University of British Columbia REBs Standard Operating Procedures

Section 100: General Administration

101: Authority and Purpose

1	Purpose:	The purpose of this standard operating procedure (SOP) is to: 1. State the institutional authority under which the REB is established and empowered. 2. Define the purpose of the REB 3. State the principles governing the REB to assure that the rights and welfare of subjects are protected 4. State the authority of the REB 5. Define the relationship of the REB to other committees and to officials within the University system
3	Procedure:	3.1 Statement of Institutional Authority 3.2 Purpose of the REBs 3.3 Governing Principles 3.4 REB Authority
4	Specific Policies:	4.1 Federally Funded Research 4.2 U.S. Federally Funded or U.S. FDA Regulated Research 4.3 Relationship of the REB to Institutional, Hospital and Health Agency officials and other committees 4.4 Board of Record Agreement 4.5 Use of Policies and Procedures 4.6 Authorization

102: Activities Requiring REB Review

1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe specific research activities that require REB review, and conversely, those activities that do not require REB review.
3	Procedure:	All research involving human subjects (as defined below), and all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by a UBC affiliated REB. No intervention or interaction with human subjects in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, consent documents and recruitment materials. Specific determinations as to the definition of "research" or "human subjects", and their implications for the jurisdiction of the REB under University of British Columbia policy are determined by the REBs. Determination of exemption from REB review must be based on regulatory and institutional criteria.
3	Specific Procedures:	3.1 Research that Requires REB Review 3.2 Research Exempt from REB Review 3.3 Activities Not Requiring REB Review 4.0 Failure to Submit Project for REB Review

103: Policies and Procedures Maintenance

1	Purpose:	The purpose of this standard operating procedure (SOP) is to state the REB's commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles regarding the conduct of research with human participants.
3	Procedure:	Following the regulations and guidance of Health Canada's Food and Drugs Act, ICH-GCP, (where applicable) U.S. Federal Regulations, and the Tri-Council Policy Statement, supported by institutional policies, assures that the rights and welfare of human research participants will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures must be in place to ensure that the review, oversight, and documentation of research involving human participants is of the highest quality and integrity. Standard operating policies (SOPs or Policies) and procedures provide the framework for the ethical and scientifically sound conduct of research involving human participants.
4	Specific Policies:	4.1 Development, Review, Revision, Approval of Policies and Procedures 4.2 Policy Dissemination and Training 4.3 Forms, Memos and Guidance Documents

104: Training and Management of REB Members and Office Personnel		
1	Purpose:	This policy describes training and education for REB members and staff.
3	Procedure:	REB members, Office Personnel, and others charged with responsibility for reviewing, approving, and overseeing human participant research should receive detailed training in the regulations, guidelines, ethics, and policies applicable to human participant research. Such training is fully supported by the management of the REB. Adequate training of REB members and REB Office Personnel is critical if the REB is to fulfill its mandate to protect the rights and welfare of research participants.
4	Specific Policies:	4.1 Training and Education – REB Members 4.2 Training and Education – REB Office Personnel 4.3 Documentation of Training and Education
105: Management of REB Office Personnel		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe management policies and procedures to promote the long-term commitment of REB Office Personnel and ensure the efficie and effective administration and enforcement of REB decisions.
3	Procedure:	REB Office Personnel provide consistency, expertise, and administrative support to the REB, and serve as a daily link between the REB and the research community. REB Office Personnel are the most vital component in the effective operation and enforcement of the University of British Columbia human participants protection program, thus the highest level of professionalism and integrity on the part of the REB Office Personnel is expected.
3	Specific Procedures:	3.1 Job Descriptions 3.2 Responsibilities 3.3 Hiring and terminating REB Office Personnel 3.4 Delegation of Authority or Responsibility 3.5 Performance Evaluations and Documentation 3.6 Periodic Evaluation of REB Office Human Resource Needs
106a: Conflicts of Interest – REB Members and REB Office Personnel		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to outline concerns of possible conflict of interest (COI) for REB members, REB Chairs, and REB Office Personnel. This extends to consultants who are not REB members but may be asked to review a project because of their expertise.

