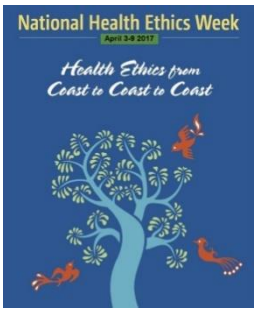

National Health Ethics Week 2017: April 3-9th

Research Ethics Bulletin #5: Consent for Research

The ethical requirements for consent in research involving humans are that consent must be free, informed and ongoing (Articles 3.1-2.3 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014). Consent should also precede collection of, or access to, research data. These concepts are outlined in more detail below.

Free

Informed consent must be voluntarily given, that is, without manipulation, undue influence or coercion. Consent can be withdrawn at any time; if a participant withdraws consent, they can also request the withdrawal of their data or human biological materials. The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.

Informed

Researchers must provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project. Application of Article 3.2 of TCPS2 outlines the elements of consent to be considered in the context of a particular research project.

Ongoing

Consent must be maintained throughout a research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in research. Consent encompasses a process that begins with the initial contact (e.g. recruitment) and carries through to the end of participants' involvement in the project. Throughout the process, researchers are required to provide participants with all information regarding any changes to a research project that may affect them. This information may be relevant to their decision to continue their research participation.

TCPS 2 advocates an approach to consent based on decision-making capacity rather than age. Some children begin participation in a project on the basis of consent from a guardian and on the basis of their own assent. If the children mature sufficiently during the course of the study to decide on their own behalf, the researcher must seek the children's autonomous consent in order for their participation to continue. Similarly, for children who are unable to assent to research participation (e.g., infants) at the beginning of a project, the researcher must seek their assent to continue their participation once they are able to understand the purpose of the research as well as its risks and benefits.

Departures from General Principles of Consent

The research ethics board (REB) may approve research that involves an alteration to the requirements for consent if the REB is satisfied that the following conditions apply: the research is minimal risk, the alteration to consent requirements is unlikely to adversely affect the welfare of participants, it is impossible or impracticable to carry out the research and to address the research question properly if prior consent of participants is required, the precise nature and extent of any proposed alteration is defined, and the plan to provide debriefing (if any) is in accordance with Article 3.7B of TCPS2.

Consent Must be Documented

Evidence of consent must be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. In cases where verbal consent is being obtained (e.g. telephone interviews), the date, time and place of consent must be documented.

Consent and Secondary Use of Identifiable Information for Research Purposes

Researchers who have not obtained consent from participants for secondary use of identifiable information can only use such information for these purposes if they have satisfied to the REB all of the criteria outlined in article 5.5A of TCPS2. When secondary use of identifiable information without the requirement to seek consent has been approved by an REB, researchers who propose to contact individuals for additional information must, prior to contact, seek REB approval of the plan for making contact. Researchers must seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information.

For more information on Secondary Use of Data please refer to the Research Ethics Bulletins #3 (2015) and #4 (2016), available online: http://www.hrea.ca/Ethics-Review-Required.aspx.

NEWFOUNDLAND AND LABRADOR HREA HEALTH RESEARCH ETHICS AUTHORITY