



RESEARCH ETHICS BOARD

GUIDELINES for COMPLETION of a REQUEST FOR AMENDMENT OF AN APPROVED PROJECT (FORM 5), ANNUAL RESEARCH STATUS REPORT/RENEWAL REQUEST (FORM 6), FINAL REPORT, TERMINATION or COMPLETION (FORM 8)

FOR RESEARCH INVOLVING HUMAN SUBJECTS AND THEIR PARTICIPATION IN
QUESTIONNAIRES, INTERVIEWS, OBSERVATIONS, TESTING, VIDEO & AUDIO TAPES, ETC.

INTRODUCTION

The following notes are provided to assist in the completion of the *Request for Amendment of an Approved Project (Form 5)*, *Annual Research Status Report/Renewal Request (Form 6)* and *Final Report, Termination or Completion (Form 8)* for the Research Ethics Board (REB).

The REB's procedures and policies comply with the Tri-Council Policy Statement (TCPS), which states a need for continuing review of ongoing research. It says specifically that "continuing review should consist of at least the submission of a succinct annual status report to the REB" and that the report should "...include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed".

REQUEST FOR AMENDMENT OF AN APPROVED PROJECT (FORM 5)

An amendment is a minor change to an ongoing previously approved project. If the original research project has been completed, similar research must be submitted on a new Application for Ethical Review. Completion of a research project is defined as follows: Procedures and data collection described in the original application have been completed, data analyzed and findings have been published (i.e. reported to others).

When is an amendment not appropriate?

Significant changes in the selection of study participants, the nature, number or content of questions studied, and changes in the experimental intervention or manipulation all exceed the requirements for amendments and must be submitted as a new proposal.

The following questions should be considered when proposing an amendment:

- Does the amendment affect the risk/benefit ratio?
- Does the amendment affect recruitment? If so, is a revised recruitment ad or letter attached?
- Does the amendment affect what the subject is asked to do, or the confidentiality of the data? If so, is a revised consent form attached?
- Does the consent form adequately reflect the change in time, risk, or confidentiality?
- When reviewed initially did the REB have any significant concerns about the study that should be considered when reviewing the amendment?

If the proposed amendment increases the level of risk to study participants, the amendment application should be submitted for full board review, along with a copy of the original application. New procedures that must have full board review include those that involve: a sensitive topic, action research, deception, initial contact by telephone, database linkage with identifiers, oral or passive consent, minors (less than 19 years of age), those unable to be fully informed, and videotaping.

Completion of Form 5

- 1 – 8 Please provide pertinent information.
- 9 – 11 If you have received a new grant or contract to support an ongoing previously approved project, you may use this form to add a new sponsor, title or time period to the existing file.
- 12 - 13 Please indicate where this research is being carried out and the positions/titles of all involved in performing the project.
- 14 – 17 Please obtain all appropriate signatures. Original signatures are required for the principal investigator and student (if the project is part of a student program). Every effort should be made to obtain original signatures from co-investigators and the Okanagan College (OC) administrative head (in the case of a faculty project) and faculty dean (in the case of a graduate student project), but if this cannot be accomplished, fax or e-mail copies will be accepted.
18. Check any areas of study design that have changed.
19. Check any study documents that have been revised. Attach a copy of any amended documents with the changes highlighted in bold type or underlined. Remember to include a new version date on all amended documents.
20. Provide information on new investigators, co-investigators or graduate students. Obtain the signatures of any new study personnel. Original signatures are required for any new researchers. Indicate the title, position and affiliation of any new personnel.

Note: the name of the principal investigator on the initial Certificate of Approval can only be changed at the original principal investigator's written request. Otherwise, a new Application for Ethical Review must be submitted. The principal investigator cannot be changed on only part of the research; the entire record **MUST** be changed. The original principal investigator should sign Page 1 (item 14) of this amendment request form and the new principal investigator should sign on Page 2, in item 20.

21. If the study title has been changed, include the new title.

Note: In all cases there must be an exact match of title and funding agency or company between the grant application, or funded project, and the Certificate of Approval. Use this form to add a new title or agency to the record.

