Post REB Approval: On-going Responsibilities of Researchers

After receiving ethical approval for the conduct of research involving humans, there are several ongoing responsibilities that researchers must meet to remain in compliance with University and Tri-Council policies.

1. Additional Research Ethics approval
   Prior to conducting any research, researchers must ensure that all required research ethics approvals are secured (in addition to this one). This includes, but is not limited to, securing appropriate research ethics approvals from: other institutions with whom the PI is affiliated; the research institutions of research team members; the institution at which participants may be recruited or from which data may be collected; organizations or groups (e.g. school boards, Aboriginal communities, correctional services, long-term care facilities, service agencies and community groups) and from any other responsible review body or bodies at the research site.

2. Reporting adverse events
   Any significant adverse events experienced by research participants must be reported in writing to Research Ethics within 24 hours of their occurrence. Examples of what might be considered “significant” include: an emotional breakdown of a participant during an interview, a negative physical reaction by a participant (e.g. fainting, nausea, unexpected pain, allergic reaction), report by a participant of some sort of negative repercussion from their participation (e.g. reaction of spouse or employer) or complaint by a participant with respect to their participation. The above list is indicative but not all-inclusive. The written report must include details of the adverse event and actions taken by the researcher in response to the incident.

3. Seeking approval for protocol / consent form changes
   Prior to implementing any changes to your research plan, whether to the protocol or consent form, researchers must submit them to the Research Ethics Board for review and approval. This is done by completing a Request for Ethics Approval of Amendment to an Approved Project form (available on the website) and submitting three copies of the form and any documents related to the change. Please note that no reviews are conducted in August.

4. Submitting annual reports
   Ethics approvals are valid for up to 12 months. Prior to the end of the project’s approval deadline, the researcher must complete an Annual Report (available on the website) and return it to Research Ethics for review and approval before the approval end date in order to prevent a lapse of ethics approval for the research. Researchers should note that no research involving humans may be conducted in the absence of a valid ethical approval and that allowing REB approval to lapse is a violation of University policy, inconsistent with the TCPS (article 6.14) and may result in suspension of research and research funding, as required by the funding agency.

5. Submitting final reports
When the researcher is confident that no further data collection or analysis will be required, a Final Report (available on the website) must be submitted to Research Ethics. This often happens at the time when a manuscript is submitted for publication or a thesis is submitted for defence. After review and approval of the Final Report, the Research Ethics file will be closed.

6. Retaining records in a secure manner

Researchers must ensure that both during and after the research project, data is securely retained and/or disposed of in such a manner as to comply with confidentiality provisions specified in the protocol and consent forms. This may involve destruction of the data, or continued arrangements for secure storage. Casual storage of old data is not acceptable.

It is the Principal Investigator’s responsibility to keep a copy of the REB approval letters. This can be important to demonstrate that research was undertaken with Board approval, which can be a requirement to publish (and is required by the Faculty of Graduate Studies if you are using this research for your thesis).

Please note that the University will securely store your REB project file for 5 years after the study closure date at which point the file records may be permanently destroyed.

7. Current contact information and university affiliation

The Principal Investigator must inform the Research Ethics office of any changes to contact information for the PI (and supervisor, if appropriate), especially the electronic mail address, for the duration of the REB approval. The PI must inform Research Ethics if there is a termination or interruption of his or her affiliation with Dalhousie University.

8. Legal Counsel

The Principal Investigator agrees to comply with all legislative and regulatory requirements that apply to the project. The Principal Investigator agrees to notify the University Legal Counsel office in the event that he or she receives a notice of non-compliance, complaint or other proceeding relating to such requirements.

9. Supervision of students

Faculty must ensure that students conducting research under their supervision are aware of their responsibilities as described above, and have adequate support to conduct their research in a safe and ethical manner.

October 2013