# Canadian Journal of Bioethics Revue canadienne de bioéthique



# Central Management of Research Misconduct in the USA and Canada

Jonathan J. Shuster

Volume 7, numéro 4, 2024

URI: https://id.erudit.org/iderudit/1114970ar DOI: https://doi.org/10.7202/1114970ar

Aller au sommaire du numéro

Éditeur(s)

Programmes de bioéthique, École de santé publique de l'Université de Montréal

**ISSN** 

2561-4665 (numérique)

Découvrir la revue

#### Citer ce document

Shuster, J. J. (2024). Central Management of Research Misconduct in the USA and Canada. *Canadian Journal of Bioethics / Revue canadienne de bioéthique*, 7(4), 131–137. https://doi.org/10.7202/1114970ar

#### Résumé de l'article

Cet article propose des changements majeurs dans la façon dont les cas d'inconduite en matière de recherche devraient être gérés aux États-Unis et au Canada. Plus précisément, je plaide en faveur d'une surveillance centralisée qui retire complètement ce rôle aux institutions de recherche afin d'atténuer les conflits d'intérêts institutionnels, de normaliser les définitions de l'inconduite en matière de recherche, de mieux préserver la confidentialité des plaignants (ceux qui allèguent une inconduite), de s'assurer que les cas ne sont pas sélectionnés pour être rejetés, de mobiliser un comité d'examen composé d'experts exempts de conflits d'intérêts, d'éviter une punition collective inappropriée des institutions et, en fin de compte, d'économiser des ressources par rapport aux systèmes décentralisés actuels. Des détails sur la manière dont les affaires pourraient être portées devant la justice sont proposés. Deux cas dans lesquels cet auteur, en tant que plaignant, a allégué une faute de recherche (aux États-Unis et au Canada) montrent clairement jusqu'où les responsables de l'intégrité de la recherche des institutions peuvent aller pour empêcher une évaluation impartiale par des experts. Étant donné que nos institutions et la communauté scientifique ont, à juste titre, une tolérance zéro à l'égard de l'inconduite en matière de recherche, la pratique décentralisée actuelle devrait être une source de grave préoccupation pour ceux qui espèrent avoir confiance en une surveillance adéquate. Une discussion s'ensuit, comprenant des commentaires sur les nouvelles directives pour 2025 de l'Office of Research Integrity des États-Unis et les implications des cas très médiatisés. Je conclus en donnant des détails sur la facon dont les cas pourraient être portés devant la justice dans le cadre du processus centralisé proposé.

© Jonathan J. Shuster, 2024



Ce document est protégé par la loi sur le droit d'auteur. L'utilisation des services d'Érudit (y compris la reproduction) est assujettie à sa politique d'utilisation que vous pouvez consulter en ligne.

https://apropos.erudit.org/fr/usagers/politique-dutilisation/



## Cet article est diffusé et préservé par Érudit.



**TÉMOIGNAGE / PERSPECTIVE** 

# Central Management of Research Misconduct in the USA and Canada

Jonathan J. Shustera

#### Résumé

Cet article propose des changements majeurs dans la façon dont les cas d'inconduite en matière de recherche devraient être gérés aux États-Unis et au Canada. Plus précisément, je plaide en faveur d'une surveillance centralisée qui retire complètement ce rôle aux institutions de recherche afin d'atténuer les conflits d'intérêts institutionnels, de normaliser les définitions de research misconduct, better preserve confidentiality of l'inconduite en matière de recherche, de mieux préserver la confidentialité des plaignants (ceux qui allèguent une inconduite), de s'assurer que les cas ne sont pas sélectionnés pour être rejetés, de mobiliser un comité d'examen composé d'experts exempts de conflits d'intérêts, d'éviter une punition collective inappropriée des institutions et, en fin de compte, d'économiser des ressources par rapport aux systèmes décentralisés actuels. Des détails sur la manière dont les affaires pourraient être portées devant la justice sont proposés. Deux cas dans lesquels cet auteur, en tant que plaignant, a allégué une faute de recherche (aux États-Unis et au Canada) montrent clairement jusqu'où les responsables de l'intégrité de la recherche des institutions peuvent aller pour empêcher une évaluation impartiale par des experts. Étant donné que nos institutions et la communauté scientifique ont, à juste titre, une tolérance zéro à l'égard de l'inconduite en matière de recherche, la pratique décentralisée actuelle devrait être une source de grave préoccupation pour ceux qui espèrent avoir confiance en une surveillance adéquate. Une discussion s'ensuit, comprenant des commentaires sur les nouvelles directives pour 2025 de l'Office of Research Integrity des États-Unis et les implications des cas très médiatisés. Je conclus en donnant des détails sur la façon dont les cas pourraient être portés devant la justice dans le cadre du processus centralisé proposé.

