance of the evidence.[81]

Responsibilities of Federal Agencies and Research Institutions

In the US system, agencies and research institutions are considered partners who share responsibility for the research process. In such an arrangement, federal agencies have ultimate oversight authority for federally funded research, while research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry,

[80] http://www.ostp.gov/cs/federal_policy_on_research_misconduct
[81] United States Regulation, 42CFR93 (revised October 1, 2007)

investigation and adjudication of research misconduct alleged to have occurred in association with their own institution.

Thus, federal agencies look to a researcher's home institution to make the initial response to allegations of research misconduct and in keeping with this approach, agencies will typically refer allegations of research misconduct made directly to them to the appropriate research institution.

Furthermore, the federal agency (i.e. ORI or OIG) reserves the right to proceed with its own inquiry or investigation in cases, for example, where the agency determines that an institution is not prepared or is too small to handle an allegation in a manner consistent with federal policy, or where agency involvement is needed to protect the public interest.

The federal policy also specifies "Guidelines for Fair and Timely Procedures", "Agency Administrative Actions and Roles of Other Organizations", the details of which to follow.

Definitions

The basic code (law) contains the following definition of "research misconduct" which now forms the basis for all research integrity and misconduct policies across all departments of the United States government and, by extension, to all institutions that receive research funding from those organizations:

> *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

As noted, institutions are encouraged to go beyond those in their individual Policies. In a study commissioned by the ORI in 2000, nine areas of research misconduct are identified and which institutional policies might include[82]:

- Falsification of data,
- Plagiarism,
- Improprieties of authorship (including improper assignment of credit such as excluding others or including others who have not made a definite contribution),
- Misappropriation of the ideas of others,
- Violation of generally accepted research practices
- Material failure to comply with federal requirements affecting research (including regulations of human research and animal care),
- Inappropriate behaviour in relation to misconduct,
- Deliberate misrepresentation of qualifications, experience or research accomplishments to obtain funding or other professional advancement,
- Misappropriation of funds or other resources.[83]

This same report, which reviewed 156 institutional policies in 18 substantive areas including definitions, reporting allegations, conduct of inquiries and investigations, appeals processes, and whistleblower policies, reported that just over 50% of the policies had definitions that went beyond the basic FFP criteria of the CFR.

Administration of Policies

In accordance with the Federal Policy, the administration of research integrity and misconduct policies is left, in the first instance to the individual institution. Where federal funding is involved, the funding bodies' investigative branches retain the right to intervene in the investigation process.

As granting agencies, both the ORI and the OIG can receive allegations of wrongdoing, in which case, they will refer to case to the proper institution if and as warranted. In addition, all institutions are required to report any cases that they investigate to the appropriate body and at that point they reserve the right to conduct a "review" of the investigation, which can amount to a re-investigation of the allegation.

Institutions are directed to appoint a "Research Integrity Officer" (RIO) whose role is to act as the point of contact on questions of research integrity and to provide advice to the head of the

[82] ORI Study, "Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct" Final Report by CHPS Consulting, September 2000.
[83] Ibid.

institution in cases where an inquiry or an investigation is undertaken. In a study involving 90 interviews and a survey of 500 institutions, it was found that the designated person is rarely actually called the Research Integrity Officer and in most (over 50%) of the cases, that person also has responsibility for the administration of the codes for research involving human participants. Only 40% of the RIOs had researchers sign a document indicating that they knew about the research misconduct policy at their institution and just over 30% of them indicated that their responsibilities included the promotion of the "responsible conduct of research".[84]

Prevention and Training

Both the NIH and the NSF leave prevention and training to the institutions, although both agencies acknowledge that they play a high-level role in the promotion of good research practices by attending and speaking at conferences, issuing reports and documents, and providing advice. One respondent indicated that in some cases where they hear "no one ever told me!" during an investigation, they will go to that institution to discuss future education and training.

In addition, the ORI collaborates with the Association of American Medical Colleges to provide financial support to scientific and academic societies to hold workshops and conferences on research integrity issues. They both worked with the Council of Graduate Schools to do pilot projects at 10 institutions to provide formal training in the responsible conduct of research. Examples of the projects included: (1) a program at the University of Utah to provide 12 stipends of $1,000 each to selected graduate program directors to increase participation by graduate students in existing courses and to develop workshops, discussion groups and "brown bag" sessions in the various departments; (2) a program at Arizona State University to develop ongoing workshops, to adopt the web-based University of Miami CITI (Collaborative IRB Training Initiative), and to establish a speaker series; (3) a program at Florida State University to develop a cross-disciplinary, one credit graduate course addressing the nine elements of the responsible conduct of research education as identified by ORI; and, (4) a program at the University of Rhode Island to create a series of bi-weekly, semester-long workshops attended by faculty members, graduate students and practitioners from local organizations and industry.[85]

Otherwise, the substance and uptake of education or training courses or programs varies widely. They range from voluntary, web-based training through compulsory lecture courses. Where an institution is in receipt of a "training grant" they are required to have the new researchers complete a course in research integrity and misconduct.

An example of a web-based program is the "Program for the Education and Evaluation in Responsible Research and Scholarship" (the "PEERRS Program) at the University of Michigan. The PEERRS Program includes modules on: (1) foundations of research responsibility, (2) research administration, (3) Conflict of Interest, (4) animal research, and (5) human subject protection. All faculty, staff and students are encouraged to undertake to the course and obtain

[84] Office of Research Integrity, ORI Newsletter, Vol 16, No. 4 (September 2008), p 2.
[85] See: www.cgsnet.org/Default.aspx?tabid=123

the "certification". On issue that has been identified (and this is reasonably wide-spread) is that there has been no formal evaluation of these courses to determine if they make a difference in increasing "research integrity" or reducing "research misconduct". Beyond that, the use of web-based courses even removes the personal interaction between teacher and student where, questions, concerns, and misunderstandings can be identified and dealt with.

In some universities, entire courses are dedicated to the issue of research integrity and misconduct. The University of California at Berkeley, for example, presents a full-term course that uses case studies of real, worked examples to generate discussion of the general principles and "lessons learned".

Inquiry and Investigation Procedures

The Federal Policy specifies that any allegation of research misconduct, which are the responsibility of each institution, will usually consist of several phases, including: "(1) an inquiry – the assessment of whether the allegation has substance and if an investigation is warranted; (2) an investigation – the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; (3) adjudication – during which recommendations are reviewed and appropriate corrective actions determined." Separation of phases, whereby adjudication is separated organizationally from inquiry and investigation and appeals are separated organizationally from inquiry and investigation is a required feature.

The policy also provides guidelines for institutions for improving fairness and timeliness. For example, it recommends that individuals selected to review allegations and conduct investigations should have appropriate expertise and have no unresolved conflicts of interests help to ensure fairness. With regard to timeliness, the policy recommends that reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal phases (if any), be specified with allowances for extensions where appropriate.

When the ORI and OIG become involved they may choose to redo the original investigation. For research conducted under NSF jurisdiction, the OIG leaves the institution to do the investigation but retains the right to take over if it feels that the institution is not doing a proper job.

B.3.3 Enforcement and Sanctions

Agency Follow-up to Institutional Action. After reviewing the record of the investigation, the institution's recommendations to the institution's adjudicating official, and any corrective actions taken by the research institution, the agency will take additional oversight or investigative steps if necessary. Upon completion of its review, the agency will take appropriate administrative action in accordance with applicable laws, regulations, or policies. When the agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the institution regarding its disposition of the case. The agency finding of research misconduct and agency administrative actions can be appealed pursuant to the agency's applicable procedures.

The enforcement of the policy and the determination of sanctions is left with the institutions. The determination of the type of sanction is most often directly related to or determined by the "seriousness of the misconduct". Other factors taken into account include: the impact or scope of the misconduct, whether it is an isolated event or part of a pattern; the deliberateness of it, and any mitigating circumstances.

The types of sanctions range from a letter of reprimand, probation, suspension or removal from the project to, ultimately, termination of employment and expulsion from the university. Very few of the policies provide for "training" as a possible sanction.[86]

Reporting, Communications and Transparency

The Federal Policy requires that research institutions notify the funding agency(ies) of an allegation and finding of research misconduct if a) they involves Federally funded research and meet the Federal definition of research misconduct given above, and b) if the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. Once an investigation is complete, the research institution is responsible for forwarding a copy of the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations, if any to the agency. When a research institution completes the adjudication phase, it will forward the adjudicating official's decision and notify the agency of any corrective actions taken or planned.

Furthermore, additional reporting is required if, during an inquiry or investigation, an institution finds the following:

- public health or safety is at risk;
- if agency resources or interests are threatened;
- if research activities should be suspended;
- if there is reasonable indication of possible violations of civil or criminal law;
- if Federal action is required to protect the interests of those involved in the investigation;
- if the research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or
- if the research community or public should be informed.

Under 42CFR93, institutes must submit an annual report via the web of any allegations and findings of misconduct. Both the ORI and NSF issues newsletter that summarizes (highlights) the results of investigations, newsletters that for the Canadians interviewed that receive them are

[86] ORI Study (2000), op cit. p D-30

considered informative and useful for learning about how to respond to cases. While the NSF does not generally "name names" the ORI does for those found to have committed misconduct.

B.3.4 Strengths and Weaknesses

The US system benefits from a Federal Policy that is clear and from a meaningful body of precedent in support of the definitions used. Once the system identifies an alleged violation, it generally viewed as working fairly well to reach an end result. Moreover, the use of precise and limited definitions for "misconduct" is also considered an asset to the extent that it provides for clearer investigations and findings of fact. As one interviewee implied, if the ultimate sanction involves depriving a person of their career or their livelihood, you must be precise in defining the behaviours that they should not be doing – the types of behaviour that you will sanction.

There are a number of weaknesses however, as recognized by those interviewed. First, the Federal Policy and Department Codes allow for considerable variance in policies across institutions which can lead to some difficulties. This has led to discussions of how the lack of consistency across institutions affects the conduct of research (especially in cases of collaborative research involving multiple institutions) as well as the management of research integrity and misconduct issues. Having different definitions, standards and policies across institutions can lead to problems in multi-institutional collaboration and as institutions interact with journals and professional societies who may have their own policies. In fact, for over 10 years there have been calls for a revisiting of the regulated definitions, but there have been no major changes.

Another weakness is what the system does not catch. This may be because of a lack of commitment at the institutional level or because of a lack of resources, or both. In addition, given that the system is legislated, it is cumbersome to adjust (it would require Congressional action).

