C A R E B | A C C E R

September 27, 2011

Canadian Research Integrity Committee
consultation@nserc-crsng.gc.ca

Dear Canadian Research Integrity Committee,

RE: CAREB's response to the *Consultation Document on the Tri-Agency Framework: Responsible Conduct of Research (RCR)*

Thank you for providing the Canadian Association of Research Ethics Boards (CAREB) the opportunity to respond to this framework document. Establishing consistent policies and procedures for promoting RCR and investigating and disciplining research misconduct is an important step forward in developing a strong foundation for research integrity in Canada. CAREB understands the importance of RCR at it applies to human participant and other types of research and recognizes the need to strengthen the governance structure. We wholeheartedly agree that RCR must be promoted throughout the research cycle – from application for funding and development of the research protocol, through data collection and analysis, to authorship and publication. Students should be taught, as part of their research training, best practices in their respective disciplines and that RCR is a fundamental aspect of science and scholarship.

Members of our Board of Directors have reviewed the document and while we agree that this framework is well written, several aspects of the document could be strengthened in scope and in process. We have therefore provided the following comments:

1. Responsibilities of Researchers

Lines 94 to 96
2.1.1
The scope has been limited to researchers applying for, or in receipt of, Agency funds. CAREB cannot understand why the the scope is so limited and strongly recommends that the framework should apply to all research conducted at institutions that have signed the MOU and receive Agency funds, regardless of whether the specific project is funded by one of the Agencies. This would be consistent with TCPS. Recognizing that the Agencies' governance is limited to institutions that receive funds, we suggest that the framework be recommended as a voluntary guidance document to all Canadian research institutions.

Lines 128 to 129
2.2c
It is important for applicants to disclose past findings of policy breaches. However, it is important to recognize that the Agencies (or institutions) will require a mechanism by which to verify the accuracy of applicants' disclosures, or lack thereof. Moreover, it is important to detail breaches of what types of policies (Tri-Agency, Canadian or international regulations, institutional policies, etc.) would require disclosure, whether disclosure would only apply to projects that have received Agency funding, and by what process would the findings of breach be relevant (i.e. whether the institution's process is in accordance with the MOU to ensure procedural fairness).

Further, it is unclear how privacy would be protected, how this would be enforced or how this information may affect the Agencies decision on funding.

These missing elements are crucial to establishing a fair system for researchers.

Lines 135 to 146
2.4
Privacy legislation and Good Clinical Practice should be included on the list.

2. Breaches of Agency Policies by Researchers

Lines 191 – 194
3.1.4

This section is very broadly defined. Combined with other aspects of the framework, may in fact require institutions to review any breach of policies as if it were potential research misconduct.

Lines 195
3.2
Why is this titled "Roles of Individuals Addressing Allegations of Policy Breaches" rather than "Roles of Individuals Addressing Allegations of Research Misconduct"? From our perspective, the more important issue is that of research misconduct, as the impact reaches far beyond that of the Agencies.

Lines 199 to 201
3.2a
An institution should have the opportunity to investigate and respond to the allegation first, and report to the relevant Agency if necessary. More guidance should be given about who the institution's "point of contact" is. That individual needs to be in a senior position and able to maintain the confidentiality of the allegation. It is expected that MOU-bound institutions follow a compliant research integrity policy, but this is not specified.

The current framework states that if a complaint is made directly to the institution, the institution must only report if the allegation has been upheld. The proposed framework appears to mandate reporting, regardless of whether the allegations are upheld.

Lines 205 to 206
3.2b
Recourse for the complainant should be spelled out, or reference should be made to an MOU compliant research integrity policy.

Lines 207 to 210
3.2c
Researchers are "expected to be proactive in rectifying a breach…before the Institution submits its report to the Agency". Given that the institution has been required (under 3.2a) to report the breach to the Agency already, it no longer has the leverage to require a researcher to be 'proactive'. CAREB recommends that the Agency allow reporting to occur after all attempts to 'rectify the breach' have been made.

3. Responsibilities of Institutions

Lines 222 to 223
4.2a
This section should refer to examples or templates of best practices to guide institutions on creating policies and procedures.