3	Procedure:	COI (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated. REBs should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict. The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or non-professional sources. The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare and safety of the participants. Pursuant to UBC Policy 97, the Conflict of Interest Committee has the authority to determine when conflicts of interest exist as defined by UBC Institutional Policy and to impose and enforce disciplinary action in the event that COI is not disclosed.
3	Specific Procedures:	3.1 REB Reviewer Assignment 3.2 Full Board Meeting 3.3 Delegated Review 3.4 REB Chair 3.5 REB Office Personnel 3.6 External Ad Hoc Advisors 3.7 Documentation 3.8 Education and Training in Conflicts of Interest
106b: Conflicts of Interest - Researchers		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to outline concerns of possible conflict of interest (COI) for UBC Researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

3	Procedure:	COI (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. Researchers are subject to the University of British Columbia's Policy 97 on Conflict of Interest and Conflict of Commitment. Researchers must disclose in the RISe application the existence of any potential, actual, or apparent COI. Researchers and research staff should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict. This SOP is not intended to prohibit Researcher relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI. REBs should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict. The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research. The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or nonprofessional sources. The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare and safety of the participants.
3	Specific Procedures:	3.1 Researcher Disclosure of Conflicts of Interest 3.2 REB Review of Researcher Conflicts of Interest
106c: Conflicts of Interest - Organization		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to outline potential Conflicts of Interest (COI) in the relationship between the organization (the University of British Columbia) establishing the Research Ethics Board (REB) and the REB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.
3	Procedure:	Organizational policies should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to REBs. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the organization. The REB must be fair and impartial, immune from pressure by the sponsor, the parent organization and the Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the REB must act independently from its parent organization, and avoid or manage real or apparent COI. The organization must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties. The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the REB actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

3	Specific Procedures:	3.1 Disclosure of Conflicts of Interest 3.2 Management of Conflicts of Interest
107: Signatory Authority		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe who has the authority to sign documents on behalf of the REB and describes the responsibilities of such individuals, and circumstances under which signing authority may be delegated.
3	Procedure:	The REB Chair or designee is authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as participants, which have been reviewed and approved pursuant to REB policies and procedures, and upon decision of the REB. Implementation shall be the responsibility of the REB Chair and REB Manager. REBs are accountable for their activities and decisions, and appropriate controls must be applied to ensure that documentation related to REB review and approval of research are signed by a person or persons having the appropriate authority to do so.
3	Specific Procedures:	3.1 Authorization and Delegation of Signing Authority 3.2 Results of REB Reviews, Decisions and Other Correspondence with the Researcher 3.3 Correspondence with External Agencies
108: Uses and Disclosures of Personal Information (PI)		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the safeguards to protect the privacy of personal information, defined by the B.C. Freedom of Information and Protection of Privacy Act as "recorded information about an identifiable individual other than contact information", disclosed to the REB by faculty, staff and students of the various covered entities of the University of British Columbia. The SOP provides guidance for the protection of information that: • Is disclosed to the REB for the purposes of ethical review • Arises during the review and approval processes, or • Is related to the operation of the REB itself.
3	Procedure:	It is the policy of the Office of Research Ethics at the University of British Columbia that personal information (PI) will be used and disclosed in a manner that respects individual's rights to privacy, and in accordance with federal and provincial privacy regulations and applicable laws. The Researcher is responsible for submitting information to the REB and to the participant regarding the nature of the PI (including personal health information (PHI)) that will be collected for the research, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected. The University of British Columbia's Office of the University Counsel is responsible for providing Researchers and research staff with guidance on privacy policies and regulations. Privacy is a fundamental value that is essential for the protection and promotion of human dignity. Breaches in privacy and confidentiality may cause harm to individuals or groups of individuals. Hence, PI must be collected, used and disclosed in a manner that respects a research participant's right to privacy, and in accordance with applicable federal and provincial privacy regulations. Privacy regulations permit the use and the limited disclosure of PI for research purposes as long as certain requirements are met. One of the key ethical challenges for the health research community is in protecting appropriately the privacy and confidentiality of PI used for research purposes. The REB plays an important role in balancing the need for research against the risk of the infringement of privacy and in minimizing invasions of privacy for research participants. Individuals should be protected from any harm that may be caused by the unauthorized use of their PI and they should expect that their rights to privacy and confidentiality are respected.
3	Specific Procedures:	3.1 REB Review of Privacy Concerns 3.2 Receipt, Use and Disclosure of Personal Information by the REB Office

