# Guidance for Applications for Ethics Review:

# Research with Populations Requiring Special Consideration

The information presented in this guidance document briefly describes how certain populations may be vulnerable as research participants and to stress the importance of extra care needed during the ethics reviews of studies involving these populations. Researchers are encouraged to develop a research protocol that will most effectively and adequately protect the rights of these research participants.

**General Principle[[1]](#footnote-1)**

Depending on the context and the circumstances, extra care and ethical precaution may be required by researchers when their research projects involve certain populations. This may include, but is not limited to:

* Children;
* Humans in underprivileged communities
* Women
* Indigenous people;
* Visible minority populations;
* People who are homeless;
* Immigrants with insecure status;
* People with psychiatric, cognitive, or developmental disorders;
* Persons who have been abused;
* Persons with low socio-economic status;
* Educationally disadvantaged persons;
* Prisoners; and
* Elderly persons.

**Research Involving Children**

There are four categories of research involving children. The categories are determined by the degree of risk and prospect of benefit to the child-participant. For any research project involving children, the REC, in consultation with the researcher, is responsible for determining in which of the four categories of research the study belongs and for documenting in the minutes the rationale for its choice.

It is desirable for the researcher to address these issues directly in the protocol, identifying which of the categories the study fits into and the rationale for this categorization. The four categories of research which may be approved by the REC are:

* Category 1: Research that involves minimal risk to children;
* Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child-participant.
* Category 3: Research involving greater than minimal risk and no prospect of benefit to the individual child-participant. In order to approve research in this category, the REC must determine that:
  + the risk of the research represents no more than a minor increase over minimal risk;
  + the intervention or procedure presents experiences to the child-participant that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations; and
  + the intervention or procedure is likely to yield generalizable knowledge about the participant’s disorder or condition which is of vital importance for understanding or amelioration of the disorder or condition.
* Category 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Such research must be in keeping with the principles outlined in the categories 1, 2 and 3.

Confidentiality and anonymity must be explained in a way that children can understand. It must be made very clear who will have access to the data and what will happen to the data when the research is complete. Anonymization in the form of removing names and other identifying information should be explained. The extent of the anonymity and any potential areas where the confidentiality of the interview may be broken should be explained to the child at the outset of the interview. For example, the researcher has a duty to take steps to protect the children, if they are considered to be ‘at risk of significant harm’. The child needs to know what action may be taken in the event that he or she discloses that they or others are at risk of ‘significant harm’, or where the researcher observes or receives information of incidents likely to cause harm. Arrangements need to be made in advance, following professional advice, on agreed procedures in these cases, and for support for the child.

**Research Involving Humans in underprivileged communities**

Before undertaking research involving humans in underprivileged communities, whether in developed or developing countries, the researcher must ensure that:

* The research is responsive to the health needs and the priorities of the community in which it is to be carried out;
* Every effort will be made to meet the ethical imperative that the consent of individual research participants be free and informed; and
* The research proposals have been reviewed and approved by a REC that has among its members or consultants who are thoroughly familiar with the customs and traditions of the community to ensure these values are respected; and
* Efforts have been taken to consult with the community whose population is to be recruited.

**Research Involving Women**

Women have historically been excluded from participating in some research largely because of concerns including:

* damaging either the foetus or the woman’s reproductive capacity;
* harming the newborn through breastfeeding;
* failing to recognize that diseases and conditions might affect men and women differently; and
* fear of liability by research sponsors.

Women will not automatically be excluded from research solely on the basis of sex or reproductive capacity. The REC may permit research on pregnant women, breastfeeding women or foetuses when the following conditions are met:

* The potential benefits of including women and their embryo, foetus or infant outweigh the risks of excluding women from the research; and
* Scientifically appropriate research on pregnant animals and non-pregnant women have been conducted and provide data for justifying research and assessing risks and benefits.

Research involving neonates (viable, nonviable or of uncertain viability) may be permissible. However, researchers should have no part in determining the viability of a neonate.

**Research Indigenous People**

Research involving First Nations, Inuit and Métis individuals should also involve the communities or groups to which they belong. First Nations, Inuit and Métis Peoples have rights and interests which deserve recognition and respect by the research community[[2]](#footnote-2). Researchers should respect Indigenous governing bodies, community interests, and customs. Collaboration and engagement between researchers and research participants is required.

In addition to the guidelines in Chapter 9 of the TCPS2, researchers must also refer to, and comply with, statutes, regulations, departmental policies and other requirements concerning research involving First Nations, Inuit and Métis People. Prior to submitting an application to the REC for an ethics review, the researcher must ensure that the Indigenous communities in question have been consulted in the development of the proposed research project.

The researcher should include, in his or her REC application, the following information:

* The results of the consultation undertaken with the communities and a copy of the exchange of correspondence with these communities, including any letters of support;
* The recruitment processes to be undertaken in these communities;
* The nature and extent of community engagement determined by the community and by the researcher;
* The consent processes for obtaining informed consent from both these communities;
* The communication of the report of findings to these communities and the research participants; and
* The documentation pertaining to these processes.

**Research Involving Prisoners**

Research involving prisoner should only be done in specific conditions and according to relevant ethical guidelines. The risks involved in such research should be commensurate with risks accepted by non-prisoner research participants.

It is essential that the individual has full information about the research in order to give their informed consent to take part and that consent is freely volunteered. The ability of prisoners to consent freely and voluntarily to participation to research may be modified due to their incarceration. The influence of power relationships on voluntary choice should be judged according to the particular context of prospective participants[[3]](#footnote-3). Prisoners should not be offered large inducements for their participation in research, as this presents a risk of undue inducement to participate. The salary they would otherwise get in prison should be considered as an example of the maximum amount offered for research participation. The individual should also know that she or he can withdraw at any time and that their participation will not influence their parole, or the way they are treated by prison staff and others in positions of authority, etc.

Participants should know who will have access to identifying information. The research project needs to inform participants if the information gathered from their participation to research will be provided to authorities monitoring the research in question. REC members will also consider the interests of prisoners and the possibility of stigmatization of this particular population. Data gathered from incarcerated individuals should only be provided to administrative bodies for policy making purposes and if it is unlinked, to any specific individual.

**Research Involving Elderly Persons**

Research on various aspects of aging and the lives of the elderly are necessary to ensure that such individuals stay fully integrated in society and maintain a high quality of life. As such, the TCPS2 states that: "Elderly people shall not be inappropriately excluded from research solely on the basis of their age.[[4]](#footnote-4)" Appropriate care must be taken to ensure this population is able to fully consent, with consideration of how best to communicate information about the study and how to assess ability to consent in populations that may have experienced cognitive decline.

1. For more information, please consult TCPS-2, art. 4.1-4.7 and CGSB, art. 4.4.4.2.14 & 4.4.4.2.15. [↑](#footnote-ref-1)
2. TCPS2, chapter 9. [↑](#footnote-ref-2)
3. TCPS2, p. 28 [↑](#footnote-ref-3)
4. TCPS2, art. 4.5. [↑](#footnote-ref-4)