Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.109**
Title	Addendum for US-Regulated Research
Effective Date	July 1, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   The purpose of this standard operating procedure (SOP) is to describe the necessary changes to REB processes, procedures and composition required for review of human participant research that falls under the jurisdiction of US federal regulations (45CFR46).

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review a proportion of human participant research in compliance with US federal regulations.

4. **Responsibilities**
   All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

5. **Procedures and/or Specific Policies**
   The REB must review human research that falls under the jurisdiction of US federal agencies in compliance with US federal regulations. These requirements may differ from the policies and guidelines governing Canadian REBs and therefore necessitate changes to REB processes, procedures, and composition.

   5.1. **Determination of Research under US Federal Regulations**

   5.1.1. Human participant research that is conducted, funded, or supported by a US government agency and falls under the US Office of Human Research Protections' (OHRP) definition of "human subjects research" must comply with US regulations 45CFR46, otherwise known as the "Common Rule";

   5.2. **REB Composition and Quorum**

   5.2.1. In addition to the TCPS requirements for membership, the following REB composition requirements apply:

   - If the REB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women,

or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these groups.

- Membership may not consist entirely of members of one profession.
- At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

5.2.2. Quorum must additionally include 50% + 1 of the voting membership including a nonscientist.

5.3. **REB Procedures**

5.3.1. The REB Chair or designee shall determine if the project is defined as "human subjects research";

5.3.2. For research determined to fall under the definition of "human subjects research", the REB may only use expedited (delegated) review procedure for the initial and ongoing review of research that appears on the Secretary, Health and Human Services' (HHS) list of categories for expedited review and is determined to involve no more than minimal risk and/or minor changes in previously approved research during the period for which approval is authorized;

5.3.3. At the time of continuing review, the REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving vulnerable populations,
- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or Research Staff complaints,
- Any other situation that the REB deems appropriate;

5.3.4. The REB has the authority to observe or have a third party observe the consent process and the research.

5.4. Research involving prisoners as participants

5.4.1. When reviewing research involving prisoners, the REB must additionally comply with the requirements outlined in 45CFR46 Subpart C, including:

- A majority of the REB members shall have no association with the prison(s) involved, apart from their membership on the REB;
- At least one member of the REB shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity;
- The research under review represents one of the categories of

research permissible under 45CFR46.306(a)(2);

- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;
- Adequate assurance exists that parole boards will not consider a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;
- Where the REB finds there may be a need for follow-up with participants after the end of their participation, adequate provision has been made for such activities, considering the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

5.5. Reporting to the Organization

5.5.1. The Chair or designee will report any serious or continuing non-compliance with the Common Rule requirements and any suspension or termination of REB approval to the appropriate Organizational Official(s) and has the authority to notify the regulatory authorities (as applicable). The REB may delegate regulatory authority reporting to the organization.

5.6. Informed Consent Form

5.6.1. The informed consent form, when applicable, must additionally comply with the requirements set out in 45CFR50. For observational research, this includes, as appropriate/applicable to the research:

- The approximate number of research participants,
- The process involved for participation withdrawal,
- The effects of a participant choosing to withdraw,
- A statement identifying those with the authority to modify the research subject's participation (such as the Researcher or Sponsor).

5.7. REB Records

5.7.1. The REB Chair or designee will maintain the REB membership roster which includes name, degree(s), area(s) of expertise and organizational affiliation(s), role on the REB (e.g., scientific, nonscientific), sex, and sufficient detail to describe each member's chief anticipated contribution to REB deliberations (as applicable);

5.7.2. A vote will be held for each submission requiring a decision; the REB minutes will reflect the number of members voting for, against or abstaining for each submission.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.109	New - Implementation of new SOP outlining US-Regulated Research	July 1, 2021