

Steps in the CFREB Application Process

Overview

As per TCPS2, [Article 6.1](#), “Institutions shall establish or appoint an REB (or REBs) to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with this Policy.” This means that if research will be conducted under the auspices of University of Calgary (UCalgary), then an application needs to be submitted through IRISS; e.g., if the Researcher is using the UCalgary name, research is being conducted at UCalgary or resources from UCalgary are used for recruitment or data collection.

If a Researcher has various affiliations (e.g., is cross-appointed at different institutions, including UCalgary), and would be using that UCalgary affiliation, applications through IRISS would still be required. When a researcher does not have a UCalgary institutional affiliation, appropriate permissions must be sought from the REB to recruit on UCalgary premises. These cases are reviewed on a case-by-case basis.

Steps:

1. Creation and Submission of Application

Applications for New Ethics Certifications are facilitated through IRISS, an online system that manages all human ethics and animal care protocols at the UCalgary. All applications are electronic and submitted online using IRISS (www.ucalgary.ca/iriss); Student Researchers, Academic Faculty, and Staff can use their UCalgary IT account to access IRISS. Applications created in IRISS are in the “Pre-submission” state up until they are submitted. New applications may only be submitted by the Principal Investigator. Please note that only applications that are submitted will be reviewed.

When submitting your application, be sure to include all associated participant-facing and contextual documentation (e.g., consent forms, recruitment notices and scripts, interview questions, debriefing information, letters of permission, letters or correspondence of acknowledgement, data sharing agreements etc.).

We have a number of resources listed on our [web page](#), you may find the document “Common Issues and How to Avoid Them” on the CFREB webpage for advice and tips to facilitate the review process.

Along with New Certifications, the IRISS system also allows you to submit study Modifications (e.g., any changes such as increasing the sample size or adding a new recruitment method, as long as this does not change the study research question), Renewals (certifications need to be renewed at least annually to remain active), and Reportable Events (any complaints or deviations from the study protocol are reported).

To determine if you need to complete a full application or a Modification, please see the 'New Certification vs. Modifications' document under the 'Application Documents' section of the CFREB web page. <https://research.ucalgary.ca/conduct-research/ethics-compliance/human-research-ethics/conjoint-faculties-research-ethics-board-cfreb>

For information about creating and submitting modifications, please see the 'Modify Your Study' under the Research Ethics web page <https://research.ucalgary.ca/iriss/iriss>

2. Review of Full Applications

Once submitted, applications are checked by Research Ethics Analysts (REA) for completeness through an administrative review. If the application is judged to be below minimal risk, a substantive review is conducted next by a CFREB Board Member who serves as a Delegated Reviewer. The application receives a final review by the CFREB Chair.

Applications are reviewed in the order they are received, but the timeline in which they are reviewed depends upon the volume of applications under review. Please review our web page for approximate current submission times.

Applications judged to be greater-than-minimal risk (exposing the participants to greater risks than they would experience in their everyday life) are reviewed by the entire CFREB Board. The CFREB Chair, Co-Chair, REA and Board member(s) with relevant expertise will discuss if the file is above minimal risk and requires Full Board review.

The CFREB Board comprises of faculty members from various departments and disciplines, community members, and student representatives. The CFREB meets on the first Friday of each month (with the exception of statutory holidays). The schedule of CFREB meetings and submission deadlines is listed on the CFREB web page "CFREB Meeting Dates and Board Members." If you believe your research will involve a greater than minimal risk, then you should plan to submit your application before the submission deadline (2 weeks before the scheduled monthly meeting) to ensure that it is reviewed at the next meeting. The schedule of CFREB meetings and submission deadlines is listed on the CFREB web page.

3. Feedback and Revision of Application

For applications judged to be of minimal risk, an REA, a delegated reviewer (Board member), and the Chair will provide feedback on your application via IRISS. The feedback will include questions from the Chair and a description of the revisions that will be necessary to receive approval, including uploading any requested document revisions (consent forms, etc.). Please note that requested changes will relate to the ethical feasibility of your study. This review is not meant to evaluate or alter your study design or methodologies; however, if a method is used without appropriate considerations about how it may

impact participants, you may be asked to account for these considerations in your risk mitigation strategies.

You will receive a system-automated email when your review is complete, after which you can respond to feedback via IRISS. Your revised application is then reviewed by an REA and the Chair and approved subject to the acceptability of the revisions. Please note that there is no deadline to re-submit changes to a study, but you will receive system automated messages providing reminders and deadlines to submit by. You are not obligated to re-submit within a certain time period, but in the case that there are no changes made to the file, it will become inactive and move into a 'dormant' state.

If your application required Full Board review, you and your study team will be invited to attend an upcoming CFREB Full Board Meeting. Prior to the meeting, you will receive a memo from the Chair (via email) that details the Board's concerns. The Full Board meeting will serve as an opportunity for you to provide a brief summary of the file, respond to the Board's concerns noted in the memo, answer Board Members' questions, and have a discussion with the Board about the best ways to move forward.

You will receive post-meeting comments via IRISS. Applicants can respond to this feedback in IRISS by making changes to the application, including uploading any revised documents (consent forms, etc.). Your revised application is then reviewed by the Chair and approved, subject to the acceptability of the revisions. Applications requiring extensive revisions may need to be reviewed by the full CFREB Board again prior to approval.

4. Approval of Application

Your application can be approved when the CFREB is satisfied with all the necessary changes to the application have been made. When approved, you will be issued an approval certificate. These documents will be issued electronically and will be available in IRISS for downloading and printing. Certificates are issued for a period of one-year and must be renewed annually (described below) if the research will continue beyond the one-year approval period.

For more information about Renewals, please see the 'CFREB Renewal Guidance Document' listed under the 'Application documents' tab on the CFREB [Web page](#). As renewals are to be submitted on an annual basis, you will receive system automated reminders via email to submit your renewal. You can create a renewal and submit it the same way you would a new certification, but in order for the Renewal to be processed, you must formally 'submit' it. If a renewal is not submitted by the file expiry date, please see the 'Expired Ethics Certification' Guidance document under the 'Application documents' tab on the CFREB web page.