Section 200: REB Organization		
201: Composition of the Board		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to state the requirements for the composition of the REBs responsible for reviewing research conducted under the auspices of the University of British Columbia.
3	Procedure:	The membership of the REB will be sufficient to ensure the appropriate expertise, multi-discipline backgrounds, and independence required for competent research ethics review. The membership of the UBC Research Ethics Boards will include individuals with varying backgrounds and appropriate professional competence to review the diverse types of protocols that are received. The Board members will be qualified to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards of professional conduct and practice pertaining to human participant protection. To promote complete and adequate review of the type of research commonly reviewed by the REB, the REB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. The membership will be diverse so selection will include consideration of race, sex, cultural backgrounds, research, healthcare or professional experience, organizational affiliation, and sensitivity to such issues as community attitudes to assess the research submitted for review.
3	Specific Procedures:	3.1 Selection of REB Members 3.2 Composition of the REB 3.3 Regular REB Members 3.4 Alternate Members 3.5 REB Chair 3.6 Ad Hoc Advisors 3.7 Observers at REB Meetings
202: Management of the Board		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the management and oversight of the REB to ensure continuity of membership and the expertise to meet guidelines, regulations and institutional mandates.
3	Procedure:	The management of the membership of the REBs and oversight of member appointments, REB related activities, communications, and other administrative details are the responsibility of the Director, Research Ethics.
3	Specific Procedures:	3.1 Appointments – Regular Members and Alternates 3.2 Appointments – REB Chair and Co-Chair 3.3 Ad Hoc Advisors 3.4 Terms of Appointment 3.5 Qualifications and Training of REB Members 3.6 Resignations and Removals 3.7 Compensation 3.8 Liability and Coverage 3.9 Documentation
203: Duties of REB Members		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the management and oversight of the REB to ensure continuity of membership and the expertise to meet guidelines, regulations and institutional mandates.

3	Procedure:	Each REB member's primary duty is the protection of the rights and welfare of the individual human beings that are serving as the participants of research. The reviewer must understand that he or she is not serving on the Board to expedite the approval of research, but to serve as a link between the investigator and the research participants. In order to fulfill his or her duties, REB members are expected to be knowledgeable of the guidelines and regulations governing human participants' protection and research ethics, and the policies of the University of British Columbia, germane to human participant protection. The REB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources. The REBs are appointed as University Committees. As such, the REB members serve the University of British Columbia as a whole, rather than a particular school, department or hospital. Therefore, members must not allow their own interests or that of their departments or schools to supersede their duty to protect the rights and welfare of research participants.
3	Specific Procedures:	3.1 Attendance 3.2 Terms of Duty 3.3 Duties 3.4 Primary and Secondary Reviewers 3.5 Training and Education 3.6 Conflict of Interest
204: REB Office Personnel Serving as REB Members		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the duties of REB Office Personnel serving as members of the Research Ethics Board (REB).
3	Procedure:	Each REB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, REB members must be versed in regulations governing human participants' protection and research ethics, and policies germane to human research participant protection.
3	Specific Procedures:	3.1 Duties 3.2 Appointment Criteria 3.3 Training and Education 3.4 Conflict of Interest

