

GUIDANCE NOTES FOR REQUEST FOR RENEWAL OF A PREVIOUSLY APPROVED PROJECT

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INTRODUCTION

The following notes are intended to assist researchers with completion and submission of a Request for Annual Renewal form.

The UBC REBs conduct continuing review of research taking place within their jurisdiction at intervals appropriate to the degree of risk, but not less than once per year. UBC Policy 89

<http://www.universitycounsel.ubc.ca/policies/policy89.pdf> the TCPS

<http://www.pre.ethics.gc.ca/eng/policy-politique/tcps-epc/>

the ICH-GCP's <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>

the US DHHS <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

and the FDA http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html

Federal Regulations all mandate that the REB must require a progress report from the responsible investigator on at least an annual basis.

Article #1: What Researcher Need to Know to Submit a Request for Renewal Form

1.1. REB Policies on Consent Form Requirements

The annual review conducted by the REB includes ensuring that any consent forms used in the study under review reflect the current policies of the REB with respect to consent form requirements.

1.2. Expiry Dates of Studies

A Certificate of Research Ethics Approval will be valid for no longer than a **one-year term**. This means that at a minimum, approved studies must be re-reviewed on or before the one-year anniversary date of the previous REB review. Subsequent renewals of approval will expire on the one-year anniversary date of the previous REB review.

Amendments approved after the initial approval/renewal date also expire at the same time as the initial approval/renewal of the study.

Requests for Annual Renewal of a Previously Approved Project must be submitted by the Principal Investigator until the study can be considered closed by the REB, and until a Notice of Completion Form is received and acknowledged by the REB. All ongoing projects must have a valid ethics approval. See the [Guidance Notes For Notification Of Study Closure](#) to determine when a study may be submitted for closure and annual progress/renewal requests may be discontinued.

1.3. Automated Email Reminders

Automated emails reminding the Principal Investigator and Primary Contact that the Certificate of Research Ethics Approval will be expiring are generated at the following intervals:

- six weeks prior to expiry
- two prior to expiry, and
- on the day that the Certificate of Research Ethics Approval is no longer valid.

It is the responsibility of the Primary Investigator to request on-going review or submit a Notice of Completion Form to the REB prior to expiry. See section 1.5. Timelines for Submitting Renewal Requests.

1.4. On-Going Review at the Request of the Investigator

Annual renewal of studies may always continue at the request of the investigator. This may occur, if for example, the investigator believes that there may be a future need to obtain more data for a research project.

1.5. Timelines for Submitting Renewal Requests

The Principal Investigator is responsible for submitting the application for annual renewal to the REB office in a timely manner. **The REB office should receive the submission in advance of the expiry date of the study (the expiry date is noted on the Certificates of Approval and in the RISE system).** This will ensure that the Principal Investigator has time to respond to any concerns raised by the REB before the approval certificate expires.

- **Renewals requiring expedited (delegated) review** should be submitted 2 weeks in advance of expiry.
- **Renewals requiring full board review** should be submitted by the deadline date for the applicable REB full board meeting. See [BCCA REB Deadline & Meeting Schedule](#). If an annual renewal requires full board approval the Investigator is responsible for ensuring that the application is submitted by the appropriate REB meeting deadline.

1.6 Simultaneous Submission of Amendments

The RISE system may indicate two form options;

Option 1: 'Annual Renewal'

Option 2: 'Annual Renewal with Amendments' (*not an option for submission to UBC BCCA REB*)

For all UBC REBs: Do not use the 'Annual Renewal' form for amendments.

For UBC BC Cancer Agency REB: The form Option 2; 'Amendment with Annual Renewal' form is not available. Instead a separate "annual renewal" form and a separate "amendment form" may be submitted simultaneously and each may be individually marked for either full board or expedited review. This allows the REB to process one or the other independently. The Certificate of Approval for each submission will be issued separately.

For studies submitted to the UBC Clinical Research Ethics Board (CREB) or UBC Behavioural Research Ethics Board (BREB), amendments may be submitted with, and will be reviewed at the same time as, a request for Annual Renewal, using the 'Annual Renewal with Amendments to Study' form. For CREB and BREB studies, the Certificate of Annual Renewal will include the approval of any amendments if these were submitted at the same time as the request for annual renewal.

1.7 Whom to Contact For Assistance

Questions regarding the preparation of an Annual Renewal submission can be directed to:

BC Cancer Agency Research Ethics Board - (604) 877-6283 or (604) 877-6223 or email reb@bccancer.bc.ca

Providence Health Care Research Ethics Board - (604) 682-2344 ext. 63496 or email VBearder@providencehealth.bc.ca

Clinical Research Ethics Board - (604) 875-4111 ext.68918 or email creb.rise@ors.ubc.ca

Behavioural Research Ethics Board - (604) 827-5114 or email nadia.rad@ors.ubc.ca

Children & Women's Health Centre Research Ethics Board – (604) 875-3103 or email cwreb@cw.bc.ca

UBC Okanagan Research Ethics Board – (250) 807-8832 or email Kristen.kane@ubc.ca

ARTICLE #2: SUBMISSION CRITERIA FOR FULL BOARD or EXPEDITED APPROVAL

2.1. Delegated/Expedited Approval

[TCPS Article 1.6](#) stipulates that the REB can delegate the authority for the approval of annual renewals to the Chair (or designate) of the REB when “there has been little or no change in the ongoing investigation”. If this criterion is met and provided that the study Sponsor, Funding Agency or Regulatory Agency (see 2.2. below) does not require that annual review be conducted by the convened REB the Chair (or designate) will review the request for approval under the category of ‘Delegated Review’.

