CONJOINT HEALTH RESEARCH ETHICS BOARD
Ethics and Compliance, Research Services
2500 University Drive NW
Calgary, AB, Canada T2N 1N4
sapage@ucalgary.ca

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The Panel on Responsible Conduct of Research
secretariat@srcr-scrr.gc.ca

Dear Members of the Panel,

Thank you for the opportunity to provide feedback on the proposed revisions to the RCR Framework. Our comments for your consideration are below.

New responsibility (2.7) Adding researcher responsibilities relating to oversight and training is a good thing. The inclusion/specification of "fair treatment" might benefit from definition. What is meant by "fair treatment?" Dictionary definition of fair as an adjective is "in accordance with the rules or standards; legitimate" and of it as an adverb is "without cheating or trying to achieve unjust advantage." These are quite narrow definitions. Perhaps balance and equal treatment are what is meant. Use of the word "fair" in the current social climate could be interpreted as having justice/EDI implications.

In addition, a supervisor role is one where there is a power differential; a peer review implies equal status. It might be good to reconcile these. Rather than indicating fair treatment is necessary to resolve an intellectual disagreement, is there a way of stating a positive action that would preclude such a disagreement arising (e.g., fair treatment in recognizing (intellectual) contributions)?

New breach 3.1.1 (a) "Lack of rigour" If rigour is part of RCR, it might be good to explicitly allocate some responsibility to institutions in terms of both ensuring researcher competence to undertake research generally and of ensuring scholarly standards are met for research undertakings. In practice, this will be challenging, many projects go forward without any review. Rigour might be difficult standard to uphold consistently, context is important. Sloppy, uncaring and incompetent are distinct from measured choices in specific contexts. What might be acceptable for a student project, an unfunded project, a low-risk project or a project that has to be deployed on a very short timeline might not be acceptable in more ideal circumstances. It is very likely that most research lacks rigour when compared to the ideal. It is the honest reporting of imperfect methods that allows the relevant peer community to assess the value/importance/impact of the findings.

3.1.1 (b) No comment

3.1.1 (c) No comment

New responsibility for institutions 4.2 . We agree with the allocation of responsibility to institutions. As above, a definition of what is meant by "fair" might be useful. How is it operationalized? It might be good to reword "in their research team" to "under their supervision" for consistency.

4.3.4 (a) No comment

4.3.4 (d) No comment

Accountability 4.3.6 (a) Adding guidance to what should be disclosed.

The new guidance broadens what might be disclosed from decision to relevant information. In doing so, it adds subjectivity to the process and consequently may limit further what is considered relevant and by whom. If, as a function of an upheld allegation, institutional process found to be in need of improvement, they should be addressed transparently and accountably. Using language encouraged to disclose condones some element of secrecy or need to keep quiet.

In addition, at this time, we would like the Panel to consider offering more explicit guidance on identifying "affected parties" when substantiated allegations of breach are found in research involving humans.

The comments below are drawn from our previous work on this topic (Stacey A. Page & M. Anne Stalker (2019): Canadian policy on reporting breaches of research integrity: When should Research Ethics Boards be informed? Accountability in Research, DOI: 10.1080/08989621.2019.1661243)

The ambiguity of the current phrase "affected party" and reference to privacy laws and regulations may unduly limit information disclosure within an institution. In our previous work, we concluded that Research Ethics Boards should always be advised of breaches of scholarly integrity in research involving humans, where allegations have been upheld. Specifically, to enhance transparency in process, to relieve burdens of subjective decision making in the determination of who constitutes an affected party and to reduce the possible perception of conflict of interest, institutions should make explicit within their research integrity policies and procedures that where misconduct has occurred during research with humans, their REBs must be informed.

The rationale for this is detailed in the article, the most relevant sections have been copied and provided below:

Affected parties, responsibilities and privacy considerations

Determining when the REB is an "affected party" depends upon whether such misconduct breaches research ethics standards and is therefore limited to research involving humans. Generally, issues such as invalid authorship, redundant publication or plagiarism occur in contexts outside the conduct of a study. Therefore, while these actions are breaches of scholarly standards, they are not breaches of research ethics standards.

Research ethics standards are breached when the validity of research is violated or participants' rights and welfare are compromised by the actions of a researcher. This may occur while the study is actively under the purview of the REB and may also arise when a participant's involvement is concluded or after a study is completed. When institutions uphold allegations of misconduct, REBs should be informed of the outcome permitting them to take appropriate action congruent with their mandate of ensuring that human research participants are respected and protected. Whereas institutional sanctions relate primarily to the terms and conditions of employment for the individual respondent, the REB's decisions extend to the approval and monitoring of studies. This includes ensuring participants are treated with respect, specifically relating to ongoing consent, their right to know study results and their welfare.