Section 300: Functions and Operations		
301: Research Submission Requirements		
1	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.
3	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	Specific Procedures:	3.1 Submission Requirements for Initial Review 3.2 Submission Requirements for Continuing Review 3.3 Documentation is not Adequate or Additional Information is Required 3.4 Deadlines and Timelines 3.5 REB Administration Fee
302: REB Meeting Administration		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to provide the framework to ensure that REB meetings are conducted and documented in a consistent manner in order to meet regulatory and institutional requirements.
3	Procedure:	Except when a delegated review procedure is used, the REB must review proposed research at convened Full Board meetings at which a quorum is present. The UBC REBs will generally meet at least 12 times a year or at some other frequency as determined by the REB Chairs. The REB meeting agenda provides the meeting content and establishes a sequence of review. It also provides an overview of all items that have been previously (i.e., during the preceding time between REB meetings) reviewed and approved by delegated review procedures, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items. Information documented in the REB meeting agenda provides the foundation for the REB meeting minutes. The REB meeting minutes document the actions that occur during an REB meeting. The minutes should enable a reader who was not present at the REB meeting to determine how and with what justification the REB arrived at its decisions. They should also provide the REB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.
3	Specific Procedures:	3.1 Quorum 3.2 Agenda Preparation 3.3 Primary and Secondary Reviewers 3.4 Prior to the REB Meeting 3.5 Meeting Minute Preparation 3.6 Meeting Minute Approval 3.7 Documentation 3.8 Approval by Consensus
303: Administrative Review and Distribution of Materials		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the requirements for document pre-review and distribution prior to REB review.

2	Procedure:	The efficiency and effectiveness of the REB is supported by administrative procedures that assure that REB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and documentation. The requirements for REB submissions are made available to all Researchers. The REB Office Personnel are responsible for maintaining and disseminating this information to Researchers.
3	Specific Procedures:	3.1 Administrative Review Procedures 3.2 Scheduling for Review 3.3 Distribution Prior to REB meetings 3.4 Confidentiality 3.5 Destruction of Copies
304: Documentation and Document Management		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the REB for initial or for continuing review, as well as to all REB administrative documents.
3	Procedure:	The REB office must retain REB files in a manner that contains a complete history of all REB actions related to review and approval of a protocol, including scientific reviews, approved sample consent documents, progress reports submitted by Researchers, and reports of injuries to participants. The REB office must also retain all relevant records respecting REB activities, including minutes as described in UBC REB SOP 302, records of continuing review activities, copies of all correspondence between the REB and Researchers, REB membership lists as described in UBC REB SOP 202, and written procedures relating to review and reporting (as described in UBC SOPs 404 and 408), and statements of significant new findings. Such records must be retained for the length of time required by applicable regulations and guidelines. Relevant records must be made accessible to authorized regulatory authorities, representatives of the organizations, Researchers and funding agencies within a reasonable time upon request.
3	Specific Procedures:	3.1 Research-Related Documents 3.2 REB Administrative Documents 3.3 Document Access, Storage and Archiving 3.4 Confidentiality and Document Destruction

Section 400: Reviews of Research		
401: The Review Process		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the REB review process and the decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research for ethical acceptability. This SOP also describes knowledge generating projects that do not require REB review because the activity does not constitute human research.
3	Procedure:	All research involving human subjects must be submitted for REB review according to the specified application format and process, otherwise the Researcher will be notified that the REB will not review the research activity until all required elements are submitted. No intervention or interaction with human participants in research, including recruitment, may begin until the REB has reviewed and approved the research protocol, consent documentation, recruitment materials, and any other relevant study documentation submitted upon initial review. As a result of its review, the REB has the authority to approve or disapprove the proposed research activity, or to require modifications to the project/protocol/documents in order to secure REB approval of the research activity. Except when the delegated review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with REB's conflict of interest policies. When reviewed via delegated review, the REB Chair or his/her designate can take any of the actions outlined below, except to disapprove a study. REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the REB (if applicable), in accordance with the REB and organization's conflict of interest policies. When the delegated review procedure is used, the REB Chair and/or REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to disapprove the research must be made by the Full Board. Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.
3	Specific Procedures:	3.1 Activities Not Requiring REB Review 3.2 The Application Process 3.3 REB Decisions 3.4 Reconsideration and Appeal of REB Decisions 3.5 Documenting REB Decisions
402: Delegated Review		
1	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.

