DALHOUSIE UNIVERSITY

Ongoing Responsibilities of Researchers

Research Ethics

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

---

1. Additional Research Ethics approval

Prior to conducting any research involving humans, researchers must ensure that all required research ethics approvals are secured (in addition to Dalhousie approval). This includes, but is not limited to, securing appropriate research ethics approvals from: other institutions with whom the lead researcher is affiliated; the institutions of research team members; the institution at which participants may be recruited or from which data or biological materials may be collected or shared; communities, organizations or groups (e.g. school boards, Indigenous communities, 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: a negative physical reaction by a participant (e.g. fainting, nausea, unexpected pain, allergic reaction), an emotional breakdown of a participant during an interview, 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, report of neglect or abuse of a child or adult in need of protection, or a privacy breach. The above list is indicative but not all-inclusive. The written report must include details of the situation and actions taken (or proposed) by the researcher in response to the incident.

3. Seeking approval for changes to research

Prior to implementing any changes to your research plan, whether to the risk assessment, methods, analysis, study instruments or recruitment/consent material, researchers must submit them to the Research Ethics Board for review and approval. This is done by completing the amendment request process (described on the website) and submitting an updated ethics submission that includes and explains the proposed changes. Please note that reviews are not conducted in August.

4. Continuing ethical review - annual report

Research involving humans is subject to continuing REB review and oversight. REB approvals are valid for up to 12 months at a time (per the Tri-Council Policy Statement (TCPS2) article 6.14). Prior to the REB approval expiry date, researchers may apply to extend REB approval by completing an Annual Report (available on the website). The report should be submitted 3 weeks in advance of the REB approval expiry date to allow time for REB review and 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 the University Scholarly Misconduct Policy, inconsistent with the TCPS and may result in the suspension of research and research funding, as required by the funding agency.

5. Final review - final report

When the researcher is confident that all research-related interventions or interactions with participants have been completed (for prospective research) and/or that all data acquisition is complete, there will be no further access to participant records or collection of biological materials (for secondary use of information research), a Final Report (available on the website) must be submitted to Research Ethics. After review and acknowledgement of the Final Report, the Research Ethics file will be closed.

6. Retaining records in a secure manner

Researchers must ensure that records and data associated with their research are managed consistent with their approved research plans both during and after the project. Research information must be confidentially and 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 records, or continued arrangements for secure storage.

It is the researcher's responsibility to keep a copy of the REB approval letters. This can be important to demonstrate that research was undertaken with Board approval. Please note that the University will securely store your REB project file for 10 years after the REB approval end date at which point the file records will be destroyed.

7. Current contact information and university affiliation

The lead researcher must inform the Research Ethics office of any changes to contact information for the lead researcher (and supervisor, if appropriate), especially the electronic mail address, for the duration of the REB approval. The lead researcher must inform Research Ethics if there is a termination or interruption of their 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 they receive 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.

10. University policies

Researchers are additionally responsible to comply with other University policies and procedures as applicable to the project.

Last updated: November 2024