HREBA | Health Research Ethics Board of Alberta

**SOP 403.002G(a) Guidance**

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| **Title** | **Guidance for Submitting a Study** |
| **Related SOP** | 403 – Initial Review - Criteria for REB Approval |
| **Effective Date** | 01 February 2018 |

## Registering as a first-time HREBA 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. Depending on your role, you may 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

If you are already registered with one of the HREBA committees, contact us if you need access to another committee. Submitting another registration will not give you access to the additional committee.

Note that there are two IRISS systems: the University of Calgary (U of C) IRISS system, and the HREBA IRISS system.

## Accessing IRISS to submit an application for ethics review

Once you are registered as a HREBA IRISS user, you can go directly to the HREBA IRISS login page to access your study workspace and initiate applications.

For users who have both a U of C and HREBA IRISS account:

- Most users' accounts are separate. This means that you need to access U of C studies through your U of C account, and HREBA studies through your HREBA account. An exception to this is U of C studies which have been transferred to HREBA; these need to be accessed through your U of C account.
- Some users may have linked accounts. If your account is linked you will be able to initiate and access all studies (U of C and HREBA) regardless of the IRISS account you sign in through.

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.

## Submitting a study for review

### Criteria for the initial submission of a study

Please be advised that all required documents must be included in your IRISS application before review of a study proposal commences. Informed consent / assent forms are to be in Microsoft Word format and all other documents are to be in pdf format. As IRISS is a secure system, do not upload password protected documents. Required documents:

- For all submissions:
  - study protocol / proposal:
  - study budget
  - billing information form, for industry-funded studies *
  - departmental approval form *
- As applicable per the study design:
  - informed consent / assent forms
  - investigator brochures / product monographs for the study drugs
  - recruitment materials such as posters, web pages, etc.
  - letters of initial contact with participants
  - questionnaires, cover letters, surveys, tests, interview scripts, etc.
  - Health Canada No Objection Letter *

** Do not need to be submitted to HREBA with the initial study submission, but must be received before final approval of the study is granted.*

The use of the following consent templates is mandatory for studies which do not include a pediatric population:

- HREBA Cancer Committee Main Consent Template, for clinical trials;
- Informed Consent Form Template for Participation in a Research Study: Non-Clinical Trial Research, for non-clinical trails;
- Optional Research Consent Template, for studies which include optional research

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. For studies requiring full board review, a deadline will be noted in the administrative change request. If the missing information / documents are not provided by the deadline, the study will not be reviewed at the next full board meeting. Note that notifications sent by IRISS are system generated and do NOT correspond with the deadline provided by administrative staff.

In order to be considered for review at a meeting, applications must be received by the submission deadline for that meeting. Cancer Committee deadlines in 2018.

### 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 HREBA Standard Operating Procedure (SOP) 401: Delegated Review.

Multisite applications

When the same research protocol is undertaken at two or more sites which receive ethics review through HREBA, the multisite process applies. This process 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 certificate. Do not add the version number and / or date as part of the document name, 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.

Billing Information

If your study is funded by industry, HREBA charges a fee for the initial review. A study which receives full board review is charged $4000, while a study which receives delegated review is charged $1000.

Please complete the HREBA Billing Information Form with your submission so an invoice for the review fee can be sent.

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 |
|---|---|---|
| SOP 403.001G | 01-July-2016 | Original version |
| SOP 403.002G(a) | 01-July-2016 | Version 2; updated hyperlinks |
| SOP 403.002G(a) | 21-Nov-2016 | Added explicit instruction that all studies must be received by submission deadline.<br>Added hyperlink to 2017 dates and deadlines. |
| SOP 403.002G(a) | 01-Feb-2018 | • Minor updates to language, deletion of outdated information, update to links<br>• Added information re: U of C IRISS system<br>• Specified mandatory documents for submission and mandatory consent templates<br>• Added link to multisite application process<br>• Added ethic review fee and billing information |