plaignant, conflit d'intérêt, surveillance de l'inconduite en complainant, recherche, agent d'intégrité en recherche, répondant

#### **Abstract**

This paper proposes major changes in how research misconduct cases should be managed in the USA and Canada. Specifically, I advocate for centralized oversight that completely removes research institutions from this role in order to: mitigate institutional conflicts of interest, standardize definitions of complainants (those alleging misconduct), ensure that cases are not screened for rejection, mobilize a review panel of experts who are free of conflicts of interest, avoid inappropriate collective punishment of institutions, and ultimately save resources as compared to current decentralized systems. Two cases which this author, as complainant, alleged research misconduct (in the USA and Canada) demonstrate clearly how far institutional Research Integrity Officers can go to prevent an impartial expert review. Given that our institutions and scientific community rightly have zero tolerance for research misconduct, the current decentralized practice should be a grave concern to those who hope to trust in proper oversight. A discussion follows, including comments on new directives for 2025 from the US Office of Research Integrity and the implications of highprofile cases. I conclude with details as to how cases might be brought to justice under the proposed centralized process.

#### Keywords

conflict-of-interest. oversight misconduct, research integrity officer, respondent

<sup>a</sup> Department of Health Outcomes and Bioinformatics, College of Medicine, University of Florida, Florida, USA Correspondance / Correspondence: Jonathan J. Shuster, Shusterj@ufl.edu

#### INTRODUCTION

Many people would agree that the current methods of managing research misconduct cases at American and Canadian universities leave much to be desired. There are five key issues that I will address here: 1) There is zero tolerance for mismanagement; 2) The current systems, which rely heavily on university Research Integrity Officers (RIOs) have substantial potential for conflict-of-interest; 3) The current systems create excessive administrative costs for universities but are under resourced for the central governing bodies; 4) Complainants logically fear retaliation and premature release of their identities to defendants (respondents); and 5) The current systems can inadvertently apply collective punishment to universities rather than target the parties responsible for misconduct. Although a good proposal was made by Garfinkel and colleagues (1) as to how research misconduct cases might interface between institutions and journals, I argue for central management that eliminates direct university involvement in the adjudication process. Specifically, I propose new systems that can overcome the five issues raised above, make the administration more equitable, improve the efficient use of resources available for complainants and federal governing bodies, and lessen the burden on American and Canadian universities.

Before launching into this analysis, and to help clarify the current problems, I summarize two cases in which I have been personally involved, where universities seem to have mishandled the allegations of research misconduct. In each case, conflicts of interest on the part of the university RIOs appear to have been the major contributing factor. It should be noted that although strong arguments can be made that research misconduct occurred, I object here only to the fact that these cases were screened by the RIOs for rejection without going to an impartial hearing before a committee of experts in the scientific

disciplines involved. Since there was no such process, respondents never received their due process; the guilt or innocence of two respondents are beside the point. We need to ask if the two universities' methods of handling research misconduct cases were fair to the complainant. If they were not, and since other universities apply similar methods, this is a serious indictment as to how universities manage research misconduct in the USA and Canada. Following the presentation of these two cases, I then propose a process for how misconduct cases might be better administered. I conclude with a discussion as to how these recommendations might play a positive role in conflict resolution, while at the same time taking advantage of the economy of scale and superior resources to collectively study the scope and impact of research misconduct.