The system is also recognized as being deficient as a result of the fact that it does not deal with "conflict of interest". One of the reasons for this is that the issue of Conflict of Interest is most often dealt with as a part of the employer-employee relationship, which relationship is usually governed by laws at the State level. Finally, in some cases, it is clear that technological advances are outpacing the ability of the system to keep up with identifying and dealing with cases of abuse.

B.3.5 Conclusions

The United States system for research integrity and misconduct is a legislated, quasi-criminal regulatory regime designed to focus attention on the most serious cases of fabrication, falsification and plagiarism (FFP). Final authority for investigation and sanctions rests with the major funding organizations, principally HHS through ORI and NSF through OIG. On the other hand, detailed policy making, initial inquiries, formal investigations, education and training are left to the institutions. As a result, there is significant variation among policies and administration

across the country. There seems to be some consensus that “Conflict of Interest” (not dealt with in these policies) is emerging as a larger issue that needs to be addressed in the future.

B.4 Germany

Research Integrity System Attributes - Germany	
RI System:	Type 2
National Policy or Code:	Yes, Mandated by Commission Report
Reach:	Universities and Research Institutes
National Research Integrity Body:	Yes, Office of Ombudsman in DFG
Investigation Authority:	Home institution
Enforcement/Sanctions:	Institutions and DFG

B.4.1 Overview

In 1997, the misconduct case of Prof. Herrmann, then at Ulm University, and Prof. Brach at Lübeck University came to light, prompting an initial investigation of some 37 papers published between 1988 and 1996 which indicated serious cases of "fabrication" of results. This led to a wider, two-year investigation of all 347 scientific articles published by the two researchers which indicated that the problem was "far more extensive than previously thought"[87].

This case prompted the appointment of a Commission comprising 12 members, including 3 international members, to examine the issue of research integrity. The Commission reported back in January 1998 in a report entitled, "Recommendations of the Commission on Professional Self Regulation in Science: Proposals for Safeguarding Good Scientific Practice", making some 16 recommendations for a new German system. One of these is a recommendation that all institutions must create policies in accordance with recommendations 1 through 8. The eight recommendations called for:

1. Basic principles of good scientific practice,
2. Formulate and teach rules for scientific practice based on the above principles,
3. Adequate organizational structure to manage science,
4. Standards for mentoring of students,
5. Independent mediators for disputes,
6. Stress originality and quality of work over quantity,
7. Secure primary data for 10 years, and
8. Procedures for dealing with allegations of misconduct.

With regard to the basic principles of good scientific practice, the report identified the following:

[87] Robert Koenig, "Panel calls Fabrication in German Case 'Unprecedented'", Science, vol. 277, p 894 (1997) and Michael Hagman, :Panel finds Scores of Suspect Papers in German Fraud Probe", Science, vol. 288, p 2106, (2000)

- observing professional standards;
- documenting results;
- consistently questioning one's own findings;
- practicing strict honesty with regard to the contributions of partners, competitors and predecessors;
- cooperation and leadership responsibility in working groups;
- mentorship for young scientists and scholars;
- securing and storing primary data;
- scientific publications.

Another set of recommendations (9 through 16) is addressed to various actors in the research systems especially research institutions, learned societies, scientific publishers and research-funding institutions.

These recommendations are now at the core of the German system and have been taken on by Germany's national Granting Council, the Deutsche Forschungsgemeinschaft (DFG), which provides funding for research across all the disciplines. The DFG now asks applicants if their institution has implemented the recommendations on good scientific practice and as a result all universities and research institutions in Germany have implemented their own guidelines as requested in the DFG document.

The Max Planck Society, although not an organization that receives funding from the DFG, has created a very precise and concise policy for the management of good scientific practice and for dealing with cases of misconduct and which has subsequently become a quasi policy standard for other institutions. The 13 page document captures its position of the following: (1) rules of good scientific practice, (2) rules of procedure in cases of suspected scientific misconduct, (3) catalogue of conduct to be regarded as scientific misconduct, and (4) catalogue of possible sanctions or consequences in cases of scientific misconduct.

One aspect of the German system of note is that it must maintain harmony with academic freedom, a principle that is enshrined in the basic (constitutional) law of the state. As one commentator points out, this has its origins in the Prussian Constitution of 1850 which declares that "science and its teaching shall be free." From this, Germany observes two related concepts of *Lehrfreiheit* (the right of faculty to teach on any subject): one is freedom of scientific research; and the other is the right of students to attend any lectures, and the absence of class roll calls."[88]

[88] Ronald B. Sandler, "Academic Freedom in the United States", http://www.rbs2.com/afree.htm (2000)

B.4.2 System Attributes

Governance[89]

Based on the recommendations of the Commission, the DFG created the Office of Ombudsperson, as an independent organization of the DFG. The Office acts as an advisory and mediatory body for questions involving good scientific practice and scientific misconduct.

The Office maintains a team of three scientists (appointed by discipline), all of whom are appointed by the DFG Senate for a three-year renewable term. The office of the ombudsperson is assisted by a secretariat that the DFG financially supports.

The roles of the ombudsperson team are to assess allegations of research misconduct, provide mediation between the conflicting parties and, if appropriate, refer cases to the appropriate tribunal if the initial assessment justifies the allegations. When DFG funding is involved, the ombudsperson refers the case to a *DFG Committee of Inquiry on Allegations of Scientific Misconduct*. This Committee, which is appointed by the DFG Joint Committee[90], comprises four member scientists and up to two experts from the subject area concerned. It is chaired by the DFG Secretary General (who does not have a vote) and is supported by legal office of the DFG. The remit of the Committee of Inquiry is to investigate allegations of scientific misconduct carried out by applicants, funding recipients, reviewers and members of DFG bodies and to make recommendations to the DFG Joint Committee, which then imposes the appropriate sanction. Once it hears a case and determines that there has been misconduct, its findings are forwarded to the Joint Committee with a recommendation as to sanctions.

The office will also follow up on allegations of research misconduct involving research that has not been funded by the DFG. In such instances where no DFG relationship applies, cases are referred to the research institute concerned.

Definition

In accordance with the recommendations of the Commission, the definitions in the German system begin with descriptions of what is "good scientific practice". These recommendations have been interpreted in turn by respective institutions each of whom have created their own policies.

The Max Planck Society, which as noted is recognized as a model, has identified three groups of "good scientific practice":

[89] The following overview draws from the 2008 publication of the European Science Foundation, entitled Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practice in Europe, which provides an excellent survey and review of the research integrity policies and practices in 18 countries in Europe.

[90] The "Joint Committee" is responsible for research funding and policy for the DFG.

- Regulations governing day-to-day scientific practice (including, for example, observing discipline specific rules, securing and preserving primary data, and the rule of "systematic skepticism);
- Regulations governing relations with colleagues and cooperation (including, non-hindrance of the work of others, active promotion of junior scientists' qualifications, openness to criticism and careful, unprejudiced assessment of colleagues);
- Regulations governing publication of results (including publication as a matter of principle, publication also of falsified hypotheses, and strictly honest recognition of the contributions of others).

As for research misconduct, it is defined as follows:

- False statements, including the fabrication and falsification of data, or incorrect statements in applications for financial support,
- Infringement of intellectual property, including plagiarism, misappropriation of research methods or ideas, usurpation of authorship or co-authorship, or unauthorized publishing of material not yet published,
- Impairment of the work of others, including the sabotage of research,
- Joint accountability, including active participation in the misconduct of others, knowledge of falsification by others, co-authorship of falsified publications or gross dereliction of supervisory duties.

Administration of Policies

In the German system, the responsibility for the policies lies with the institutions as do the administration of the practices in support of those policies. One of the recommendations of the Commission was that each institution should appoint or elect an Ombudsperson for that institution to act in cases of conflict on matters of good scientific practice. The ombudsperson is to be available to all concerned on a confidential basis in any case where there is a suspicion of misconduct.

Under proposed amendments to the guidelines, it will be necessary for the institution to ensure that the ombudsperson has no other official responsibilities or duties at the institution during their three-year term in the post; this is to reduce as much as possible any potential conflicts of interest. In more serious (or more senior) cases, the institution can refer the case to the DFG Office of the Ombudspersons.

Prevention and Training

For the most part, education and training in "good scientific practice" is left to the individual institutions. It is the view of the DFG Office of the Ombudsperson that the office should have a

larger role in prevention and training but that the Office lacks the resources at this time. There is a need for a "course" on good scientific practice that could be disseminated to institutions for their use.

The DFG Office does hold an annual meeting for all ombudspersons as a vehicle to share "best practices" and lessons learned. This national information system is admitted to be less than perfect but it is agreed that it is working reasonably well.

Inquiry and Investigation Procedures

In general, a suspicion of misconduct is reported to the institution, if the institution is adhering to the Max Planck policy template. For example, at the Max Planck Institutes, the Managing Director must be informed and that person must inform the relevant Vice President in writing. If the Managing Director is implicated, the complainant may notify the Vice President directly. The local ombudsperson is also available for consultation at this early stage.

If there appears to be sufficient indication of misconduct, the Managing Director will notify the head of the Department of Personnel and Legal Affairs and notifies the suspect of the incriminating facts and evidence. The suspect is given two weeks to respond. At this stage the informant's identity is not revealed without their permission.

On receipt of the response or after the passage of the time limit, the Managing Director and the Vice President must decide whether a formal investigation is warranted. The matter can take one of three courses at this stage: (1) if the matter is not proved, the preliminary inquiry is terminated and the suspect is so notified, (2) if the misconduct is proved, the Managing Director and the Vice President must make a recommendation as to the appropriate sanction, or (3) if the inquiry shows grounds for the suspicion but has not proven misconduct, they call for a formal investigation.

The formal investigation is conducted by an investigating committee chaired by the standing chairperson (not a member of the Max Planck Society), and including the relevant Vice President, three conciliators from different sections and the head of the Department of Personnel and Legal Affairs. The committee may co-opt scientific experts to act as non-voting advisers.

The investigation is conducted as an oral hearing. The suspect has a right to be heard and to be assisted by "a person whom he or she trusts". The institute has a right to be heard. The disclosure of the name of the informant may be necessary at this stage to permit the suspect to present a full defence. Once the decision is made, the decision and the reasons must be provided in writing to the President, the person affected and to the institute.

Enforcement and Sanctions

Typically, the person suspected and found to have committed scientific misconduct will be an employee of the institution where the misconduct occurred (or where the research was

conducted). In such a case, the labour law consequences would be considered first which could range from formal reprimand to mutual rescission of the employment contract to dismissal.

Academic consequences can include withdrawal of a doctoral or other degree or withdrawal of the licence to teach. Scientific publications must be withdrawn or corrected and in cases of serious breaches, other affected institutions and professional organizations would be notified. In addition, there may be civil law or criminal law consequences depending on the nature and severity of the misconduct.