Actions or decisions the REB can take depend on the magnitude of the breach and on the institutional sanctions imposed on the researcher(s). In cases of significant misconduct, and where the researcher's affiliation with an institution has been terminated, the REB should withdraw approval from studies where that individual is named as part of the research team until the individual is removed. In cases where the researcher is the principal investigator, studies should be closed unless they can be transferred to alternate, eligible investigators. This is conditional on the validity of the study and the well-being of participants. REBs have a regulatory duty to evaluate the qualifications of investigators to conduct studies (e.g., ICH GCP, TCPS2). Substantiated allegations of misconduct bring into question these qualifications. If the researcher's affiliation with the institution is maintained and research activities are permitted, the REB is within its mandate to exercise increased vigilance in both initial and ongoing review consistent with a proportionate approach to the application of standards.

When an REB receives notice of research misconduct, it must consider what information participants are entitled to receive, in line with ongoing consent as well as participant's right to access research results. TCPS2 states that when new information relevant to the welfare of all participants arises, researchers and the REB have a duty to ensure that all participants are informed (Article 11.8).Welfare is broadly defined as the quality of a person's experience of life in all its aspects (Article 1.1).Misconduct affects welfare for a variety of reasons. It is a violation of the trust relationship participants hold with investigators. Knowing a researcher has not played by the rules, or has lied or cheated may influence participants' ongoing consent to remain in a study and, therefore, they should be informed. If studies have been compromised to the point they have been invalidated and terminated, participants should also be informed as they have the right to know the outcome of the research (World Medical Association 2013; Patient-Centered Outcomes Research Institute 2016). Finally, welfare can be compromised by direct

physical harms if participants have been subject to unnecessary, inaccurate or inappropriate interventions. Providing this information to participants permits them to seek care and legal recourse at their discretion.

Privacy law and information transmission

Institutions are in a conflict of interest when investigating, managing and reporting on cases of research misconduct since findings of misconduct bring with them the possibility of damage to their reputations (Hickling Arthurs Low (HAL) 2009; Master, McDonald, and Williams-Jones 2012; Schoenherr and Williams-Jones 2011; Council of Canadian Academies 2010). Criticisms about lack of transparency in the process and in reporting have frequently been made (Collier 2015; Komnenic 2016; Titus, Wells, and Rhoades 2008; Godlee and Wager 2012). In a 2009 report on the state of research integrity and misconduct policies in Canada, the reporting, communication and public disclosure of findings of research misconduct were described as eliciting the most ambivalence and confusion from academic institutional representatives questioned about their procedures in these areas (Hickling Arthurs Low (HAL) 2009). The need for greater transparency and a system wide approach to research integrity was also recognized in the 2010 review undertaken by the Canadian Council of Academies (Council of Canadian Academies 2010). The recommendations from this report informed the 2016 Tri-Agency Framework and Policy. However, the observed variation in procedural direction that the U15 institutions currently provide in terms of post-investigation reporting suggests amending the standards in this area might be warranted. Naming the REB as an affected party in research misconduct cases involving human participants will reduce ambiguity and subjective decision-making in this regard. Reluctance in sharing information may also be tempered with this specific policy or procedure direction.

Legal constraints may be raised as rationale for blocking information disclosure. Indeed, the RCR framework stipulates that in the course of reporting to affected parties, institutions should consider applicable privacy laws and regulations. However, where the information is to be transmitted within an institution, such constraints may not apply. Information held by academic institutions, which are public bodies, falls under provincial privacy legislation. Within such statutes, use and disclosure of personal information is to be only with consent or "for the purpose for which the information was collected or compiled or for a use consistent with that purpose," (e.g., Alberta's Freedom of Information and Protection of Privacy Act (2000)). "Consistent with that purpose" means that the use or disclosure both has a reasonable and direct connection to the purpose and is necessary to perform the statutory duties of, or for operating a legally authorized program of, the public body (s 41 (a)(b)). Most other jurisdictions in Canada use similar language (Office of the Privacy Commissioner of Canada 2017).

Universities in Canada are normally authorized by statute to perform research (e.g., in Alberta, by the Post-Secondary Learning Act (2003)) Therefore, part of their substantive function is to support the conduct of research including regulation and oversight of research integrity and research ethics. If the purpose of a research integrity policy within an institution is to ensure research is undertaken with integrity

and if research misconduct breaches research ethics standards, it is within the mandate of the institution's REB to act subsequent to these breaches. Therefore, REBs should be notified in cases where there has been a substantiated breach of integrity in research involving humans. It is essential to foster openness in communication about issues that affect the integrity of research within a university.

4.3.6 (b) No comment

Appendix B - Glossary

Responsible allegation – no comment

New Definition – no comment

Once again, thank you for the opportunity to comment, we hope our contribution is useful. Please do not hesitate to follow up should you have any questions about the foregoing.

Sincerely,

Stacey Page, PhD
Chair, Conjoint Health Research Ethics Board
Associate Professor, Department of Community Health Sciences
Cumming School of Medicine
University of Calgary,
Calgary, AB.

M. Anne Stalker
Member, Conjoint Health Research Ethics Board
Professor of Law Emerita,
Faculty of Law
University of Calgary,
Calgary, AB