#### RESEARCH MISCONDUCT CASES THAT WERE SCREENED FOR REJECTION

I filed two cases of research misconduct, one in the USA and one in Canada, and although as the complainant in each case I believe that misconduct by the respondent (defendant) did occur, the sole interest here is the question as to whether the oversight was biased on the part of the university. I am not naming the universities nor the people involved, but the editor of this journal has seen all of the supporting material.

# Case 1: USA (filed 2024)

As a whistle blower, I filed a research misconduct case with the university against a senior faculty member after discovering potentially dangerous activities conducted in their outside employment. The case centered on three things. There were two articles of research misconduct, both involving allegations of public health dangers involving the respondent's extramural activities. To properly adjudicate the case, experts were needed in at least two research areas. The third article of misconduct was more straight forward. To conduct outside employment, every faculty or staff member at this university requires annual permission. Failure to meet this requirement is listed on the university's website as a research integrity violation. The respondent filed initial paperwork, but according to the university's public records was 15 months delinquent on refiling. In addition, the first filing did not provide sufficient detail as to what the faculty member would be doing. This requirement obliges the university to monitor professors' outside duties as they change over time, or if the previously acceptable activities of the faculty member become ethically problematic. Also, according to university public records, the US Office of Research Integrity (ORI) was not notified per Paragraph 9 of Section 93.318 and 93.223 below of ORI regulations.<sup>1</sup>

§ 93.318 Notifying ORI of special circumstances	§ 93.223 Research misconduct proceeding
At any time during a research misconduct proceeding, as defined in §93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:  (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.	alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals

In short, the RIO, to protect the Respondent, gave an erroneous reason to dismiss the case and failed to comply with a key responsibility to protect the public from harm caused by the alleged misconduct. The RIO did not refute any elements of the case. Arguably, the RIO falsified data (a synonym for information) on the claim of lack of standing on the case, and therefore the RIO is alleged to have committed two research misconduct occurrences. Table 1 gives a chronology of correspondence on the case, including rejecting it on the first working day after it was filed. Note the lack of transparency of the RIO policies toward all complainants.

Table 1: Chronology of key correspondence in the US Case

Day#	Sender	Recipient	Crux of Content
0 (Fri)	Complainant	RIO	Case e-mailed
3 (Mon)	RIO	File	Case dismissed on first working day after filing case     Complainant found out on day 35 following a public records request
6	VP Research	RIO	<ul> <li>Supports RIO action as case dismissed but acknowledges possibility of danger to public health.</li> <li>Found out on day 146 following a public records request</li> </ul>
24	Complainant	RIO	Request for follow-up
24	RIO	Complainant	Claimed that matters are confidential, and RIO is unable to provide additional information or updates
24	Complainant	RIO	Requested report when final
24	RIO	Complainant	"In accordance with university policy, RIO is unable to share updates with you, including case resolution."     No avenue of appeal

<sup>&</sup>lt;sup>1</sup> I filed a research misconduct case against the respondent and the university RIO with the US Office of Research Integrity, but it declined on the grounds that the respondent's outside employment did not involve Public Health Service (PHS) funding.

# Case 2: Canada - filed with university 3 times: 2019, 2021, 2024

#### 2019 Filing

With a co-author, I wrote an article that was e-published (prior to final publication) in a leading medical journal in 2019. One of the journal editors not involved with the paper invited another researcher (the respondent in this case) to write a letter to the editor that would require peer review before being accepted for publication. Just two days later, after a flurry of communication inviting cosigners, the letter was submitted to the journal. The lead author of the letter, which was explicitly critical of our methods, had no background in two key disciplinary areas pertinent to our paper. Before this critique was circulated unedited to the vast majority of my professional circle, it should have been first submitted to the journal for peer review to test the merit of its arguments.

In the case, I alleged that the authors of the letter falsely accused us of misconduct (due to misunderstanding of a basic tenet in one of the key disciplines and lack of evidence for an unmanaged financial conflict of interest), and that they violated the university's prohibition of accusations not made in good faith. Despite the letter being rejected for lack of scientific merit by the journal editors, our e-publication was also withdrawn by the journal. We subsequently published a scientifically identical paper in another journal.