The DFG itself outlines six possible sanctions regarding findings of misconduct that have involved DFG funds. These are: (1) reprimand; (2) ban on submitting proposals for a period from one to eight years; (3) request to pay back research funds; (4) request to withdraw publications (or to publish an erratum/corrigendum); (5) ban on acting as a DFG reviewer; and (6) deprivation of the right to stand for election for DFG bodies.

Reporting, Communications and Transparency

Institutions are required to notify the DFG of misconduct cases that they have investigated and the three Ombudspersons report annually to the DFG. These reports do not "name names" but provide an annual statistical report of the number and nature of the cases of misconduct reported and actions taken.

Every three years, the Ombudsperson appears personally at the DFG Senate to provide a more detailed, personal view of the state of research integrity and misconduct in Germany.

B.4.3 Strengths and Weaknesses

The German system, according to those interviewed, benefits from the precision and conciseness of the basic principles involved, and from the descriptions or definitions of what constitutes "good scientific practice" to the definitions of conduct to be regarded as misconduct.

The implementation of these principles and practices has been facilitated by the centralized nature of Germany's research system. This has been helpful for DFG in establishing a central Office of the Ombudsman. On the other hand, the Office is seen to be overloaded and under-resourced so that it cannot do all that it might wish. The Office has indicated that education is an area deserving of more attention across the system and that it would be more active if it had more resources.

One of the main recognized weaknesses is the current treatment of "whistleblowers". Whether or not the allegation is proven, the complainant often becomes an outcast in their laboratory or institute and often is forced to move on. That is, there is little or no protection for the whistleblower. There is some suggestion that this deficiency will be addressed in the new rules that are under development.

The commitment of institutional management is also seen as a weakness. They are often inclined to sweep these matters under the table rather than deal with them. For example, in one case a senior official noted that "yes, it was plagiarism, but we decided not to do anything about it."

Furthermore, the system does not deal with conflict of interest issues whereby between for example good scientific practice of the researcher and the needs or desires of an industrial partner involved in or supporting the research. Again, it is anticipated that the new rules will include a chapter on conflict of interest.

Finally, the system does not do enough to keep these matters out of the courts. While individuals must always retain the right to seek the assistance of a court in a dispute, the courts are not well equipped to deal with matters of scientific misconduct due to the fact that they lack the scientific expertise necessary and once the courts get involved, these matters can take up to 10 years to resolve.

B.4.4 Conclusions

As with many other countries, the current German system emerged out of the need to deal with a serious, high-profile case of scientific misconduct. The DFG created an independent Commission to investigate and make recommendations for a "system" to deal with issues of good scientific practice and cases of misconduct. The end result is a national system that is fairly uniform across all research institutions in the country and one that is reportedly seen by other European countries as a model from which to start and adjust to their own local (national) circumstances.

It should be noted that there is an ongoing review of the current system being led by the Office of the Ombudsmen. Issues under discussion include: (1) weaknesses in the systems for the protection of whistleblowers (it is acknowledged that this is an issue that is difficult to solve), (2) issues of Conflict of Interest, (3) continued discussion of the protection of data (note: Germany requires that it be preserved for 10 years), and (4) improved (more) teaching of "good research practices". The Office of the Ombudsmen held a conference of all institutional ombudsmen February 14, 15, 2008 in Hamburg to discuss such issues, among other matters.

B.5 United Kingdom

Research Integrity System Attributes – Highlights	
RI System:	Type 2
National Policy / Code:	No
Reach:	Non-government research organizations / government research
National Research Integrity Body:	No
Investigation Authority:	Home institution
Enforcement/Sanctions:	Home institution, granting councils, regulatory / professional body

B.5.1 Overview

The formalization of United Kingdom's policies on research integrity and misconduct started on 18 December 1998 when the Director General of the Research Councils and the Chief Executives of the UK Research Councils[91] issued a joint statement *"Safeguarding good scientific practice"*.[92] The Statement outlines general principles to avoid scientific misconduct and elements to ensure sound scientific conduct, and it has oriented subsequent policies towards "research integrity" as opposed to "research misconduct". For example, ten years later in 2008 the Research Councils UK (RCUK) prepared a public consultation document, *Code of Conduct and Policy on the Governance of Good Research Conduct: Integrity, Clarity, and Good Management*. The purpose of the consultation document was to facilitate a review of UK's policies on research integrity and misconduct. The RCUK is expected to release its report in the beginning of 2009.[93]

The biomedical and health field has spearheaded the UK policy landscape governing research integrity. The two main research integrity organizations are: the Research Councils UK (RCUK), an umbrella organization of seven research councils, and the UK Research Integrity Office (UKRIO) hosted by The Universities UK. Of the seven research councils of the RCUK, the first council to issue a policy on research integrity was the Medical Research Council. The main support for the UKRIO is from government and the major regulators and funders of health

[91] There are eight chief executives representing: Arts & Humanities Research Council, Biotechnology & Biological Sciences Research Council, Council for the Central Laboratory of the Research Councils, Engineering & Physical Sciences Research Council, Economic & Social Research Council, Medical Research Council, Natural Environment Research Council, and Particle Physics & Astronomy Research Council.

[92] The Statement is available at http://www.ukoln.ac.uk/projects/ebank-uk/docs/scientific-practice.doc

[93] Examples of Research Integrity Policies since the Joint Statement:

- Medical Research Council, Good Research Practice, original version in December 2000, and updated in September 2005;
- Wellcome Trust, Guidelines on Good Research Practice, first published in January 2002, and updated in November 2005;
- Engineering and Physical Sciences Research Council, Guide to Good Practice in Science and Engineering Research, 2002-2006; and
- Biotechnology and Biological Sciences Research Council, Statement on Safeguarding Good Scientific Practice, June 2006.

and biomedical research. It is also a part of the UK Panel for Research Integrity in health and biomedical sciences.[94]

The research integrity policies of the RCUK and the UKRIO are not backed by legislation. Policies that are backed by legislation in the UK are professional accreditation bodies, such as the General Medical Council[95] which regulates medical doctors. In the biomedical and health field, there is also the Medical Schools Council which is concerned with medical undergraduate education, health related research, and the interface with the health service and postgraduate education and training.[96] As UK's national health service is devolved to regional/local jurisdictions, guidance in health care research and codes of practice differ. For biomedical and health, these policies apply to researchers in both the public and private sectors.

Other aspects that affect research integrity policies in the UK include the Committee on Standards in Public Life which requires individuals in a public office / serve on public committees (e.g., board member of UKRIO) to declare any interest they may have, and the Freedom of Information and Privacy Act.

B.5.2 Introduction to the System

There is no single oversight organization, no national standards, and no single law concerned with research integrity in the UK. Like Canada, the various policies, codes and guidelines that shape the core of the oversight system in the United Kingdom, implicitly recognize that the responsibility for responding to allegations of misconduct resides with the institutions where the research is conducted. Institutions respond to allegations in accordance with their own policies for addressing research integrity and misconduct, which have been developed with guidance from the RCUK, UKRIO, other granting organizations (e.g., Wellcome Trust), professional accreditation bodies (e.g., General Medical Council) and, or regional / local policies (e.g., National Health Service).

Granting (research) councils are typically explicit in requiring institutions who receive their funds to have research integrity policies in place as a condition of funding, whereas others are more implicit by focusing on the individuals (scientists, visiting researchers) it funds to follow the policies/procedures outlined by the research (granting) councils. The biomedical and health field is a good example of this variance from explicit to implicit. The Wellcome Trust explicitly states that "each host institution must have in place formal written procedures for dealing with allegations of research misconduct against its staff and students." The Biotechnology and Biological Sciences Research Council (BBSRC) on the other hand is implicit by stating that individuals must follow policies. These may include researchers, fellows and scientific support staff at higher education institutions, or institutions funded by the BBSRC, administrators at higher education institutions, any person involved in BBSRC's peer review process.

[94] UK RIO web sites http://www.universitiesuk.ac.uk/AboutUs/AssociatedOrganisations/Pages/UKRIO.aspx and http://www.ukrio.org.uk/home/index.cfm
[95] See http://www.gmc-uk.org/
[96] Reference http://www.chms.ac.uk/

Misconduct is treated as employee misconduct. Funding councils may have contractual agreements requiring them to be informed of misconduct and/or to be involved in an investigation. Regulatory and/or accreditation bodies may also have an interest, but in the end it is up to the employer.

The Research Councils UK (RCUK) and the UK Research Integrity Office (UKRIO) in particular are attempting to consolidate the various policies, codes and guidelines. Over the period from July to October 2008, the RCUK consulted with the UK research community in much the same manner as this project for the Canadian Research Integrity Committee (CRIC) and Health Canada which acts as a secretariat to CRIC. The intent of the RCUK consultation exercise is to bring together all codes (e.g., Medical Research Council, Engineering and Physical Sciences Research Council), however the consolidated code is not intended to displace any individual subject matter codes as they may need to develop their own protocols further in regards to unique requirements specific to their field. The RCUK is expected to release its report in early 2009.

The UK Research Integrity Office (UKRIO) is also working on measures to further develop UK's research integrity system including procedures for the investigation of misconduct in research (released in August 2008), code of practice for research, research integrity helpline, and awareness, prevention and training. The UKRIO and the RCUK along with other organizations (e.g., Wellcome Trust, Association of Medical Research Charities, Higher Education Funding Councils) are collaborating on their common goal to further develop UK's policies and systems on research integrity and misconduct.

The Committee on Publication Ethics (COPE) is mentioned in this overview as its codes and guidelines complement the work of the RCUK and the UKRIO. COPE was established in 1997 or one year prior to the Joint Statement. COPE has published a Code of Conduct, Guidelines on Good Publication Practice, and as indicated on their web site, flowcharts on how to handle the more common publication misconduct problems.[97]

B.5.3 System Attributes

Overview of Guidelines and Standards

The main organizations concerned with research integrity policies, guidelines and standards include the Research Councils UK (which represents seven research councils), the UK Research Integrity Office, medical research charities (e.g., Wellcome Trust), and the Committee on Publication Ethics. We describe below each of these organizations and their research integrity policies, guidelines and standards.

[97] See http://publicationethics.org/

The Research Councils UK (RCUK) is a strategic partnership of the UK's seven Research Councils. According to the RCUK web site[98], together the Research Councils invest around £2.8 billion in research each year covering the full spectrum of academic disciplines from the medical and biological sciences to astronomy, physics, chemistry and engineering, social sciences, economics, environmental sciences and the arts and humanities. UK's seven Research Councils are funded by the Department for Innovation, Universities and Skills (DIUS). Typically, research integrity policies and codes are included in funding agreements between the Research Council and the researcher.

