

Research Ethics Bulletin #2: DEFINITION OF HEALTH RESEARCH

In response to requests from the research community, the Health Research Ethics Authority (HREA) developed an interpretation of the definition of health research to further refine its scope.

The Health Research Ethics Authority Act (HREA Act) 2011, section 2(d) defines health research involving human subjects as “*activities whose primary goal is to generate knowledge in relation to human health, health care and health care systems, and involving human beings as research subjects, health care information respecting human beings or human biological material*”.

At the end of 2015, a more fulsome definition of health research was released. The interpretation can be found in the Ethics Application Screening Tool (further information below) and on the HREA website: www.hrea.ca. A summary of the interpretation is available below:

Health research includes all research related to health education (e.g. curriculum development in nursing or medicine). Health research does not include tests on non-healthcare equipment or tools to be used by humans, even where the research methods may put humans at risk (e.g. automobile or helicopter safety studies, research to study early childhood learning patterns, human kinetic research to establish parameters of safety for sports equipment).

To note: *health research being conducted where the researcher is not affiliated with MUN and participants or data are not about Newfoundland and Labrador or its population does not require local ethics review.*

In addition, national health surveys being conducted where the researcher is not affiliated with MUN that include Newfoundlanders and Labradoreans as participants, but do not identify Newfoundland and Labrador as an aggregate and do not report findings specific to Newfoundland and Labrador or to aggregates within Newfoundland and Labrador, do not require local ethics review.

One of the major implications of the interpretation is that medical education research (e.g. developing a new style of teaching to see if it helps nurses to administer a drug correctly) is now considered to be within the scope of the definition of health research, where it was previously excluded. Also, the scope of research was narrowed whereby research being conducted by an unaffiliated researcher in NL where data collection is external to the province, and does not generate results about the inhabitants of the province, would not require HREB review.

The interpretation of the definition of health research was first released as part of the newly developed Ethics Application Screening Tool (<https://rpresources.mun.ca/triage/>). The Ethics Application Screening Tool is an interactive tool to help guide researchers to the appropriate application for ethics review for the various REBs in the province.

By responding to ‘Yes/No’ questions, researchers determine whether or not their research requires REB review and are navigated to the relevant application form for their study.

It is highly recommended that all researchers complete the Ethics Application Screening Tool prior to accessing an application for ethics review by any of the REBs in the province.

For further information on the definition of health research, or the Ethics Application Screening Tool, you can contact Sandra Veenstra, Ethics Director to the HREA at ethicsdirector@hrea.ca or (709) 777-8905.