I issued a demand to the respondent (the lead author of the letter), with a four-week deadline, asking them to write to the cosignatories of the letter (a large number, but still a small fraction of those exposed to the draft letter to the editor) to state that the two accusatory statements were false. Copies were required to be sent to me and my co-author, and the journal editor. No such acknowledgement was made.

#### **RIO Oversight**

Despite lack of expertise in any of the subject areas and with no evidence they had consulted with experts, the RIO screened the case for rejection. The RIO report committed serious deception, calling my demand letter a request for circulation of a rebuttal to the entire respondent letter to the editor. This let them call my demand a matter of opinion. In fact, it was laser focused on two allegations made against me and my co-author. Another deception that appears to be intentional was to first quote the Tri-Agency (granting agency) definitions of Research Misconduct, and then falsely say that these aligned with the definitions on the university's website. I supplied a link to the university's criteria and cited the clause number for the prohibition of bad faith accusations. The Tri-Agency criteria (at least at the time) conveniently do not specify this. Thirdly, the RIO deceptively and falsely stated that me and my co-author acknowledged a conflict-of-interest as an attempt to discredit my argument; we did not. The RIO committed an additional misjudgment when they failed to pick up the prominent confession of the respondent in their rebuttal to my charges. The respondent admitted that they had no evidence that we had a conflict-of-interest but instead alleged a perception of conflict-of-interest. The RIO stated that their review was final, with no avenue of appeal. I nonetheless sent them a rebuttal of factual errors made in the RIO report, and I was thanked for thoughtful input, but no changes were made. At this time, the RIO was guilty of falsification, by failing to correct the report and circulating the revision to the respondent and complainant.

#### 2021 Filing – The alleged conspiracy begins

After learning in the fall of 2020 that the RIO on the 2019 case was being replaced by a new RIO, I immediately wrote the new RIO to give a heads-up on the situation. In that e-mail, I informed them that I planned to file a new case and cited the deceptions committed by the first RIO. A new case was filed against the same respondent in early 2021 with the new RIO, who had two important conflicts of interest. They were 1) the new RIO was a signee of the original letter and 2) the new RIO was a close professional colleague of the respondent. The new case provided the details of the deceptions of the first RIO and requested that they be disqualified from the case. Despite this, the new RIO assigned the case to the previous RIO, who as expected, stated that this was the same case and once again screened it for rejection.

There were two major differences between the 2019 and 2021 cases. First, the respondent as part of their 2019 rebuttal claimed that no accusations were made. This led me to solicit feedback from five members of the University of Florida Health Center Institutional Review Board who, blinded as to context, where I asked whether the two targeted letter statements (misinterpreting a basic tenet of one of the disciplines and conflict-of-interest) constituted personal accusations of misconduct. Three of the five responded, with all asserting "yes" to both questions. Further, the argument that this was not an accusation falls apart because the letter to the editor twice called our paper offensive and it was copied to a professional association that oversees certain accusations against its members. The university prohibition makes no distinction between accusations against the person and accusations against what the person wrote. Second, the 2021 case showed in detail that the RIO committed multiple acts of deception. Intent is not relevant, as lack of knowledge in making a screening determination is as unacceptable as intentional deception.

After the new RIO screened the case for rejection, I wrote to the provost, citing ten errors that the previous RIO committed on the case. These were ignored. In legal matters in the US or Canada, if either side of a case cites judicial misconduct, a retrial requires a new judge. Further, I have repeatedly asked the second RIO why the first RIO was assigned. No response has been received, but I believe the answer lies with a major Canadian Government multi-year grant that was about to be awarded to the respondent. A finding of a research integrity violation, let alone research misconduct, would have made the respondent ineligible.

## 2024 Filing – The alleged conspiracy continues

In the Fall of 2023, I learned of the death of the senior journal editor who edited our withdrawn paper. He strongly opposed the withdrawal of our paper which caused lasting discord with the journal. In my view, the respondent caused collateral damage to this colleague, and that motivated me to reopen the case. I first tried to go through the university president's office, but despite good efforts by an assistant to the president, that proved impossible. I then followed the university's management process and submitted directly to the Associate RIO office. I added the first RIO as a second respondent due to their mishandling of the first two filings.