The Research Councils UK (RCUK) was established in 2002 to "optimise the ways that Research Councils work together to deliver their goals, to enhance the overall performance and impact of UK research, training and knowledge transfer and to be recognised by academia, business and government for excellence in research sponsorship." Each of the seven Research Councils noted above is an equal partner in the RCUK. The RCUK is governed by the RCUK Executive Group comprised of the chief executives of the seven Research Councils. A small Secretariat supports the RCUK.

As noted above, the RCUK prepared a consultation document in 2008 that served as a basis for soliciting comments and suggestions for moving forward UK's research integrity and misconduct system. The document outlines a policy for the governance and management of good research conduct and research ethics, a code of conduct for ensuring good research conduct and research integrity (including a definition of misconduct), and procedures for the reporting and investigation of allegations of misconduct or performance below acceptable levels of good conduct. The document asks the UK research community to comment on six key questions as follows:

- The overall policy statement and any additions or amendments needed
- The code of conduct: including whether this needs to be expanded, re-focussed or developed in any way
- Suggested guidance on desirable management arrangements in research organisations
- General guidance on procedures for reporting and investigating complaints, identifying any key weaknesses without making the guidance overly prescriptive
- The need for a central repository of information on cases of proven misconduct, and how this might be established and managed
- The need for a national advisory body on a voluntary basis to establish common guidance on codes of conduct, desirable management systems to ensure best practice, procedures for dealing with problematic cases, sanctions/penalties for varying failures in conduct. Such a body might also oversee and advise on investigations into serious allegations of

[98] RCUK web site: http://www.rcuk.ac.uk/default.htm

misconduct, and liaise with non-UK national authorities on cases of cross-border misconduct.[99]

The intent of the consultation exercise, as noted above, is to develop a consolidated code without displacing any individual subject matter codes of individual Research Councils. The RCUK is expected to release its report in early 2009.

We profile below the research integrity policies and codes pertaining to each of UK's seven Research Councils that are in addition to those included in the funding agreements, followed by a profile of the consolidated policies and codes of the RCUK.

- Arts and Humanities Research Council (AHRC[100]): focuses on research integrity (as opposed to misconduct). In December 2008 it released a *Code of Practice for Council, Committee Panel, Peer Review College and Advisory Group Members*.[101] According to AHRC, its Code is based upon the principles of public life as set out by the Committee on Standards in Public Life. The AHRC also has policies covering fraud, complaints, appeals, whistle blowing, privacy and access to research outputs.
- Biotechnology and Biological Sciences Research Council (BBSRC[102]): also focuses on research integrity. For example in April 2003 it revised its *Joint Code of Practice for Research*[103], and in June 2006 it issued a *Statement on Safeguarding Good Scientific Practice*. The BBSRC also has policies on access to research outputs and on the use of animals in bioscience research.
- Engineering and Physical Sciences Research Council (EPSRC[104]): like other Research Councils focuses on research integrity. In 2002, it published a *Guide to Good Practice in Science and Engineering Research*. The EPSRC also has policies on general complaints, complaints about the peer review process, allegations of scientific misconduct, whistle blowing, and a code of practice[105] for those who assist in the work of the EPSRC.
- Economic and Social Research Council (ESRC[106]): also focuses on research integrity and published *Research Ethics Framework* in 2005. As noted on ESRC's web site, five regional workshops were held to consider issues and provide practical assistance to applicants and managers.
- Medical Research Council (MRC[107]): was the first research council to publish policies on research integrity. Its first RI publication was in 1997 when it released *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct*. In 2000, it published

[99] Research Councils UK, *Code of Conduct and Policy on the Governance of Good Research Conduct: Integrity, Clarity, and Good Management*, Public Consultation Document, July – October 2008.
[100] AHRC web http://www.ahrc.ac.uk/Pages/default.aspx
[101] AHRC's Code is available at http://www.ahrc.ac.uk/About/Documents/Code%20of%20Practice.pdf
[102] BBSRC web http://www.bbsrc.ac.uk/
[103] Issued jointly by the BBSRC, the Department for Environment, Food and Rural Affairs, the Food Standards Agency and the Natural Environment Research Council.
[104] EPSRC web http://www.epsrc.ac.uk/default.htm
[105] EPSRC's Code is based upon the principles of public life as set out by the Committee on Standards in Public Life.
[106] ESRC web http://www.esrc.ac.uk/ESRCInfoCentre/index.aspx
[107] MRC web http://www.mrc.ac.uk/index.htm

Good Research Practice and later revised it in 2005. The MRC also has policies on complaints, data protection, freedom of information and privacy.

- Natural Environment Research Council (NERC[108]): has issued an Ethics Policy[109] which includes a statement on honesty and integrity. The NERC has also developed three guides (*Planet Earth authors guide*, *Communicating your ideas*, and *Science and the media*) to help researchers communicate their science to a wider audience.
- Science and Technology Facilities Council (STFC[110]): published a Health and Safety Policy in 2008. Policies and codes pertaining to research integrity are included in funding agreements.

The UK Research Integrity Office (UKRIO), as indicated on its web site[111], is an independent advisory body, hosted by Universities UK. Established in 2006 the UKRIO is supported by government and the major regulators and funders of health and biomedical research. Although the UKRIO was originally established with a focus on health and biomedical research, it considers its work to be relevant and applicable to all fields. The UKRIO, as with the RCUK and the Research Councils, emphasizes research integrity as opposed to misconduct. It aims to:

- Promote high standards of integrity in the leadership, governance and management of health and biomedical research across the university and NHS (National Health Service) sectors;
- Provide practical support to employers and the research community in the prevention and effective management of research misconduct; and
- Provide advice and guidance to people wishing to raise concerns about possible misconduct in research.[112]

The UKRIO's programme of work, as noted on their web site, includes a number of interesting aspects such as:

- Research Integrity Helpline: provides "confidential advice and guidance to anyone with concerns about the conduct of research or who is involved in the investigation of allegations of misconduct in research."
- Register of Advisers: consist of "experienced individuals, knowledgeable about the various aspects of research integrity, who offer guidance in relation to specific queries and who are available to join an institution's investigation panel if required." All registered advisers follow the principles outlined by the Committee on Standards in Public Life.
- Procedure for Investigating Allegations of Research Misconduct: the UKRIO recently published (August 2008) a "step-by-step manual for the investigation of allegations of

[108] NERC web http://www.nerc.ac.uk/
[109] NERC Ethics Policy is available at http://www.nerc.ac.uk/publications/corporate/documents/ethics_policy.pdf
[110] STFC web http://www.stfc.ac.uk/Home.aspx
[111] UKRIO web http://www.ukrio.org.uk/home/index.cfm
[112] From Universities UK web http://www.universitiesuk.ac.uk/AboutUs/AssociatedOrganisations/Pages/UKRIO.aspx

misconduct in research."[113] In addition to describing the procedure, the document includes several annexes covering principles to be followed, definitions (including what constitutes misconduct in research), forms for communicating with the UKRIO, operation of the screening panel, investigation panel, communications and record-keeping, and three flowcharts covering informal resolution, screening, and formal investigation.

- Education and Training: involves "working with universities and other research organisations to provide education and training in the principles of the good practice of research and the use of UKRIO's Procedure for Investigating Allegations of Misconduct in Research." The first courses are planned to take place at King's College London in April and June 2009.

Medical Research Charities - Wellcome Trust: The Association of Medical Research Charities (AMRC[114]), as noted on its web site, is a membership organization of the leading medical and health research charities in the UK. The AMRC has 114 member charities that contributed approximately 800 million in 2006/07 to medical research. We highlight below the research integrity policies of one of AMRC's members: The Wellcome Trust.

The Wellcome Trust is an important player regarding UK's research integrity system. It has been collaborating with the UKRIO, the RCUK and others to advance UK's policies and systems on research integrity and misconduct. As indicated on its web site, The Wellcome Trust[115] is an independent charity funding research to improve human and animal health. Established in 1936 and with an endowment of around £13 billion, it is the UK's largest non-governmental source of funds for biomedical research. The charity funds roughly £600 million each year both in the UK and internationally.

In January 2002 it published Guidelines on Good Research Practice, Including a Statement on the Handling of Allegations of Research Misconduct[116], and later updated the Guidelines in November 2005. The document includes guidelines on good research practice (including the storage of research data), statement on the handling of allegations of research misconduct (recipient organizations of Wellcome Trust grants are required to have in place formal written procedures for the handling of allegations of research misconduct), and procedures for investigation of research misconduct by the Wellcome Trust.

The Committee on Publication Ethics (COPE[117]), as indicated in its web site, was established in 1977 as a registered charity in the UK. It is a forum for publishers and editors of peer-reviewed journals to discuss issues related to the integrity of work submitted to or published in their journals. Four cases of misconduct in the biomedical field was the original impetus behind

[113] UK Research Integrity Office, Procedure for the Investigation of Misconduct in Research, August 2008 available at http://www.ukrio.org/resources/UKRIO%20Procedure%20for%20the%20Investigation%20of%20Misconduct%20in%20Research.pdf

[114] AMRC web http://www.amrc.org.uk/HOMEPAGE/Default.aspx?Nav=810

[115] The Wellcome Trust web http://www.wellcome.ac.uk/index.htm

[116] Wellcome Trust Guidelines on Good Research Practice are available at http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd002754.pdf

[117] COPE web http://publicationethics.org/

the formation of COPE. Today, it has over 5200 members from all continents, up from 600 members when it started over a decade ago. COPE's membership is composed primarily of Editors-in-Chief of scientific journals. Other members include companies and individuals interested in publication ethics. COPE documents related to research integrity include:

- COPE Code of Conduct[118];
- Code of Conduct for Editors of Biomedical Journals[119];
- COPE Best Practice Guidelines for Journal Editors[120];
- Guidelines on Good Publication Practice[121]; and
- Flowcharts for editors to follow when they suspect publication misconduct[122].