The Chair (or designate) can at any time put a request for annual renewal forward to the Full Board.

2.1.1. Timelines for Expedited (Delegated) Review

The time from submission of a renewal application to review will vary according to the volume of submitted renewals as well as amendments, which is why Investigators are advised to submit the Request for Annual Renewal at least two weeks prior to the expiry date of the previous approval.

2.1.2. Issuing REB Decisions

All decisions arising from the review are emailed to the Principal Investigator and the contact person identified in Question #1.2 of the Application for Initial Review. A certificate of Approval is provided by a hyperlink to it noted on the application homepage in RISE, as well as on the Renewal submission, and this constitutes the REB's official notification of the decision.

2.2. Full Board Review

If there has been *more than* “little or no change” to a study or if the granting agency, study sponsor or regulatory agency requires it, the application for annual renewal will be reviewed by the convened (full) REB. These requirements are described below. If any of these apply, please ensure that ‘No’ is selected in Question #1.1 of the Application Form.

2.2.1. Sponsors that Require Full Board Review

Some sponsors, such as the NCIC Clinical Trials Group or the National Cancer Institute (U.S.) may require Full Board Review for renewal. Please review sponsor requirements prior to selecting Expedited (Delegated) or Full Board Review in Question #1.1 of the Annual Renewal Application Form and refer to Article #3 for details on the required documentation.

2.2.2. Studies sponsored by the United States Department of Health and Human Services

Studies sponsored by the [United States Department of Health and Human Services \(DHHS\)](#) (e.g. [NIH](#) and its related [Institutes](#), [US Center for Disease Control](#), etc.) may require Full Board Review under [45 CFR 46.109 \(e\)](#) and [45 CFR 46.110](#) (Code of Federal Regulations). Refer to [Guidance on the Use of Expedited Review Procedures](#) issued by the US Department of Health and Human Services for an interpretation of these codes as they apply to studies sponsored by the DHHS. Generally, if a study subject to these regulations was initially reviewed by Full Board Review, the annual renewal must also be conducted by the Full Board.

2.2.3. Studies sponsored by other United States federal agencies or subject to the US Food & Drug Administration regulations.

Studies that are funded by other American federal agencies (e.g. [US Department of Defense](#)) or that are subject to the US Food & Drug Administration Regulations may require Full Board Review under [21 CFR 56.110](#). Generally, if a study subject to these regulations was initially reviewed by Full Board Review, the annual renewal must also be conducted by the Full Board.

2.2.4. Timelines for Full Board Review

See Item 1.5 above.

2.2.5. Issuing REB Decisions

All decisions arising from the review are emailed to the Principal Investigator and the contact person identified in Question #1.2 of the Application for Initial Review. A certificate of Approval is displayed on the application homepage in RISE, as well as on the Renewal submission, and this constitutes the REB's official notification of the decision.

Article #3: Required Documentation

Monitoring or Summary Report: If a sponsor's summary or monitoring report is available, it should be attached to the annual renewal coversheet in RISE. For studies sponsored by the National Cancer Institute of Canada – Clinical Trial Group (NCIC-CTG) a copy of the recent NCIC CTG Data Safety Monitoring Committee Report must be attached or an explanation provided concerning why one is not available.

3.1. Certificate of Annual Renewal

For renewals approved by the REB Chair or designate (expedited or delegated review), the approval date on the Certificate(s) of Annual Renewal will be one-year from the date of approval by the REB Chair (or designate) as noted on the certificate of approval.

For renewals approved by the REB full board, the expiry date will be one-year from the full board meeting date at which the renewal was approved.

Industry sponsors/institutions that require renewal at a particular time before the expiry date must submit their application for renewal before this required date.

If the request for renewal is approved after the expiry date, the Certificate of Approval will be dated as noted above.

The Certificate of Annual Renewal will not be backdated for any reason.

Article #4: Progress of Study, Monitoring and Summary Reports

The summary of progress to date should include information about the status of the study and the status of subjects on the study. This should include whether subjects are still participating in the research study, especially, when in the case of clinical trials, the trial is closed to enrolment, the number of subjects enrolled and the status of all enrolled subjects (i.e., how many on active treatment, on follow-up, withdrawals, or deceased (and whether death was possibly related to the experimental treatment) . Remarks about the ability to recruit subjects are also appropriate (explain if accrual goal was met, or if accrual closed early and why, or an explanation should be provided if enrolment is slower than anticipated and what action is proposed. Any monitoring that has been done since the last review should be detailed, together with a summary of the results and any specific steps that the Investigator will take in the next review period to ensure that there is on-going ethical conduct of the study.

Article #5: Summary of Serious and Unexpected Adverse Events

The Principal Investigator is responsible for summarizing the impact of any Serious AND Unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the sponsor for other sites in multi-centre trials.

Article #6: New Information, Changes in Conflict of Interest and Opinion on Renewal

New Information is anything that might adversely affect the safety or well-being of the study participants or the conduct of the study, or the participant's willingness to continue in a study, including any information that might alter the REB's approval or favourable opinion to continue the study. The Investigator is responsible for describing any new information that may change the scientific / ethical background, relevance or validity of the study since the last review. This includes any relevant recent literature, interim findings, preliminary results or amendments or modifications to the research since the last review. While the REB will determine in its discretion whether the study should be continued, the opinion of the Investigator concerning this is important information for the REB's in making its determination.