In addition, through public records request, I noted that the first RIO had committed two further errors: 1) they failed to correct factual errors in their report, and although the university does not classify this as research misconduct, other authors do (3); 2) the first RIO had an obvious conflict-of-interest. Had they referred the case to an unconflicted committee of experts, it would have been a major embarrassment as their mishandling of the 2019 case would have been evident. According to university public records, no conflict-of-interest declaration was filed. The deception by the first RIO in the 2019 filing amounts to falsification of information and is therefore a university defined allegation of research misconduct. In my filing, I alleged that the new RIO was an accomplice, but had I known about the respondent's grant at the time, I would have listed them as another respondent. This new RIO protected the respondent and the grant by giving the case to the old RIO, a serious breach of the university's conflict-of-interest policies. It also amounts to mishandling of federal grant funding, as the new RIO (close personal contact of the original respondent) had to know that the original respondent either was awarded or about to be awarded the federal grant.

Finally, the handling of the 2024 case violated the University's own rules. According to the university's public records, an Associate RIO wrote to the new RIO saying they were ignoring the case. All research misconduct cases must go through a RIO review, and if indicated, receive further scrutiny. But in all cases, the complainant and respondent must be provided a timely written report of the decision, and with reasons. That report has not been issued and is several months delinquent. I am convinced that to protect the initial respondent, there is a conspiracy of two RIOs, two Associate RIOs, and the university provost.

In June 2024, after three failed university filings asking for an impartial committee of experts to review the case, I filed a case with the Canadian Government. After their internal preliminary discussion, a senior investigator has been assigned to look into the allegations.

#### RECOMMENDATIONS FOR HOW RESEARCH MISCONDUCT MIGHT BE ADMINISTERED

To eliminate the potential for conflict-of-interest in the management of misconduct allegations, the US Office of Research Integrity (ORI) and/or the National Research Council of Canada (NRC) (Central Governing Bodies) should conduct the investigation. There should be no involvement in the process from the universities of the complainant or respondent. Other US funding agencies, such as the National Science Foundation, should fold their misconduct oversight activities into the ORI. Key suggested elements are as follows:

- Funding: Each American and Canadian University that receives funding from their central government will pay a tax
  to its central governing body for administration of a central adjudication system to administer all misconduct cases,
  including those where no federal funding is involved.
- Training: Each country will set up mandatory training requirements in the responsible conduct of research, including on research misconduct. The USA has CITI training, which is an excellent start.
- In each country, universal rules defining misconduct should be established by collaboration between the central governing authorities and the public. An excellent start is the British Medical Journal definitions (2). There are four elements, only partially referred to in these guidelines, that expressly need to be included: 1) Failure to correct known errors in publications and reports (3); 2) Failure to properly disclose conflicts of interest; 3) Being funded for outside employment in violation of institutional policies; and 4) Acts of sabotage of research conducted against research personnel, staff, or research subjects including animals. Note that authority for actions should extend to individuals outside of the institution.

#### How research misconduct cases might be centrally administered in each country

Direct filing of research misconduct allegations by any person with the central governing body. This would be their decision alone. Officials hired as advisors within the central government would be available to the complainant but would have no authority to block submission. Three working groups within each central governing authority should be assigned to the cases according to whether human subjects, animal subjects, or neither are involved.

- A preliminary review by the central governing body and complainant will occur, but the complainant has the final say as to whether this goes to trial. At this stage, there is no involvement of the respondent.
- Should research misconduct be confirmed by trial, the central governing body will impose appropriate penalties
  against the respondent. No collateral penalties should be applied to any member of the research community or the
  university administration unless they were directly involved in the misconduct.
- The respondent or complainant may appeal the decision and request a new trial, and the validity of the petition would be judged by different individuals within the central government. If this appeal process is approved, a new unappealable trial would be conducted with no overlap in judges with the initial case.