Definition

The definition of research misconduct is very similar across the RCUK, UKRIO, Wellcome Trust and COPE. As indicated in the figure below each of the main research integrity organizations includes the same components of misconduct, i.e., fabrication, falsification, misrepresentation, plagiarism, management and preservation of data and primary materials, and breach of duty of care. The most detailed definition of misconduct is outlined in the RCUK's public consultation document.[123]

Figure 16: Elements of research misconduct definitions, UK

Components of Misconduct	RCUK	UKRIO	Wellcome Trust	COPE
Fabrication	✓	✓	✓	✓
Falsification	✓	✓	✓	✓
Misrepresentation	✓	✓	✓	✓
Plagiarism	✓	✓	✓	✓
Management and preservation of data and primary materials	✓	✓	✓	n/a
Breach of duty of care	✓	✓	✓	n/a

Administration of Policies

The responsibility for the administration and management of research integrity policies rests with the institution, e.g., university, research institute, hospital. Oversight organizations (e.g., RCUK,

[118] Available at http://publicationethics.org/files/u2/New_Code.pdf
[119] Available at http://publicationethics.org/files/u2/Old_Code_of_Conduct_0.pdf
[120] Available at http://publicationethics.org/files/u2/Best_Practice.pdf
[121] Available at http://publicationethics.org/static/1999/1999pdf13.pdf
[122] Available at http://publicationethics.org/flowcharts
[123] See Research Councils UK, *Code of Conduct and Policy on the Governance of Good Research Conduct: Integrity, Clarity, and Good Management*, Public Consultation Document, July – October 2008, pp. 6-7.

UKRIO) provide guidance on the development, administration and management of research integrity policies. As in Canada, the larger institutions and those that manage a large number of research grants have developed their own policies and have the research integrity infrastructure in place. Smaller institutions on the other hand tend to adopt, as their policy, the policies of the oversight organizations.

Prevention and Training

In general, education and training on good research practice is left to the individual institution. For example, the RCUK's Training and Mentoring Policies advises that research institutions should have training and mentoring procedures in place, all relevant staff should be aware of the procedures and how any cases should be reported, and that standards should be applied in publication of materials, preparation of conference papers, and so forth.[124] The Wellcome Trust indicates that all grant recipients are expected to have in place systems that allow students and new researchers to understand and adopt best practices as quickly as possible, and that all researchers should undertake training in good research practices.[125]

The focus of UKRIO's efforts, as with other organizations concerned with research integrity in the UK, is on avoiding misconduct in the first place. Education and training efforts, therefore, represent a key part of UKRIO's programme of work. The efforts focus on defining what constitutes research misconduct, making sure that researchers understand how to avoid misconduct, and assisting a research institution to adopt good research practices. At the present time, education and training is contracted out to King's College London, with the first courses scheduled to take place in April and June 2009.

Inquiry and Investigation Procedures

The preference in the UK is to avoid misconduct in the first place, which is why the RCUK and the UKRIO in particular are focusing on education, training and prevention. However, once an allegation of misconduct is made, the responsibility for the inquiry and investigation rests with the institution, as indicated in UKRIO's procedure for the investigation of misconduct in research[126], the Medical Research Council's policy and procedure for inquiring into allegations of scientific misconduct[127], and the Wellcome Trust's statement on the handling of allegations of research misconduct[128]. If the case constitutes a serious misconduct (e.g., FFP), employers are urged to notify the appropriate regulatory / accreditation body (e.g., General Medical Council).

[124] Research Councils UK, *Code of Conduct and Policy on the Governance of Good Research Conduct: Integrity, Clarity, and Good Management*, Public Consultation Document, July – October 2008, p. 11.
[125] Wellcome Trust, *Guidelines on Good Research Practice, including Statement on the Handling of Allegations of Research Misconduct*, London: Wellcome Trust, updated November 2005, p. 3.
[126] UK Research Integrity Office, *Procedure for the Investigation of Misconduct in Research*, August 2008.
[127] Medical Research Council, *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct*, 1997.
[128] Wellcome Trust, *Guidelines on Good Research Practice, including Statement on the Handling of Allegations of Research Misconduct*, London: Wellcome Trust, updated November 2005.

An interesting lesson for Canada is the UKRIO's helpline. The helpline is operated by UKRIO's register of advisers, who are experts in research ethics and misconduct, covering different subject areas from institutions across the country. In keeping with the principles of UK's Committee on Standards in Public Life, all advisers declare their interest before they can provide advice on the helpline. Perhaps one downfall is that the helpline does receive a significant number of calls from the general public inquiring about an issue not related to research integrity, e.g., poor surgery, in which case the caller is directed to the General Medical Council who regulate doctors.

Respondents from the UK also noted that a significant number of allegations result from a breakdown in working relations, and have nothing to do with research integrity. In the UK, malicious allegations are not considered to be research misconduct. For example, the mistreatment of subordinates is a questionable research practice, but it is not defined as misconduct.

The UK does have in place legislation to protect whistle blowers. All UK respondents indicated that whistle blowers who make allegations in good faith should be protected. However, in practice it is often the whistle blower who gets a bad reputation.

Enforcement and Sanctions

Generally, the enforcement and the application of sanctions is the responsibility of the individual institution. Sanctions should be in line with the seriousness of the misconduct. In cases of serious misconduct where the appropriate regulatory / professional body has been notified, that body can choose to impose a legally binding sanction, such as removal of a doctor's licence to practice.

The role of oversight bodies such as the RCUK and the UKRIO is to provide guidance, advice, codes of practice, etc. Examples of sanctions identified by the UKRIO range from retraction/correction of articles in journals, withdrawal/repayment of funding, to notifying patients/patients' doctors of any potential medical issues that may arise and/or notification of misconduct to regulatory bodies[129]. The Wellcome Trust has a similar list of possible sanctions that range from a letter of reprimand, withdrawal of funding to barring of the Trust-funded researcher from applying for Trust funds for a given period and/or discussion with the host institution on the implementation of appropriate disciplinary action.[130]

Reporting / Communications and Transparency

There is no central register in the UK where cases of misconduct can be filed. One of the questions posed by the RCUK in its consultations with the research community was whether or not there should be a central repository of information on cases of proven misconduct, and how

[129] UK Research Integrity Office, *Procedure for the Investigation of Misconduct in Research,* London: Universities UK, August 2008, p. 49.

[130] Wellcome Trust, *Guidelines on Good Research Practice, including Statement on the Handling of Allegations of Research Misconduct*, London: Wellcome Trust, updated November 2005, p. 9.

this might be established and managed. As noted earlier, the RCUK is expected to release its report in early 2009.

Opponents of a central repository have noted that in addition to privacy issues, there are also ethical and legal concerns with the publication of this information. Like Canada, privacy issues prevent Research Councils from exchanging information with another.

Times Higher surveyed 105 UK institutions using the Freedom of Information Act. They found 73 cases of alleged misconduct were investigated between 2004 and 2006. Of these, 25 were upheld, 37 were dismissed, and 11 cases are still pending.[131]

B.5.4 Strengths and Weaknesses

The UK system's strengths are threefold. First, it respects self-governance and academic freedom while at the same time supports comparable and compatible policies across the main organizations concerned with research integrity (notably the RCUK and UKRIO). Second, the level of cooperation and collaboration between the main research integrity organizations (RCUK, UKRIO, medical charities such as Wellcome Trust, and COPE) is very good, and appears to have effectively led to comparable and compatible research integrity policies, while at the same time, having the flexibility for individual fields (e.g., medical through the Medical Research Council) to tailor policies, codes and guidelines. Third are the various support activities of the UKRIO including its helpline, register of advisers, and education and training initiatives.

UK's weaknesses include first, the lack of a unified system which means that identical cases can be treated differently by different institutions. Second, privacy issues prevent one institution from sharing information with another, which means that a person can move from one institution to another without the new institution knowing if there was misconduct in the previous institution. Third, is no requirement to report cases of misconduct nor is there a central repository where cases, even if they were reported, can be filed.

B.5.5 Conclusions

Both Canada and the UK have a tradition of self-governance and academic freedom, and both face similar constraints such as privacy concerns. There are useful lessons for Canada from the system in the UK. In particular, the level of cooperation and collaboration of the various oversight organizations (e.g., RCUK, UKRIO, medical charities such as Wellcome Trust, COPE) has led to compatible and complementary policies, codes and guidelines, the UK's outreach efforts notably the programme of work of the UKRIO which includes a helpline, register of advisers, and education and training initiatives.

[131] Times Higher (Phil Baty), "Plagiarists Face Clampdown", December 8, 2006, and Times Higher (Phil Baty), "Everyone is a Loser in a Misconduct Case", December 8, 2006.

B.6 Australia

Research Integrity System Attributes - Highlights	
RI System:	Type 3
National Policy / Code:	Yes
Reach:	Universities and government research organizations
National Research Integrity Body:	No
Investigation Authority:	Home institution
Enforcement/Sanctions:	Institution and Granting councils

B.6.1 Overview

Australia's research integrity and misconduct system has undergone two phases of development since first establishing guidelines in 1990. The first phase involved the creation of the 1997 Joint Statement from NH&MRC (National Health and Medical Research Council) and AVCC (Australian Vice Chancellors' Committee) which was developed to replace the original two statements from 1990.[132] These statements and the new guidelines had been introduced to assist institutions in developing their own procedures and guidelines, by way of a comprehensive framework of minimum acceptable standards.

The second phase was prompted in part by a major case of misconduct in 2001, which resulted in Australia introducing *The Australian Code for the Responsible Conduct of Research* in 2007. The case involved Dr. Bruce Hall and was instigated by four whistleblowers who had collectively raised some 450 separate allegations. Five years later and after 18 inquiries at a cost of $10 million there had still been no resolution of the case. With no charges laid, and no firings, Dr. Hall continued work as a doctor and a scientist, but with his research funding all but dried up. This case led to the creation of a Working Group, including the NH&MRC, the AVCC, which is now Universities Australia (UA), and the Australian Research Council (ARC), in 2003 to review the 1997 Joint Statement and Guidelines to make recommendations for a new Code. The consultations undertaken by the Working Group lasted through to 2006.

This national 40 page Code is now at the core of Australia's system, and is being implemented and administered at the institutional level. Without any national oversight body, the institutions rely fully on the code for addressing cases of misconduct. The funding agencies, for their part reserve the authority to remove funding, in cases of misconduct.

The code, and research integrity in general, has received strong interest and support at the political level. The Minister of Innovation, Industry, Science and Research, the Honourable Kim Carr, spoke at a Workshop organized by his department in September 2008, entitled

[132] The initial guidelines were comprised of (1) the "Statement on Scientific Practice" of the NH&MRC and (2) the "Guidelines for Responsible Practice in Research and Problems of Research Misconduct" of the (AVCC),

"Managing Serious Research Misconduct". At that time he noted the "excruciatingly slow development of the Australian Code" and indicated two main concerns that he hoped to see addressed. The first concern related to process:

> "My concern is that while researchers and universities can sort out their differences 90 to 95 percent of the time, there is no effective mechanism for handling the 5 to 10 percent of cases that prove intractable.

