

## Proposed Revisions to the Tri-agency Framework: Responsible Conduct of Research (2016)

Bloorview Research Institute

**Province:** Ontario

**Affiliation:** Hospital (Holland Bloorview Kids Rehabilitation Hospital)

**Role:** Representative of the organization (Office of Human Research Protections)

Proposed Revision	Comments/Feedback
<p>3.1.1.a) <u>Lack of rigour</u></p> <p><u>Lack of scholarly and scientific rigour in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings.</u></p>	<p>It would be helpful to have examples of what constitutes a breach categorized as “lack of rigour”</p>
<p>3.1.1.b) Falsification</p> <p>Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement, <u>such that the research is not accurately represented in the research record. and which results in inaccurate findings or conclusions.</u></p>	<p>It would be helpful to include the term “research record” in the glossary to ensure clarity on what constitutes “research record(s)”</p>
<p>4.2.d) <u>Ensuring that their researchers comply with institutional policies that may impact the responsible conduct of research, in particular those policies that relate to providing appropriate oversight, adequate training, and fair treatment to individuals in their research team. Institutions should also be proactive in supporting a healthy research environment.</u></p>	<p>As an institution, what does this expectation entail? Does this mean having policies and procedures in place is enough? Or is the expectation that institutions proactively review all research studies within its auspices for compliance with RCR?</p>
<p><b><i>*not a proposed revision</i></b></p> <p>4.3.3.a) A central point of contact at a senior administrative level, to receive all confidential enquiries, allegations of breaches of policies, and information related to allegations.</p>	<p>With consideration for new institutional requirements for promoting a healthy research environment (see proposed revision 4.2.d), are there any considerations for determining the institution’s RCR contact who receives reported allegations?</p>
<p>4.3.4.a) An initial inquiry process to establish whether an allegation is responsible and if an investigation is required. <u>An inquiry may be conducted by one or more individuals. This could include the institution’s designated RCR contact and/or other individuals qualified to assess whether the allegation is responsible. The individual(s) conducting an inquiry should be without conflict of interest, whether real, potential or perceived.</u></p>	<p>In the process of determining who should be involved in the allegation inquiry, is it possible to provide more clarity on what a perceived conflict of interest would entail?</p> <p>Would it be possible to define what a “RESPONSIBLE” allegation means? We feel that the term could create confusion given the context (ie. within the framework for <i>responsible</i> conduct of research)</p>