# How the adjudication process might work

- The central governing body assigns a chief justice from within its ranks. Three unconflicted associate justices (i.e., researchers), with expertise in the subject areas are selected from universities other than those directly involved. Their identities are not revealed, and they must sign confidentiality statements.
- The trial might proceed as follows: Stage 1, Written arguments. The complainant files written arguments of misconduct against the respondent with the chief justice. Within six weeks, the respondent files defense arguments against the charges with the chief justice. Within four weeks, the complainant files a rebuttal to the defense with the chief justice. Within four weeks, the respondent files a response to the rebuttal with the chief justice. After completion of written arguments, the justices convene to deliberate and rule on the case. If by preponderance of evidence, three or more justices rule for either side, the case is complete with the verdict going to the majority. If the judges cannot reach such a conclusion, the case moves to Stage 2, Oral arguments (conducted by video conferencing). Each side presents oral arguments (Complainant first); and this can include questions for the other side, which are answered when posed. This is followed by questions for each side by the judges, who then proceed to deliberations and a vote per Stage 1. It takes 3 votes of misconduct to produce a verdict against the respondent.
- Appeals are handled as noted above.

Note that legal fees and site visit costs where needed should be part of the adjudication process, but these are beyond the scope of this paper.

#### **DISCUSSION**

Centralized adjudication seems to be a win-win approach for research misconduct oversight. First, it would be far more cost-efficient. Although universities would be free to have research integrity offices, they would no longer have primary authority or responsibility. In fact, the need for local offices would logically not exist, with the exception of coordinating educational and awareness raising activities. Universities would be taxed to provide funding to support the central systems staff and expenses, according to a yet to be negotiated federal system in each country. No federal indirect costs would be allowable for the support of local research integrity offices.

Second, a centralized system would remove serious deficiencies in the local systems. Since many cases often involve very complex scientific issues, any screening for possible rejection by the RIO is usually beyond the knowledge level of the RIO, who must either make an uninformed decision or consult with experts, who are most likely to be members of the respondent's sphere of research. This likely prevents the identity of the complainant from remaining confidential throughout the screening process. This is a major impediment to being a complainant. The universities and their RIOs currently have an inherent structural conflict-of-interest in favour of sweeping allegations of misconduct under the rug. The two cases that I described above, where the RIO did not follow university policy in the USA case and engaged in serious deception in the Canadian case, are prime examples of institutional failure in good governance. There is rightly zero tolerance for research misconduct, and so too there must be for improper handling of misconduct cases. The screening that occurred in the two examples I presented would not have occurred under central management.

A universal set of rules as to what constitutes research misconduct should be established in each country (and I recommend the countries use the same rules). It seems logical that what constitutes misconduct at University A be considered misconduct at University B. Methods for adjudicating misconduct should also the same for all universities within each country. Notably, cases of misconduct must be guaranteed to be "leak proof" where no member of the university community can be informed of the identity of the complainant before it goes to adjudication by a committee of experts. The judges involved in the adjudication process must be guaranteed to be free of conflict-of-interest. Not only that, but the expertise would also likely be at a higher level than local adjudication, as the central system can draw upon the national set of experts, not just the local set. The experience of the national leadership will also be far more extensive than that of a local institution.

Science denial is a serious contemporary issue that threatens all spheres of our societies. A national system – based on national annual reports on research misconduct cases – can provide statistics on the extent of the problem of misconduct, the rate of conviction, the sanctions levied, and corrective measures implemented. Statistics by university, with appropriate denominators would also be extremely valuable when taken over time. Once well established, trends over time can be assessed. For example, in 2022, the US ORI received 269 cases (4) and 33 allegations were documented in 2023 at the National Science Foundation (5). With slightly over 1000 American Universities (153 Medical Schools) and slightly over 100 Canadian Universities (17 Medical Schools) offering degrees, the number of cases seems to be encouraging. But through personal communication with personnel at the ORI, I learned that cases not referred to ORI (either by screening or through local preliminary hearings), are not presently accounted for. With a centralized system, these statistics would be far more comprehensive.

Avoiding collective punishment is a critical objective of proper research misconduct management. First, any case with multiple respondents should be tried as a single case, as outlined above. If misconduct is not established in the hearing, the case is over, and all respondents are cleared. If the allegations are founded, the complainant or others can and should file cases against some or all the individual respondents, with at least one such case being filed. In all misconduct cases, only those judged to have individually committed misconduct should be disciplined. If a university is judged to have aided the misconduct,

only then should it face misconduct charges, tried as above. That would be the only situation where collective punishment is legitimate.