And,

> "We need to give scholars an avenue of appeal when they've come to the end of the line with their university – without involving them in costly, acrimonious and potentially scandalous legal action. This could be a research ombudsman, a tribunal, or an office of research integrity."[133]

B.6.2 System Attributes

Overview of Code

The Code states that its purpose is:

> "to guide institutions and researchers in responsible research practices. In describing good practice, this Code promotes integrity in research for researchers and explains what is expected from researchers by the community. In providing advice on how to manage departures from best practice, this Code assists researchers, administrators and the community in this important matter."[134]

The Code is divided into two major sections. In Part A the principles and practices for encouraging the responsible conduct of research, for institutions and researchers are set out. This includes guidelines on the following:

- general principles of responsible research;
- management of research data and primary materials;
- Supervision of research trainees;
- publication and dissemination of research findings;
- authorship Peer review;
- conflicts of interest; and
- collaborative research across institutions.

[133] Honourable Kim Carr, "Address to Managing Serious Research Misconduct Workshop", 18 Sep 2008
[134] Australian Code for the responsible Conduct of Research, 2007, p. 1.

Part B provides a framework for resolving allegations of breaches of the Code and research misconduct, addressing the responsibilities of both institutions and researchers. Included are guidelines on breaches of the Code and misconduct in research; concepts and definitions; responsibilities; and a framework for resolving allegations.

Governance

As discussed above, the Code was jointly developed by the NH&MRC, the ARC and Universities Australia (UA). It applies to all research supported by those two funding bodies and has the support of UA, and by extension all of Australia's university that it represents. As in Canada, the governance and administration for both the promotion of good research practices (research integrity) and for the management of breaches of the Code (research misconduct) is the responsibility of the institutions.

There appears to be some inconsistency in the application of the Code across institutions. This may be blamed in part on the Code itself: on the one hand, the Code is drafted in a way that seems quite prescriptive (for example, there are many cases where it indicates that "institutions must do …"); on the other hand, the Code is presented over all as a set of guidelines that are not obligatory to follow. Then, as in Canada, the implementation of the Code is linked to the continued right to receive funding from the national agencies.

Definition

As noted above, the Code begins in Part A with a set of positive requirements; that is, the Code is designed to encourage responsible research and help institutions to create the appropriate research culture to foster it. More specifically, the Code defines what is meant by a strong research culture:

"A strong research culture will demonstrate:

- honesty and integrity
- respect for human research participants , animals and the environment
- good stewardship of public resources used to conduct research
- appropriate acknowledgment of the role of others in research
- responsible communication of research results."

The Code establishes two (2) levels of violations: (1) the term "Breach" refers to less serious deviations from the Code that are most appropriately remedied within the institution; and (2) the term "Research Misconduct" is defined as involving ALL of the following: (a) and alleged breach of the Code, (b) intent and deliberation, recklessness or gross and persistent negligence, and (c) serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment.

"Breaches" are described in the following terms: "Specific actions or omissions that constitute breaches of this Code, but lack the seriousness of consequence or willfulness to constitute research misconduct. Such breaches should be remedied by counseling or advice. Their repetition or continuation may, however, lead to more serious consequences and may constitute research misconduct."

For "Research Misconduct", the Code identifies the following types, without claiming to be a complete list:

- fabrication of results
- falsification or misrepresentation of results
- plagiarism
- misleading ascription of authorship
- failure to declare and manage serious conflicts of interest
- falsification or misrepresentation to obtain funding
- conducting research without ethics approval as required by *the National Statement on Ethical Conduct in Research Involving Humans and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*
- risking the safety of human participants, or the wellbeing of animals or the environment
- deviations from this Code that occur through gross or persistent negligence
- willful concealment or facilitation of research misconduct by others."[135]

Administration of Policies

Both Parts of the Code are to implemented and administered by institutions, that is the institution must put in place policies and procedures to deal with the Part A "positive" aspects of the Code and to deal with the Part B "negative" aspects.

With regard to the the promotion of responsible research practices, each institution must have a policy in place to promote all guidelines and legislation related to the conduct of research and, at a higher level, "maintain a climate in which responsible and ethical behaviour in research is expected". Beyond that, the administrative policy must then deal with the substance of the eight Chapters included in Part A, as noted above.

With respect to Part B, that administrative framework is more precisely defined. The CEO of the organization where the alleged misconduct has taken place retains the responsibility for the process. In the case of a university, the CEO is the Vice Chancellor. In addition, each institution must appoint a "designated person" who receives written allegations, conducts a preliminary

[135] Australian Code for the Responsible Conduct of Research, 2007, Box B.1, p. 10.2.

investigation and provides advice to the CEO as to how to proceed. The designated person has essentially four (4) choices for that advice: (1) dismiss the allegation, (2) deal with the misconduct under other provisions (for example the Enterprise Agreement) unrelated to research misconduct, (3) refer the allegations back to the department with instructions as to how they should be handled, or (4) investigate the matter through a research misconduct inquiry.

If the advice is to investigate through a formal inquiry, the designated person should advise as to whether the inquiry should be internal to the institution or external.

In addition to the designated person, institutions are to appoint one or more "Advisers in Research Integrity". These Advisers are to provide advice to a staff member who is unsure about a research conduct issue and who might be considering whether or not to make an allegation. These Advisers "should be people with research experience, wisdom, analytical skills, empathy, knowledge of the institution's policy and management structure, and familiarity with the accepted practices in research." Of course they cannot act in any case where they might have a conflict of interest and they do not participate in any investigation or inquiry.

Prevention and Training

The Australian Code is based on the concept of the creation of a positive environment for research integrity at each institution and, as noted above, the administration of the Code is left to the institutions. Therefore, as might be expected, there is some variance across institutions.

It was noted that this process is mostly done through "mentoring" systems that teach and instil "good practices". And while there is a centralized training course for research ethics, similar resources have not been set aside for such a course for research misconduct. Some of those interviewed felt that this could be a role for a central or national body that perhaps also had responsibility for collecting data and information and, perhaps, for an appeals process.

As with discussions in other countries of "prevention, education and training", there is debate in Australia as to the efficacy of such programs. There are some simple questions that appear to be difficult to answer: Who do you teach? What do you teach them? When do you teach them? What will they remember? While the initial responses to these questions may seem obvious (e.g. We should teach graduate students as they begin their research careers) respondents, including academics in the research integrity field, do not agree as to the most effective approaches.

The Code itself attempts to answer some of these questions. In Part A, the Code notes that "it is important that institutions provide induction, formal training and continuing education for all research staff, including research trainees." Finally, there is some agreement that, at the least, simple processes could be taught; for example, the use of lab notebooks, the retention of data, and, what to do if one suspects misconduct.

Inquiry and Investigation Procedures

The steps to be taken in pursuit of an allegation are set out in the Code in significant detail. The following Figure is an extract from the Code of the steps to be taken.

Figure 17: Inquiry and Investigation Procedures in the Australian Code

"Anyone who is concerned that a researcher has not acted responsibly must take action in a timely manner in accordance with this Code and the institution's policy.

The institution has appointed a number of senior staff to act as advisers in research integrity. An adviser can be approached in confidence to discuss the issue of concern. The adviser will discuss the matter, the Code and the policies of the institution, and explain the options for taking action.

It is preferable that, in the first instance at least, complaints and allegations are dealt with at the departmental level. However, if circumstances make this difficult or not possible, the adviser will suggest other approaches.

If the complaint cannot be handled to everyone's satisfaction at the departmental level, a formal complaint or allegation must be made in writing to the designated person appointed to this role by the institution.

The designated person must advise the CEO or their delegated officer whether a prima facie case exists, and how to proceed. Options include:

− dismissing the allegations

− instructing the department on how to deal with the allegations

− dealing with the complaint under provisions unrelated to research misconduct

− investigating the matter further through a research misconduct inquiry.

If the CEO or their delegated officer decides that a research misconduct inquiry is needed, he or she must decide whether to use an internal institutional research misconduct inquiry or an independent external research misconduct inquiry.

Upon completion of its tasks, the research misconduct inquiry must advise the CEO of its findings of fact and what, if any, research misconduct has occurred.

The CEO must then determine the actions to be followed, according to institutional policy.

Subsequent actions may, as appropriate, include informing relevant parties of the outcome and correcting the public record of the research."

In making a decision to proceed to an *internal* institutional research misconduct inquiry or an independent *external* research misconduct inquiry, the CEO or their delegated officer must take into consideration the advice received from the institution's *designated person*. The CEO or their delegated officer must also take into account the potential consequences for the accused, the accuser, other parties and institutions in the event that the allegation(s) were to be upheld, and the need to maintain public confidence in research. If, in his or her judgment, these are likely to be serious, the CEO or their delegated officer must establish an independent external research misconduct inquiry.

Enforcement and Sanctions

There is no general or standard set of "sanctions" applicable to all institutions. And they do vary widely. Given the different Enterprise Agreements, it may be that the variance is necessary and proper. It has been suggested that another role for a central body of some sort would be to collect a "database" of sanctions imposed as a tool for future cases as they emerge.

The sanctions that do exist must conform to the Enterprise Agreements since an allegation of research misconduct ultimately becomes an issue of the employer-employee relationship. Sanctions may include: demotion or other financial sanction; termination of employment; denial of access to research funds; period of supervision; referral to a professional registration body; or, other conditions.

Very few of the "regular" cases end up in a termination; most often the job of the institution is to try to re-integrate a lab that has been hurt by the allegation or the misconduct or both.

Reporting, Communications and Transparency

As it stands currently, there are no reporting requirements and no central repository of information related to the research integrity policies adopted by institutions. It may be that the current review process will suggest, at least, that there be a repository for data and information from cases that institutions handle. It does not appear that a "naming and shaming" system will be adopted; there is a view that this is a "sledgehammer" approach usually only affects the most junior researchers.

B.6.3 Strengths and Weaknesses

Having only introduced the new code in 2007, Australia's research integrity system has not had sufficient time to be adequately assessed. In general, the code itself is viewed as being a comprehensive document that is positive and goal oriented. There are nonetheless some recognized weaknesses. While some have noted problems of clarity and specificity, the main concerns are with a lack of oversight /monitoring body to ensure compliance and to collect and disseminate information such as lessons learned, and the fact that there is no process for appeal.

Indeed, the failure to incorporate an appeals process has been noted by the responsible Minister, the Honourable Kim Carr. There appears to be a consensus that some process is necessary to provide a mechanism for the resolution of cases before it is decided to engage the court system and the time and costs associated with that. The government has indicated that they are looking at an "Ombudsman" system that would deal with appeals as to "fairness" and "process", but not the substance of the allegations. The appeal would examine whether or not the process had been conducted in a fair way with due process. If not, it would refer the matter back to the institution for reconsideration.

It is also important to note that the "Big 8" universities in Australia have begun to design a process to act on appeals among themselves. That is, they would create a cadre of experts that could be called upon in cases where an allegation of misconduct requires the Vice Chancellor to go outside their own institution. Such a cadre could also handle "appeals".