22. If the source of funding support has changed, please provide the new funding information.
23. Describe any changes to the original study. Explain why these changes are necessary. Attach copies of any amended documents (questionnaires, consents, etc.).

24. List and attach all documents relevant to the proposed amendment.

Number of copies

Two copies of the completed form (one with original signatures) and any attachments are required.

Submission of amendments

Submissions should be forwarded to the REB Office, Centre for Learning Building, E-416, KLO Campus.

Approval of an amendment will not affect the anniversary date of the original approval.

ANNUAL RESEARCH STATUS REPORT/RENEWAL REQUEST (FORM 6)

An Annual Research Status Report/Request for Annual Renewal should be submitted before the anniversary date of the original approval. This report should only be submitted if the project is still underway. If the project has been completed, please submit a Final Report, Termination or Completion (Form 8).

Please note that the researcher is obligated to continue to adhere to all stipulations regarding the use of and confidentiality of the data described in the original application, and not to use the data for other research purposes without application to and approval by the OC Research Ethics Board.

When is an annual review not required?

When the researcher will have no further contact with subjects for the purpose of data collection or research (e.g. for follow-up or verification) a review is not required. Renewal is also not required to analyze data or write a paper - please submit a Final Report, Termination or Completion (Form 8). However, if the project is supported by a research grant or contract funds, annual review is required for the duration of the grant or contract.

Completion of Form 6

- 1 – 11 Please provide pertinent information.
- 12 Please indicate if there have been any unexpected difficulties. If there have been difficulties or complaints, please explain the nature of the problem(s) and how you responded to them.
- 13 Please indicate if there have been changes to the original proposal. If the proposal has been changed, a Request for Amendment of an Approved Project (Form 5) should be submitted.
- 14 Indicate the number of subjects enrolled in the study to date and the number who have withdrawn.
- 15 Provide a brief summary of the progress of the study.
Copies of current consent forms should be attached to this renewal application.
- 16 – 17 Original signatures are required for the principal investigator and student (if the project is part of a student program).

Number of copies

Two copies of the completed form (one with original signatures) are required.

Deadline

Submissions should be forwarded to the REB Office, Centre for Learning Building, E-416, KLO Campus.

NOTE TO RESEARCHERS: If this form is not received within one month of the one year anniversary of your original ethical approval, your approval will automatically cease. **This form must be submitted every twelve months in order to maintain ethical approval. A new Application for Ethical Review must be submitted for projects for which approval is still needed four years following the original approval.**

FINAL REPORT, TERMINATION OR COMPLETION (FORM 8)

A Final Report, Termination or Completion (Form 8) should be submitted when contact with subjects for the purpose of data collection or research (e.g. for follow-up or verification) is complete. Form 8 should be completed and submitted before the expiry date of the project's current Certificate of Approval. This ensures that the REB has an up-to-date and accurate record of ongoing studies involving human subjects.

If the project is terminated prematurely (before the research proposed in the original application is complete), please complete and submit Form 8 to indicate the reason(s) for termination.

Please note that following completion or termination of a project, the researcher is obligated to continue to adhere to all stipulations regarding the use and confidentiality of the data described in the original application and not to use these data for other research purposes without application to and approval by the OC Research Ethics Board.

Completion of Form 8

- 1 – 10 Please provide pertinent information.
- 11 - 12 Original signatures are required for the principal investigator and student (if the project is part of a student program).
- 13 – 16 Please provide information on recruited study subjects. If there were any problems with recruitment, please outline.
- 17 Indicate all of the instruments used in the study.
- 18 Complete the declaration that the remaining research no longer requires certification because all data collection procedures described in the previously approved project have been completed.

Storage and retention of data and records

Indicate how long research records will be stored, how they will be stored and how they will be disposed of.

Summary of Final Report

Please attach a brief summary (approximately 200 words) describing your research findings. If an abstract for a presentation or an executive summary from a written report is available, you may attach this instead.

Number of copies

Two copies of the completed form (one with original signatures) and any attachments are required.

Submissions

Submissions should be forwarded to the REB Office, Student Services Building, Registrar's Office, KLO Campus.