Animal Rights Issues: This is an area where both sides can benefit from the proposed impartial oversight. With a large swath of the population skeptical of science, central oversight is the best way to judge these cases, even if they are unlikely to be totally binding in a court of law (6). Further, the general population has legitimate fears in trusting that universities properly protect animal welfare (7). On the other hand, universities have been faced with acts of sabotage both inside and outside of the university communities (8). The findings of a centralized adjudication will almost certainly be admissible contributory evidence in such cases. The advocates for animal rights, who are usually not employees of the university, would be far more likely to respect these findings than those of an internal university committee.

The proposals presented here may require new legislation to fully enact. In addition, unknown to me at the time, the US ORI has put forth new administrative structures for handling cases under its jurisdiction (9). With public input now completed as of December 2023, the ORI is working on their final document, for 2025, that will replace guidelines dating to 2005. There are good things in the proposal, especially as to refining definitions and securing outcomes of cases screened or rejected by a preliminary hearing at the local institution via an "Institutional Record" that presumably will be required by ORI. But there are troubling elements as well. First, it retains local authority as the primary focal point of cases. Second, although giving lip service to the issues of conflict-of-interest and confidentiality, at least at the investigational stage, it does not remove complainants' justifiable fears of breaches of confidentiality, institutional conflicts of interest by the university, and retaliations by the respondents. Only a centralized system can guarantee protection for the complainants. Third, the Jurisdiction claimed by the document is limited to involvement by Public Health Service supported research. Even if new legislation is required, there should be one place (presumably ORI) to address all American research misconduct claims. Fourth, the proposed system creates a double jeopardy for respondents. If ORI rules in favor of the respondent, the university can still impose penalties. Fifth, the statute of limitation is six years, which is unnecessary. Statutes of limitation have been removed in many states for sexual harassment, for example, because of the long delays in victims coming forward. Similarly in the university context, it can take years to uncover research misconduct, and statutes of limitations can cause harm, discouraging whistle blowers from acting upon new discoveries about old research. Sixth, if forensic analysis of existing data is required, and this involves use of proprietary data, ORI needs should take priority, subject to a standardized ORI issued data use agreement. Lastly, while improved language exists in the ORI proposal, collective punishment is not as well protected as it is in this paper. Lessons from this reflection in the US context would apply to similar Canadian structures, e.g., at the NRC.

While the overwhelming majority of researchers in the USA and Canada are scrupulously honest and conduct research with integrity, the scope of research is so vast that a tiny percentage of those engaging in fraudulent endeavours still represents a large absolute number of cases. The following 2023 Wikipedia compilation (10) documented 84 prominent public cases. Two cases are especially noteworthy: The Poehlman case (11) which, to the best of my knowledge, is the only case that resulted in prison time; and the Potti case (12), where Duke University settled for \$112 million US. In addition, an as yet to be adjudicated case at the Dana Farber Cancer Institute (13) involves top officials at this institution.

There is an interesting comparison between the American and Canadian government reactions to cases I filed with them in June 2024. The US ORI refused to take up the case, citing the fact that the case did not involve Public Health Service funds. Though both cases were very similar, in Canada, charges against a tenured professor not involving federal funding nonetheless led to a government agency reviewing the case. At a recent meeting, the Canadian Secretariat on Responsible Conduct of Research approved an investigation, and a senior officer has been assigned. According to the British Medical Journal guidelines (2), failing to report suspected research misconduct itself constitutes research misconduct. In this spirit, the single ORI employee who opted out due to the fact that federal funds were not directly involved, may have committed BMJ defined research misconduct. After all, tenured research faculty, at some point, are virtually certain to apply for federal funds, making it is thus highly relevant whether the alleged extramural behaviour constitutes research misconduct. In short, research misconduct, whether it involves federally funded grants or outside employment, should be of direct interest. Further, if an individual indeed has committed research misconduct, that should make them ineligible to serve on government advisory committees or to be funded on any federal grant, for a defined term (e.g., 3-5 years or in perpetuity depending on the severity of the misconduct). This case is especially egregious by the ORI oversight, since it involves alleged public health dangers in the respondent's outside employment.