Another drawback is that while the Code calls for the handling of allegations within the context of the Enterprise Agreements, "research misconduct" is a different category of employee misbehaviour because of the fact that it involves or affects people outside of the institution. Allegations and their resolution can therefore be technically very complicated.

B.6.4 Conclusions

There appears to be broad consensus that the basic principles and approaches of the Code are good. The emphasis on creating positive research environments is deemed to be the right approach as is leaving the resolution of allegations to the institutions, especially the concept that minor breaches should be dealt with internally. There is a sense that the substance of the Code should and could be reviewed in a year or two, once more evidence related to the success or failure of its implementation is available.

More significant is the general agreement among those interviewed that there is a need for some form of central or national body, although there is no consensus yet as to the type. Several considerations in establishing such a body were however, put forth. It should:

- not be an investigative body, (this should be left to the institutions);
- provide oversight of the national system;
- provide advice and assistance to institutions;
- collect data on Breaches and Research Misconduct,
- act as the appeals body,
- act as the international link for Australia to the systems of other countries (research is a global enterprise); and
- act in cases where there may be an institutional conflict of interest.

B.7 Japan

Research Integrity System Attributes - Highlights	
RI System:	Type 3
National Policy / Code:	No
Reach:	Non-government research organizations / government research
National Research Integrity Body:	No
Investigation Authority:	Home institution
Enforcement/Sanctions:	Granting councils

B.7.1 Overview

In recent years Japan has undertaken a number of initiatives to develop policies, codes of conduct, and guidelines on research integrity and misconduct. The main impetus, as in many other countries, was a number of high-profile cases. Slingsby, Kodama and Akabayashi[136] cite three high-profile cases: publication of falsified data by two researchers at RIKEN in 2004, *Nature Medicine* withdrew an article by two professors from the National Institute of Genetics who relied on data fabricated by a medical student in 2005. The Graduate School of Engineering, University of Tokyo reported in September 2005 that data published in a series of twelve articles between 1998 and 2004 in *Nature* and other journals could not be scientifically confirmed.

A review by Ryozo Tanaka, Senior Science and Innovation Officer at the British Embassy in Tokyo, noted that following these high-profile cases in Japan and other countries, the Council of Science and Technology Policy (CSTP) approved in February 2006 "Proper Counteractions against Research Misconduct". Tanaka indicates that this document requests the Japanese research community, relevant ministries, universities, research institutes and the Science Council of Japan take action against misconduct and reach conclusions by summer 2006.[137] The CSTP was established in the Cabinet Office in January 2001 as one of four policy councils on key policy fields. The CSTP is the "command center for Japan's integrated efforts to advance science and technology (S&T) in a comprehensive and well-planned manner."[138]

Later in 2006, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) published a *White Paper on Science and Technology*[139] to promote good research practice and to prevent misconduct. According to its web site[140], the MEXT Science and Technology Policy Bureau is responsible for the planning and drafting of basic science and technology policies. The Bureau is also responsible for the formulation of research programs and promotion of research

[136] Brian Taylor Slingsby, Satoshi Kodama, and Akira Akabayashi, "Scientific Misconduct in Japan: The Present Paucity of Oversight Policy", in *Cambridge Quarterly of Healthcare Ethics* (2006), 15, 294-297.
[137] Ryozo Tanaka, "Recent Counteractions against Misconduct in Research in Japan", July 2006 is available at https://ukinjapan-stage.fco.gov.uk/resources/en/pdf/5606907/5607742/36657X.pdf
[138] Source CSTP web site http://www8.cao.go.jp/cstp/english/index.html
[139] MEXT's White Paper is available at http://www.mext.go.jp/english/news/2007/03/07022214.htm
[140] Ministry of Education, Culture, Sports, Science and Technology (MEXT) web site http://www.mext.go.jp/english/

evaluation, training of researchers and technicians, regional science and technology promotion, increasing the understanding of science and technology, the promotion of a comprehensive policy on international research exchange, and duties related to safety systems for experimental nuclear reactors and radioactive isotopes.

Another organization concerned with research integrity and misconduct is the Japan Society for the Promotion of Science (JSPS). According to its web site[141], the JSPS is an "independent administrative institution" under the MEXT. Independent administrative institutions are given 3-5 year mandates by the government. In the case of JSPS, its current mandate is to advance scientific research in Japan by providing research grants, fostering young researchers, promoting international scientific cooperation, supporting scientific cooperation between the academic community and industry, and collecting and distributing information on scientific research activities. According to Slingsby, Kodama and Akabayashi, in September 2005, the JSPS discovered that a professor at Nagoya University had fabricated his curriculum vitae by claiming three articles to be in press despite having not yet submitted any one of them to an academic journal.[142]

Prior to the high-profile cases and CSTP's document in 2006, the Science Council of Japan, established in January 1949 as a "special organization" under the jurisdiction of the Prime Minister for the purpose of promoting and enhancing the field of science, and having science reflected in and permeated into administration, industries and people's lives, had spearheaded a number of research integrity and misconduct initiatives[143]. According to Slingsby, Kodama and Akabayashi, in 2003, the SCJ adopted the classification of research misconduct used by the United States Office of Research Integrity, that is *any intentional act of fabrication, falsification or plagiarism (FFP).* Two years later, in May 2005, the Science Council of Japan published *Scientific Misconduct and its Prevention*[144], and a year later in 2006 it issued a *Statement: Code of Conduct for Scientists*.[145]

Introduction to System

Beginning in April 2004, Japan's 89 national universities and four university collaborative research institutions, according to Slingsby, Kodama and Akabayashi[146], became independent administrative institutions (IAIs), which provided greater independence and autonomy to universities. Slingsby, Kodama and Akabayashi argue that the increase in allegations of misconduct among Japanese scientists may be related to a concurrent rise in competition for academic appointments and scientific funding brought about by becoming an IAI.

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[141] Japan Society for the Promotion of Science (JSPS) web site http://www.jsps.go.jp/english/
[142] Slingsby, Kodama and Akabayashi, *op. cit*., p. 295.
[143] Science Council of Japan web site http://www.scj.go.jp/en/
[144] Science Council of Japan, *Scientific Misconduct and its Prevention*, May 2005 is available at http://www.scj.go.jp/ja/print/pdf/taigai_reefe.pdf
[145] Science Council of Japan, Statement: Code of Conduct for Scientists, October 2006 is available at http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-s3e-1.pdf
[146] Brian Taylor Slingsby, Satoshi Kodama, and Akira Akabayashi, "Scientific Misconduct in Japan: The Present Paucity of Oversight Policy", in *Cambridge Quarterly of Healthcare Ethics* (2006), 15, 294-297.

According to a survey commissioned by MEXT in 2004, about three-quarters of Japan's research institutions registered with the Science Council of Japan had no research integrity policies and guidelines, nor had any allegations of misconduct been investigated. Thus, the intention of Japan's two main policy documents dealing with research integrity (i.e., *Scientific Misconduct and its Prevention* and *Statement: Code of Conduct for Scientists*, both published by the Science Council of Japan) is to encourage individual research institutes/universities to develop and implement their own research integrity system. As noted by the Science Council of Japan's (SCJ) *Statement: Code of Conduct for Scientists*:

> The Science Council of Japan herewith requests that each university, college, research institution, academic association and funding agency independently implements a specific program on research ethics (i.e. formulates and applies a code of ethics and a code of conduct) at the earliest possible date. The objectives of this request are to promote the well-balanced development of science with the help of the independent scientific community, and to promote the independent and honest conduct of scientists in light of the aims and needs of their respective organizations.[147]

Japan's research integrity system, as we describe below, is intertwined with research ethics.

B.7.2 System Attributes

Definition

The Science Council of Japan and the MEXT define research misconduct as the fabrication, falsification and plagiarism of data or research results[148]. Funding agencies and individual research institutes are free to adopt their own definition of research misconduct most, however, adopt the definitions and guidelines outlined by MEXT.

[147] Science Council of Japan, *Scientific Misconduct and its Prevention*, May 2005, p. 7.
[148] Japan's definition of misconduct is outlined in Science Council of Japan, *Scientific Misconduct and its Prevention*, May 2005, and in a MEXT presentation, "Ensuring Science Integrity and Preventing Misconduct: Japan's Challenge, Tokyo, Japan, February 22, 2007.

Administration of Policies

The administration of policies on research integrity and misconduct, as in other countries, rests with individual research institutions. As noted by the SCJ's *Statement: Code of Conduct for Scientists*, those responsible for the management of the organization should lead the program on research ethics and lay down necessary measures to be taken in the even of scientific misconduct. Each organization should arrange for their own system of response to research ethics.[149]

Prevention and Training

Education and training initiatives aimed at preventing misconduct are also the responsibility of individual research institutes. As noted by SCJ's Statement, the code of conduct essential to research activities, such as the prohibition of misconduct and the recording, storage and rigorous handling of research data, as well as research ethics that properly maintain the relationship between research activities and society, should be continuously imparted to members through education, training and information activities.[150]

Inquiry and Investigation Procedures

Again, responsibility for inquiring and investigating allegations of misconduct rests with the individual research institutions. As noted by SCJ's Statement:

> To deal with possible misconduct such as fabrication, falsification or plagiarism, the following measures should be taken at the earliest possible date:
>
> 1. A proper channel should be set up for consultation on suspected misconduct. At the same time, particular attention should be paid to the importance of ascertaining whether the suspicion is false.
>
> 2. All due consideration should be made to ensure that anyone reporting misconduct should not suffer disadvantage as a result thereof.
>
> 3. When there is suspicion of misconduct, relevant facts should be promptly investigated in accordance with due procedures, necessary measures should be taken with impartiality, and the result should be made public. Particularly strict measures should be taken in the case of fabrication, falsification or plagiarism.[151]

[149] Science Council of Japan, *Scientific Misconduct and its Prevention*, May 2005, p. 7.
[150] *Ibid*.
[151] *Ibid*. p. 8.

Enforcement and Sanctions

The enforcement and application of sanctions rests with individual research institutes and academic societies. The type of sanction depends on the seriousness of the misconduct, including dismissal. Depending on the agreement, funding institutions can also impose sanctions against researchers found guilty of misconduct. They include:

- termination of competitive funding,
- rejection of applications for competitive funds,
- return of competitive funds related to misconduct, and
- restrictions on applications for competitive funds.

Reporting / Communications and Transparency

The general view is that the number of cases of research misconduct, particularly FFP, is extremely low or rare. The reason put forward is because Japanese researchers maintain high ethical standards. However, it should be noted that there is no central repository in Japan where cases of misconduct can be filed, nor is there any obligation by individual research institutions to report cases of misconduct.