Lines 227 to 228
4.2c
At present, we are not aware of Canadian-based educational opportunities in RCR. We strongly recommend that the Agencies identify such courses and best practice documents, develop their own, or work with institutions or associations (such as CAREB) to create a programs that can be utilized across the country. This will ensure even application of this framework across the country.

Lines 244 to 246
4.3.2c
Whistleblower protection is essential for this framework to work. Best practices or template policies are needed. Also needed are procedures to evaluate allegations made in bad faith, including determination of and whether and what, if any, disciplinary action should be taken.

Lines 270 to 271
4.3.4b
Best practices are needed here. In order to have some kind of consistency between institutions, the recourse should be spelled out clearly in this document, not left to each institution to determine.

Lines 273 to 275
4.3.5a
It is important that this Policy include explicit directions that the Research Ethics Board, Animal Care Committee and/or Biosafety Committee (or equivalent) be immediately informed of a finding of research misconduct when it involves human or animal research or use of biohazards. This reporting should also be allowed in the allegation stage, if there is significant risk to human participants, animal subjects or the general community.

Lines 276 to 277
4.3.5b
Best practices on how this should be accomplished would be appropriate here.

Lines 282 to 285
4.4.b
This section contains conflicting requirements. Including the allegations and responses in reports to the Agency will make it impossible to ensure that reports to the Agency not include (i) information that is not specifically related to Agencies' funding and policies, or (ii) personal information that is not material to the findings or the report. The Complainants and Respondents typically include a great deal of information, much of which is personal and unrelated to the Agencies, in their communications. Redacting such information is an unnecessary and expensive endeavour. If the Agencies do not need to see this information, they should not request the allegations or responses but rather request a report that sets out a summary of the allegations and a summary of the steps taken and outcomes.

Lines 311 to 314
4.5a
Promoting awareness of RCR is essential, and to date there has not been a concerted focus on RCR in Canada. The Agencies, through the CRIC, should lead such an initiative and work with institutions to promote RCR to their researchers, ranging from posting a statement on institutional websites, to creating mandatory educational programs. Best practices and guidance are required here to ensure consistency between institutions.

Lines 315 to 317
4.5.6
Making public statistical annual reports on confirmed findings of non-compliance is a new requirement and not something that is typically done for Canadian research misconduct cases. Such a report should be the responsibility of the Agencies, as they collect data from each of the institutions at point of allegation and/or finding of misconduct.

4. Breaches of Policy by Institutions
No comments.

5. Responsibilities of the Agencies
Lines 344 to 347
6.1.1a
Some institutions have a policy of not accepting anonymous allegations of research misconduct, so having such an allegation forwarded by the Agency would not result in any action. The Agency should specify that the allegations must be in writing, with a name included. If not, the Agency should inform the individual that anonymous allegations may not be accepted by all institutions, and to check the institution's policy.

Lines 348 to 350
6.1.1b
The phrase "if the matter involves Agency funding" should be replaced by "if the matter involves an MOU compliant institution".

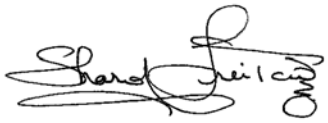
Lines 377 to 378
6.1.3b
If the Agency seeks a "refund within a defined time frame of all or part of the funds already paid" and the researcher has already spent the funds, who is responsible for repayment to the Agency?

In summary, there are two fundamental weaknesses with this document as it currently stands. First, the limited scope will result in a two-tiered system of compliance for institutions; research which is Agency funded and all other research.

Second, is the current lack of resources to fully and properly implement this framework across Canadian institutions. Resources may include developing or sharing of current best practices, educational opportunities, and directions for institutions. Making such resources available is essential to ensuring that this Policy is implemented fully and consistently across the country. The risks of not making resources available include non-compliance or inconsistent application of this framework, lack of understanding of the issues of RCR and, most importantly, the continuation of undetected practices that lead to research misconduct. Furthermore, the framework should ensure that there is sufficient flexibility to allow for complaints to be addressed in a manner that is adaptable to the context and severity of the allegations.

As RCR is an important concern of CAREB, we offer our support to the CRIC and the Agencies in the development of resources, as needed and as possible. We hope that the comments provided are helpful in the further refinement of this framework and the development of a fulsome RCR system in Canada.

Sincerely,



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