Lastly, the three RIOs reported in the US and Canadian cases presented above were given the opportunity to defend their actions, prior to the presentation of this paper. Despite a reasonable deadline and reminders, none responded. I argue that these three RIOs violated their public trust in screening these cases without an impartial hearing. Neither university offers complainants an avenue of appeal against RIO screenings for rejection. In my two cases, the grounds for their screenings did not refute the charges made, and the science behind the cases demanded hearings by impartial experts in the fields. Institutional protections trumped justice.

A centralized system would have averted the bias and lack of expertise that underpinned these cases, and undoubtedly others. A complainant who is courageous enough to file a case deserves to be heard in an impartial manner.

# Recu/Received: 3/5/2024

#### Remerciements

L'auteur souhaite exprimer sa gratitude à l'éditeur, M. Bryn Williams-Jones, pour ses contributions intellectuelles majeures et pour la révision professionnelle du contenu. Tout le travail a été effectué sur mes ordinateurs personnels et aucun soutien institutionnel n'a été demandé. Les opinions sont les miennes et aucun soutien institutionnel n'a été demandé.

#### Conflits d'intérêts

Aucun à déclarer. Ni mon université ni celle du cas américain n'ont participé à cette publication.

# Publié/Published: 2/12/2024

#### **Acknowledgements**

The author wishes to express his gratitude to the Editor, Dr. Bryn Williams-Jones, for major intellectual contributions and for professional editing of the contents. All work was done on my home computers and no institutional support was requested. Opinions are my own, and no institutional endorsement was sought.

#### **Conflicts of Interest**

None to declare. Neither my university nor the US case's university participated in this publication.

#### Édition/Editors: Bryn Williams-Jones & Aliya Affdal

Les éditeurs suivent les recommandations et les procédures The editors follow the recommendations and procedures décrites dans le Code of Conduct and Best Practice Guidelines outlined in the COPE Code of Conduct and Best Practice for Journal Editors de COPE. Plus précisément, ils travaillent Guidelines for Journal Editors. Specifically, the editors will work pour s'assurer des plus hautes normes éthiques de la to ensure the highest ethical standards of publication, including: publication, y compris l'identification et la gestion des conflits the identification and management of conflicts of interest (for d'intérêts (pour les éditeurs et pour les auteurs), la juste editors and for authors), the fair evaluation of manuscripts, and évaluation des manuscrits et la publication de manuscrits qui the publication of manuscripts that meet the journal's standards répondent aux normes d'excellence de la revue.

of excellence

#### REFERENCES

- Garfinkel S, Alam S, Baskin P, et al. Enhancing partnerships of institutions and journals to address concerns about research misconduct: Recommendations from a working group of institutional research integrity officers and journal editors and publishers. JAMA Network Open. 2023;6(6):e2320796.
- BMJ. Scientific misconduct.
- Kamoun S, Zipfel C. Class uncorrected errors as misconduct. Nature. 2016;531:173.
- Office of Research Integrity. Annual Report FY 2022. U.S. Department of Health and Human Services; 2022.
- Office of Inspector General. Research Misconduct by the Numbers. U.S. National Science Foundation.
- Mebane CA, Sumpter JP, Fairbrother A, et al. Scientific integrity issues in environmental toxicology and chemistry: Improving research reproducibility, credibility, and transparency. Integrated Environmental Assessment and Management. 2019;15(3):320-44.
- The Humane Society of the United States. Taking Suffering Out of Science.
- 8. Enserink M. Sabotaged scientist sues Yale and her lab chief. Science. 2014;343(6175):1065-66.
- 9. Department of Health and Human Services. Proposed Rule: Public Health Service Policies on Research Misconduct. HHS-OASH-2023-0014-0001. 6 Oct 2023.
- 10. List of scientific misconduct incidents. Wikipedia.
- 11. Eric Poehlman. Wikipedia.
- 12. Anil Potti. Wikipedia.
- 13. Li M. Harvard, affiliated bodies face probe over integrity. China Daily Global. 24 Jan 2024.