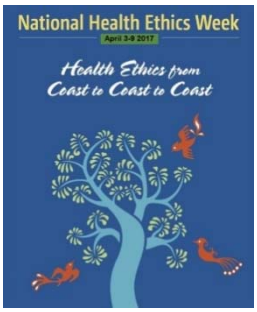

National Health Ethics Week 2017: April 3-9th

Research Ethics Bulletin #4: Roles and Responsibilities of Researchers

What are the responsibilities of researchers according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014)?

Researchers have a responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect research participants. This responsibility does not end when a study receives research ethics board (REB) approval but continues for the entire lifecycle of the research. For research participants, researchers are the front line representatives of research ethics and have primary responsibility for implementing the core principles of TCPS2: Respect for Persons, Concern for Welfare and Justice.

Researchers affiliated with an institution eligible to administer Agency funds (i.e. Memorial University) are expected to be knowledgeable about TCPS2 guidance relevant to their research, and to apply this guidance to the design and conduct of their research. In addition, any researcher applying to the Health Research Ethics Board (HREB) in Newfoundland and Labrador (NL) is expected to be knowledgeable about TCPS2 guidance relevant to their research, and to apply this guidance to the design and conduct of their research. Researchers should ensure that all research team members are trained to conduct ethically acceptable research in accordance with TCPS2. They should also be aware of their professional and other institutional responsibilities, as well as their legal obligations in the conduct of their research. Where students are named as a Principal Investigator (PI) on an application with a named supervisor, both the PI and supervisor must demonstrate knowledge about TCPS2 guidance relevant to their research by providing a copy of the TCPS2 CORE Tutorial certificate of completion to the HREB.

The HREB ethics application outlines the following responsibilities attributable to the PI named on a study. The PI:

- By submitting an application, assumes full responsibility for the research study.
- Verifies that the information provided in the application is accurate and complete.
- Will conduct the study according to applicable laws, regulations and guidelines.
- Will conduct the study consistent with applicable ethical norms.
- Will conduct the study according to the approved protocol and consent form(s).
- Will accept the authority of, and abide by, the decisions of the HREB as the board of record.
- Will comply with the HREB requirements, including timely filing of documents as required by the HREB and provide access to study documents for any random or for cause monitoring by the Health Research Ethics Authority (HREA).
- Will ensure there will be no changes to the research without prior HREB review and approval, except where necessary to eliminate an immediate hazard to participants.
- Will report immediately to the HREB any unanticipated problems in the research, significant deviations from the study protocol, or changes increasing the risk to participants or affecting significantly the conduct of the study.
- Will report promptly to the HREB all adverse reactions that are both serious and unexpected and new information that may affect participant's willingness to participate in the research.
- Will request an annual ethics renewal for each year the study is active and submit a final report once the study is complete.

For more information regarding reporting requirements to ensure compliance with ethics guidelines and the HREB, please review the Research Ethics Bulletin #2: HREB Reporting Requirements.

NEWFOUNDLAND AND LABRADOR HREA HEALTH RESEARCH ETHICS AUTHORITY