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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 301

TITLE	**301: Research Submission Requirements**
SCOPE	The activities of the Research Ethics Boards operating under the direct authority of the University of British Columbia
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011, April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to outline the required documents and supporting information required from investigators for REB submission and review. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research and any new information.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

REB members must rely solely on the documentation submitted by investigators, or other parties for initial and continuing review. Therefore, this material must provide REB members with sufficient information about a study to assess if it adequately meets the REB's criteria for approval. A submitted protocol will be scheduled for REB review only when the REB Office

Personnel determines that the information and materials submitted present an adequate description of the proposed research.

Each UBC-affiliated REB requires that applications for initial and continuing review of human participants research be submitted using the Researcher Information System (RISe) online database.

3.1 Submission Requirements for Initial Review

3.1.1 Submission requirements for initial review are outlined in the REB Application Form[1] and the accompanying Guidance Notes[2]. Investigators applying for initial approval of proposed research must follow the guidance notes and complete the online application form as required by the RISe system;

3.1.2 All sections of the RISe Application Form, including all required accompanying documentation, must be completed. Electronic signatures from both the Principal Investigator and the Department Head/Dean approving the study are required or the application will not be forwarded to research ethics administration for review assignment;

3.1.3 REB Office Personnel will review each application for completeness. If there are elements missing, the investigator will be notified by REB Office Personnel, and applications will not be assigned for review or consideration at an REB meeting until all required documents are received;

3.1.4 The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;

3.1.5 **Research Requirements:** The research question and methodology is written in sufficient detail to permit evaluation of the merit of the project. The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology;
- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Treatment allocation (if applicable),
- Primary and secondary outcome measures,
- Assessment of safety,
- Sample size justification,
- Data analysis,
- Data monitoring.

3.2 Submission Requirements for Continuing Review

During the term of the approval and the conduct of the research study, investigators must submit documentation to inform the REB about changes in the status of the study. Submission requirements are outlined in the Post-Approval Activity form for study Amendments[3]. Revisions to documents such as consent forms must be tracked using track changes, highlighted, underlined or in bold text.

3.2.1 Submission Requirements for Requests for Acknowledgement

In some instances, Investigators require acknowledgement of certain study related details including the submission of unanticipated problems, protocol deviations, safety letters, notification that a study is on hold, off hold, closed to accrual/enrolment and other miscellaneous information. Submission requirements are outlined in the Post-Approval Activity (PAA) - Request for Acknowledgment form[4]. The Request for Acknowledgment form is used by the Investigator to report any incident, experience or outcome that could result in increased or different risks to the participants that were not anticipated/expected/and/or that were not described in the original application, including serious and unexpected adverse events This includes any new information that might adversely affect the safety or well-being of the study participants including new information or literature that has come out of other studies that could potentially adversely affect study participants;

3.2.2 Submission Requirements for Requests for Information

During or after the review process, the REB may require additional information from the Investigator. Investigators are required to complete a response to Request for Information form;

3.2.3 Unanticipated Problem Reporting

During the conduct of a study which is a clinical trial, all local adverse events that are deemed to be unanticipated problems must be reported to the REB in accordance with applicable regulations and guidelines. Submission requirements are outlined in the Guidance Notes for Request for Acknowledgement[5] and the Post-Approval Activity – Request for Acknowledgement form;

3.2.4 Annual Progress Reports / Requests for Renewal

Prior to the relevant REB approval expiration date, Investigators requesting renewal of an approved research project must submit a completed Post-Approval Activity (PAA) – Annual Renewal. All of the submission requirements are outlined in the PAA - Annual Renewal form[6].

The RISe online system sends out automated reminders 60 days, 45 days and 14 days ahead of the current approval's expiry date, as well as on the actual date of expiry. It is the Principal Investigator's responsibility to submit the application for annual renewal to the REB office in a timely manner.

3.3 Documentation is not Adequate or Additional Information is Required

3.3.1 If the REB or REB Office Personnel determines that the submitted documents are not adequate, investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No substantively incomplete submission will be reviewed by the REB.

3.4 Deadlines and Timelines

3.4.1 Application deadlines vary depending upon which UBC REB will be reviewing the application. Timelines are provided in the REB Guidance Notes and on the applicable UBC Research Ethics Board's website[7].

3.5 REB Administration Fee

3.5.1 An administration fee of $1000 - $4000 shall be levied for all private industry-sponsored research projects submitted for REB review. All new studies submitted for initial ethics approval to a clinical REB will be subject to an annual renewal fee of $500 when they are submitted for annual renewal.

Questions regarding payment details may be directed to REB Office Personnel.

4.0 REFERENCES

1. *UBC Research Information Services (RISe) online system:*
https://www.rise.ubc.ca/

2. *UBC Behavioural Research Ethics Board (BREB) Guidance Notes:*
https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes
UBC Clinical Research Ethics Board (CREB) Guidance Notes:
https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes

3. *UBC BREB Post-Approval Activity (PAA) Guidance Notes:*
https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes

UBC CREB Post-Approval Activity (PAA) - Amendment Guidance Notes:

https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#amendments

4. *UBC BREB Post-Approval Activity (PAA) Guidance Notes:*
https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes

UBC CREB Post-Approval Activity (PAA) – Acknowledgement Guidance Notes:
https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#acknowledgement

5. *UBC CREB Guidance Notes for Unanticipated Problems:*
https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#unanticipated

6. *UBC CREB Post-Approval Activity (PAA) – Renewal Guidance Notes:*
https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#renewals

UBC BREB Post-Approval Activity (PAA) Guidance Notes:
https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes

RISe - Post-Approval Activity Sample Forms:
https://www.rise.ubc.ca/sample-forms-and-rise-sandbox

7. *UBC Behavioural REB Meeting Dates and Deadlines:*
https://ethics.research.ubc.ca/behavioural-research-ethics/breb-meeting-dates-deadlines

UBC Clinical REB Meeting Dates and Deadlines:
https://ethics.research.ubc.ca/clinical-research-ethics/creb-meeting-dates-deadlines

8. *UBC Clinical REB Guidance Notes regarding Fees:*
https://ethics.research.ubc.ca/clinical-research-ethics/creb-fees