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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 402

TITLE	**402: Delegated Review**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Office of 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, March 2010, April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the research that can be reviewed by the REB chair or designate and outlines the process to determine if the research meets criteria for delegated review, and the associated delegated review procedures.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

An expedited/delegated review procedure consists of a review of research involving human participants by the REB Chair or by one or more experienced reviewers designated by the Chair from among members of the REB. Full review by an REB should be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide

a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research[1].

The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

The REB delegates research ethics review to an individual or individuals. Delegates shall be selected from among the REB membership with the exception of the ethics review of student course-based research. This can be delegated to the department, faculty or equivalent level as indicated below.

Research that may be reviewed by the REB through a delegated review procedure normally includes research activities that present no more than minimal risk to human subjects, and minor changes in approved research. This SOP pertains to both initial and continuing REB review of the items included in this SOP.

3.1 Definition of Minimal Risk

3.1.1 Minimal risk research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research[2];

3.1.2 For studies that are funded or supported by the U.S. federal government or regulated by the U.S. Food and Drug Administration (FDA), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests[3];

3.1.3 Minor changes are changes that neither increase the risk, nor materially change the risk-benefit ratio of the research study and do not substantially change the specific aims or design of the study;

3.2 Determination of Qualification for Delegated Review

3.2.1 Full Board review is the default for most new research projects submitted to the REB; however, some research may be eligible for delegated review;

3.2.2 Studies that are funded or supported by the U.S. federal government or regulated by the U.S. Food and Drug Administration, are eligible for expedited/delegated review if listed in the OHRP and FDA guidance and are no more than minimal risk, or include only minor changes in previously approved research as defined by the applicable regulations and in UBC's SOPs[4];

3.2.3 Submissions that meet the following criteria may be eligible for delegated review:

- Research projects that involve no more than minimal risk,
- Minor or minimal risk changes to approved research,
- Continuing review of approved minimal risk research,
- Continuing review of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB; if permissible under all applicable governing Regulations,
- The submission by the Researcher in response to the REB review as a condition of approval, as authorized by the Board,
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB)[5]. If the REB Chair or designee considers that action is needed to protect the safety of research participants, he/she may take such action immediately and/or request a review of the report at a convened REB meeting or by a designated sub-committee to determine what further action, if any, is required;

3.2.4 The REB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following: Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,

- Authorized translations of English versions of documents previously approved by the REB;

3.2.5 The REB Chair or designee may be authorized by the Full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

3.2.6 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable;

3.2.7 Examples of categories of research that may be delegated for research ethics review include:

- Research that is confidently expected to involve minimal risk;
- Minimal risk changes to approved research;
- Annual renewals of approved minimal risk research;
- Annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis.

3.3 Delegated Review Process

3.3.1 Qualified REB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the REB may be forwarded for delegated review. For all other submissions, the REB Chair or designee will make the determination of whether the submission meets the criteria for delegated review;

3.3.2 For research that meets the criteria, delegated review may be conducted by the REB Chair, or by one or more qualified REB members as designated by the REB Chair or designee;

3.3.3 The REB Chair or designee reviewing research under delegated review must not have a conflict of interest in the research;

3.3.4 In reviewing the research under delegated procedures, the REB Chair or designee may exercise all of the authorities of the REB, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;

3.3.5 REB member(s) conducting a delegated review will contact the REB Chair or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;

3.3.6 If the REB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review;

3.3.7 The REB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring FB or delegated review) and the outcome of the review. The responsible REB Office Personnel may issue the review or decision letter.

3.4 Notification of the REB

3.4.1 At its next Full Board meeting the REB will be informed of research that was reviewed and approved using delegated review procedures.

3.5 Documentation

3.5.1 The type of REB review conducted (i.e., Full Board or delegated) is documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;

3.5.2 The Principal Investigator and the Primary Contact will receive an email notification of the REB decision via the RISe system;

3.5.3 The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous REB meeting was issued.

4.0 REFERENCES

1. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 2, Article 2.9:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6, Article 6.12:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.12

2. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 2, Part B:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1b

3. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.102(i)):*
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.102(i)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.102

4. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.110):*
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110
U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.110):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.110
U.S. Food and Drug Administration, Regulations Relating to Good Clinical Practice and Clinical Trials:
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulationsU.S

Office for Human Research Protections, Expedited Review Procedures Guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-expedited-review-procedures/index.html

5. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, (*ICH-GCP 3.3.9*): http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a3.3