HREBA | Health Research Ethics Board of Alberta

SOP 403.002G Guidance

Title	**Guidance for Submitting a Study**
Related SOP	403.002 - Initial Review - Criteria for REB Approval
Effective Date	01-July-2016

Submitting a Study

In January 2014, HREBA transitioned to an electronic platform, IRISS, to receive and process all **new** submissions for ethics review. Studies that were initially submitted using IRISS will have ongoing activities (ex. modifications, annual renewals etc.) reviewed through this system.

Registering as a first-time IRISS user

First-time users must register in this one-time only process following the steps below:

1. Access/Register with IRISS
2. Select the appropriate HREBA committee (please contact us if you need to register for more than one committee)
3. You will be asked to upload a recent CV (within 2 years), and various training certificates
4. You will receive an email with log in information to access IRISS in 1-2 business days

Accessing IRISS to submit an application for ethics review

Once you are registered as an IRISS user, you can go directly to the IRISS login page to access your study workspace and initiate applications.
There are a number of documents available to help you manage your study using IRISS, including one specifically for the initiation and submission of a new research study.

Delegated vs. Full Board Review

Studies that are deemed 'minimal risk' may be eligible for delegated review. Minimal risk research is research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

HREBA has adopted a proportionate approach to research ethics review in which the level of review is determined by the level of risk presented by the research. The lower the level of risk is, the lower the level of scrutiny (delegated review) and the higher the level of risk, the higher the level of scrutiny (full board review). For more information, please refer to SOP 401: Delegated Review.

Criteria for the initial submission of a study

Please be advised all required documents must be included in your IRISS application before review of a study proposal commences.

If you send an incomplete submission to HREBA, or if there are major discrepancies between the IRISS application and the study protocol, the administrative staff will inform you of the missing information/documents through IRISS. If all missing documents or information are not provided to HREBA before 12:00pm on the submission deadline day, the study will not be reviewed at the next full board meeting.

A list of documents required for the submission can be found here.

Naming documents in IRISS

It is important to note that how you name and date your documents in IRISS is how they will be listed in the approval letter. Do not add the version number and/or date as part of the name of the document, or it will show twice in the approval letter.

Waiver of consent

HREBA **may** grant waivers of consent in situations that meet all items (a-e) specified under the TCPS2, Article 3.7A.

The REB may approve research that involves an alteration to the requirements for consent set out in Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply:

a. the research involves no more than minimal risk to the participants;
b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c. it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
e. the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

A request to waive consent must be justified using the above criteria in **Question 1.1 of the Informed Consent Determination section of the IRISS application**. Failure to properly justify waiver of consent will result in the delay of the review and approval of the research.

Placebo controlled studies

If the research is placebo-controlled, full justification as to why a placebo is necessary **must be provided in the IRISS application** by the Researcher. This justification must refer specifically to the TCPS2 Article 11.2 (1-5);

Great care should be taken to avoid abuse of placebo comparators. However, they are acceptable in any of the following situations:

1. there are no established effective therapies for the population or for the indication under study;
2. existing evidence raises substantial doubt within the relevant expert community regarding the net therapeutic benefit of available therapies;
3. patients are resistant to the available therapies by virtue of their past treatment history or known medical history;
4. the trial involves adding a new investigational therapy to established effective therapies: established effective therapy plus new therapy vs. established effective therapy plus placebo;
5. patients have provided an informed refusal of established effective therapy, and withholding such therapy will not cause serious or irreversible harm.

The use of a placebo must be justified in **question 9.0 of the Clinical Trial section of the IRISS application** by indicating which of the above criteria your study meets. Failure to properly justify the use of a placebo will result in the delay of the review and approval of the research.

The Health Information Act

Please note that the Health Information Act of Alberta takes precedence in all privacy and confidentiality matters.

Additional criteria

If applicable, a Health Canada No Objection Letter does not need to be submitted to HREBA with the initial study submission, but must be received by the REB before final approval of the study is granted.

Length of approval period

The initial approval date for all studies is the date that the Chair or Vice-Chair approves the research, after all issues identified by the reviewers have been resolved. The research can be approved for up to 365 days until a request for ethics renewal must be submitted.

SOP Code	Effective Date	Summary of Changes
SOP403.001G	01-July-2016	Original version
SOP403.002G	01-July-2016	Version 2; updated hyperlinks