

Carleton Research Ethics Board Update June, 2025

The purpose of this newsletter is to provide you with periodic updates on REB activities, new policies and forms, and other pertinent information. In these update newsletters, you will also find guidance and support on how to prepare and submit your ethics applications, and manage your ongoing protocols.

Visit Office of Research Ethics Website

Revised Main Consent Form Template

We have revised our main consent form template, which can be found here:

https://carleton.ca/researchethics/wp-content/uploads/Final.-Consent-Form-Template-2025-03-05.docx.

In the updated template, we have included more detailed instructions regarding the future use of data, future requests by others for access to the data, or the public posting of study data, as these are increasingly required for publication or presentation of study findings. Further discussion of this issue is available in our November 2023 Newsletter, archived here:

https://carleton.ca/researchethics/wp-content/uploads/Nov-2023-Newsletter.pdf.

We encourage researchers to make realistic provisions in their study plans and consent forms for future use of study data, including public posting and making deidentified data available to other researchers. We have observed that some researchers with completed studies did not initially provide adequate provisions for the future use of data, which may be necessary for publication by journals, conference presentations, or legitimate requests for future use of their data.

If you wish to use or share study data in a manner not anticipated in the original consent form, and therefore not agreed to by study participants, you must submit a Change to Protocol for that study describing the proposed data sharing and its justification. If the study needs to be re-opened to facilitate this change, the REB Office can assist with that. The REB will review such proposed uses based on the "alteration to consent" criteria in TCPS Article 3.7A.

Change of Policy: Non-Substantive Amendments

As of June 1, 2025, the REB only requires the review of *substantive* amendments to be submitted through the Change to Protocol Form. Non-substantive amendments do not need REB review prior to being initiated, but should be summarized, with revised documents attached and changes indicated, in the next annual renewal by ASR.

Most amendments made to studies are substantive and include those that make any non-trivial changes to the study population, recruitment methods, terms of the consent, changes to study methodology, risks to participants, and changes to identifiability, confidentiality, or protection of privacy of study participants and their data. All changes to study personnel are substantive and need to be reviewed and cleared prior to making the change. Examples of non-substantive changes include minor changes to the sample size, minor wording changes, or changes to the timing of study activities or milestones, so long as these do not adversely affect the risk or voluntary, informed consent of participants.

Research Involving Indigenous Peoples and Communities

The Carleton Office of Research Ethics is working with Ānako, Carleton's Indigenous Research Institute, to create an Indigenous Research Ethics Board, to ensure that research involving Indigenous Peoples and Communities is carried out in a respectful and culturally appropriate way. This initiative is in progress, and we hope to announce details soon.

Until then, Indigenous research protocols should continue to be submitted as usual through the CUResearch platform. We remind Carleton faculty and students

proposing to carry out Indigenous research that consultation with affected Indigenous Communities must be concluded or substantially concluded, and the results described, *prior to* submitting your protocol. Among other provisions, Chapter 9 of the TCPS requires consultation with affected communities and substantial agreement about how the research will be carried out. It is not enough to say, in section 5 of your submission, that consultation *will be* carried out in future with affected communities. Consultation and substantial agreement must be in place already and we will generally ask for a letter or email from affected communities expressing support for the project and agreement with the aims and methods of the study, including agreement under OCAP principles relating to the use and ownership of study data.

Please don't hesitate to contact us for more information at ethics@carleton.ca.