B.7.3 Strengths and Weaknesses

The strengths of Japan's research integrity system is that it respects academic freedom and self-governance. It would appear that Japan is currently trying to develop a consistent set of policies, guidelines and codes of practice.

Japan's strength in respecting academic freedom is also however, a weakness as institutions are not obliged to report cases of misconduct. There is some discussion on whether allegations of misconduct should be investigated by an independent third party. As well, relatively little effort has been given to the promotion of good research practices and the prevention of misconduct. These issues are being examined by MEXT and other organizations (e.g., JSPS) concerned with research integrity.

B.7.4 Conclusions

Japan's research integrity system is evolving. Japan, as indicated by a MEXT presentation is working on the following issues: the roles and responsibilities of government and individual research institutions (IAIs), the kind of sanctions that would be appropriate for the severity of misconduct, and what measures should be taken to promote good research practice (or to prevent misconduct from occurring).[152]

[152] See MEXT presentation, "Ensuring Science Integrity and Preventing Misconduct: Japan's Challenge, Tokyo, Japan, February 22, 2007.

B.8 France

Research Integrity System Attributes - Highlights	
RI System:	Type 3 - Developing
National Policy / Code:	None
Reach:	Publicly funded scientists
National Research Integrity Body:	No
Investigation Authority:	Commission administrative paritaire (CAP)
Enforcement/Sanctions:	Management

B.8.1 Overview

France currently has no formal research integrity system. In the words of one commentator in a recent newspaper article: "the whole [research integrity] system is to be built [in France], allowing for the submission of complaints, then investigations, and possible sanctions".[153] Moreover, very few allegations of research misconduct have been proven.[154] Recently, however, two prominent French research institutions have taken steps towards to address this deficit. The Centre national de la recherche scientifique (CNRS), which is responsible for a quarter of French public spending on civilian research, has been charged with developing a national policy[155], while the Institute national de la santé et de la recherche médicale (INSERM), which accounts for approximately 40% of public research expenditures in the health sector, has been asked to develop national prevention and training initiatives related for bringing awareness to research integrity. These initiatives coincide with a nation-wide review of France's research system, which according to a recent report, is fragmented and "seriously compromises the efficient and effective use of precious research resources."[156]

Though France has yet to develop a system, there are some, in the words of one observer, "embryonic" research integrity policies. The CNRS has published on its website a short document authored entitled "Scientific Fraud at the CNRS" which covers the role of an investigating committee, and outlines a procedure for treating allegations as well as options for management when receiving advice from such a committee. The document states that any disciplinary action would need to be in accordance with rules pertaining to the status of civil employees, and relevant labour law.[157]

[153] From newspaper article from interview with Jean-Pierre Alix, CNRS: Le Monde, "La France s'attaque à la fraude scientifique", July 2, 2008, Paul Le Hir.
[154] Interview.
[155] In 2008, the Ministry of Higher Education and Research mandated the CNRS to investigate opportunities to strengthen France's RI system.
[156] See assessment of INSERM by international visiting committee: http://www.inserm.fr/en/inserm/documents_strategiques/att00003127/aeres_en.pdf
[157] See www.cnrs.fr/fr/organisme/ethique/comets/docs/fraude_scientifique.pdf

Also, the Institut de recherche pour le devéloppement created in 2000 a Consultative Committee on Professional Conduct and Ethics whose mission is "to contribute to the implementation and development of deontological rules specific to the research and works of all kinds undertaken within the context of the establishment, as well as to the formulation and taking into account of questions of an ethical nature that are associated with the said objectives." And though no specific reference is made to research integrity and misconduct, the organization has published a guide on good practices for research for international development in three categories: "Drawing up a project", "Implementation of a research [project]", and "Programme follow-up and development". The Committee can raise, or receive, matters that are brought forward by members or personnel for a determination.

In principle, allegations of research integrity can be addressed through an existing system of employee dispute settlement boards. These boards are called *Commissions administrative paritaire* (CAPs) and there is one for each organization, region or *corps* (i.e. human resource classification, such as university professor). CNRS and INSERM, for example, each have a CAP. These bodies are constituted by law[158] and have memberships representing both management and unions/staff. Given that most researchers that receive public funds are covered by CAP, including university staff, this system covers much of France's public research. For civil servant scientists, which include scientists employed at universities, Grandes écoles, or Ecoles supérieures normales, there are additional rules embedded in their terms and conditions of employment. In the work now underway to develop a national policy, it is expected that CAPS will play integral role in any new system.

B.8.2 System Attributes

The CAP Process

In cases of suspected fraud for a public servant, a preliminary investigation is conducted by experts indentified by the management of the scientist concerned. If the allegation appears founded, the matter is referred to an appropriate *Commission administrative paritaire* (CAP). After an investigation, the conclusions from a CAP investigation are submitted to management, normally to the Director General concerned. The DG has the authority to apply sanctions, including termination of employment.

Definition

N/A

Enforcement and Sanctions

The DG has the authority to apply sanctions, including termination of employment. There are no additional checks and balances, beyond recourse to the justice system.

[158] See "*Décret n°82-451 du 28 mai 1982* relatif aux commissions administratives paritaires (fonction publique de l'Etat)

Reporting / Communications and Transparency

There is no monitoring or reporting process among the various CAPs for incidents of alleged or actual misconduct.

Whistleblower protection

There is no whistleblower protection legislation in France. There are, however, various pieces of legislation that may be relevant to specific allegations of misconduct, such as legislation pertaining to the CAPs.

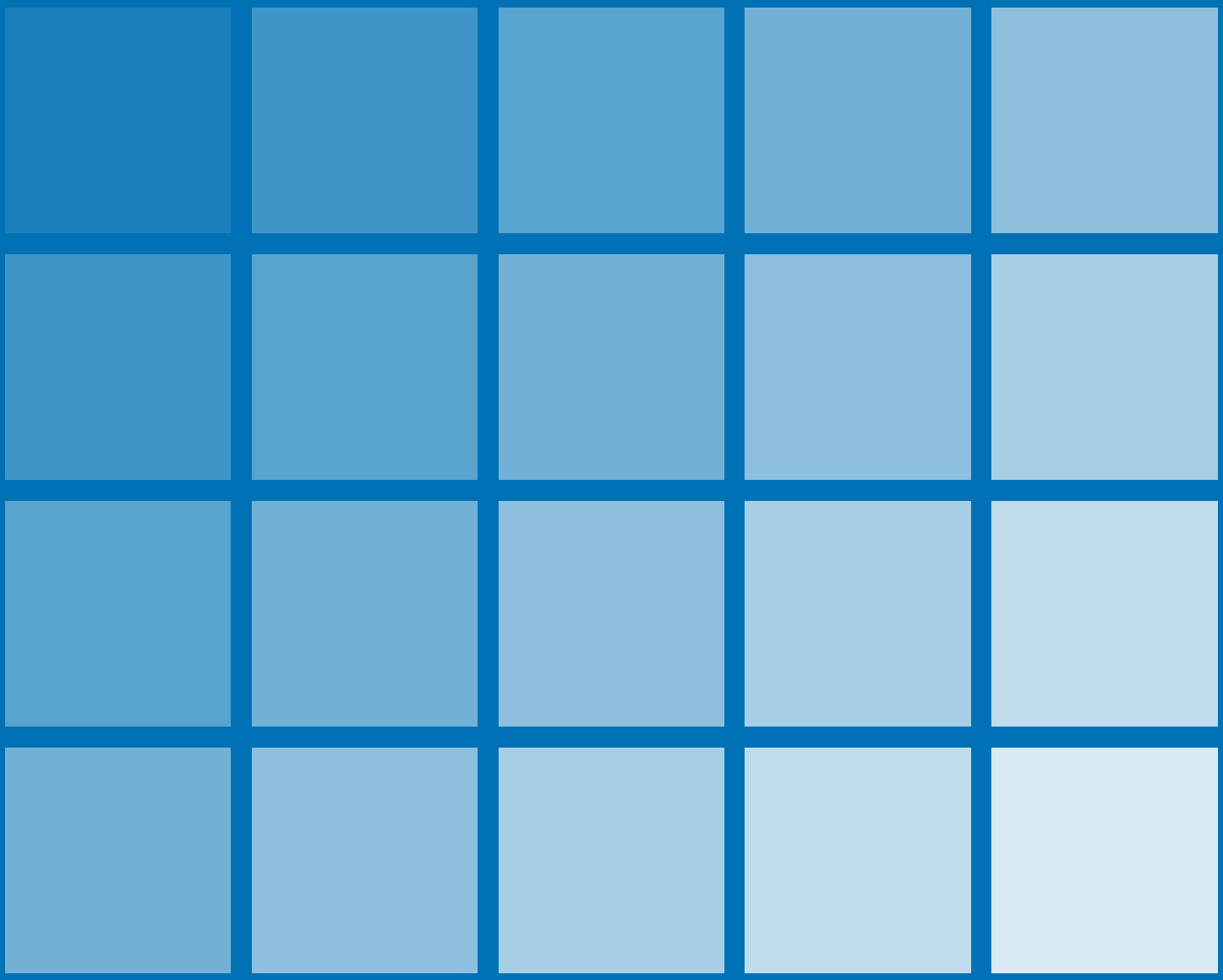
B.8.3 Strengths and Weakness

France ultimately relies on the integrity of its scientists, which is reportedly maintained by a rigorous recruitment process for public scientist, and a CAP legislation to deal with research integrity. Yet as one high profile case revealed, this is not enough. The case of the obesity researcher, which was revealed in a 1998 *Nature* article, received wide spread criticism in regard to various investigations and outcomes and highlighted the lack of a formal process or consensus around what constituted research misconduct.[159] Moreover there is no monitoring or reporting process among the various CAPs for incidents of alleged or actual misconduct.

B.8.4 Conclusions

France has yet to develop a research integrity system for dealing with related allegations. However, as has been noted, efforts are underway to address this. Though it is too early to determine what type of system will prevail, it is likely to incorporate the CAP system and be national in scope.

[159] See *Nature*, "French ministry reopens inquiry into conduct of INSERM unit" 391, 519-520, 5 Feb 1998; Nature, "French Inquiry Into Misconduct is Shelved", 395, 29 Oct 1998, p829; Nature, Accused obesity researcher returns to the French fold, 418, 1 Aug 2002Nature 395, 29 Oct 1998,829



Hickling Arthurs Low Corporation

150 Isabella Street
Suite 1300
Ottawa, ON
K1S 1V7

Phone: 613.237.2220
Fax: 613.237.7347
Email: hal@hal.ca