3	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. 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	Specific Procedures:	3.1 Definition of Minimal Risk 3.2 Determination of Qualification for Delegated Review 3.3 Delegated Review Process 3.4 Notification of the REB 3.5 Documentation
403: Initial Review – Criteria For REB Approval		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the minimal requirements that research proposals involving human participation must meet in order to be approved by the Research Ethics Board (REB), independent of the review pathway (i.e. Full Board or delegated review), for conduct at or under the auspices of the University of British Columbia.
3	Procedure:	All research proposals that intend to enroll human participants must meet certain criteria before REB approval may be granted. Initial REB approval of the research is based on assessment of a complete submission to the REB. The REB and/or REB Office Personnel may consult the Researcher for additional information as necessary. The criteria are based on the guiding ethical principles of the Tri-Council Policy Statement 2 and are specified below. Following initial review of the research, the REB should be prepared to make a determination as to the approvability of the research. In addition to REB approval, certain other criteria that are unique to the Institution, such as the provisions of UBC Policy 89, department approvals, etc. must also be met before the research may begin.
3	Specific Procedures:	3.1 Minimal Criteria for Approval of Research 3.2 Additional Criteria 3.3 Cooperative Research Arrangements 3.4 U.S. Federally Funded Research 3.5 Length of Approval Period
404: Ongoing REB Review Activities		

1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the processes for the ongoing review and monitoring by the REBs of research approved by the University of British Columbia REBs, after approval and prior to review for annual (interval) renewal. The process for follow up reporting of unanticipated problems, reporting of serious and continuous non-compliance (SOP 903), and suspension and termination of research (SOP 409) are described in SOP 408.
4	Procedure:	It may be that the real risk/benefit ratio can be evaluated only after research has begun; therefore, in addition to the formally scheduled continuing review, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such review may include: • Review of significant new findings or new information that may affect adversely the safety of the research participants or the conduct of the trial; • Review of serious and unexpected adverse events and unanticipated problems posing risks to participants or others; • Review of amendments or changes to research, including protocol deviations; • Site visits; and • Third party verification. Information reviewed by the REB may include: • Modifications or changes to the previously approved research, • Reports of unanticipated problems involving risks to participants or others, • Reports of any serious or continuing non-compliance, • Reports of any changes significantly affecting the conduct of the research or increasing the risk to research participants, • Results of any interim analysis or Data and Safety Monitoring Board (DSMB) assessments, • Deviations to the previously approved research, • Adverse events that meet the reporting criteria, • Reports of any privacy breaches, • Summary reports of any audits and inspections, • Any other new information that my affect adversely the safety of the research participants or the conduct of the research, Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.
4	Specific Procedures:	4.1 Amendments to the Approved Research 4.2 Reportable Events 4.3 Review of Reportable Events by the REB 4.4 Site Visits/Audits 4.5 External Verification
405: Continuing Review		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the policy and notice requirements for annual (interval) renewals and related continuing review prior to the expiration of the REB approval period. It should be read together with SOP 404 which articulates the Boards' responsibilities, policies and processes for conducting on-going review (continuous oversight) of approved projects. This SOP will also outline the process to be followed by REB Office Personnel to track and monitor continuing review submissions. The SOP will delineate the options of the REB in the event that the Principal Investigator fails to comply with the requirement to notify the REB, on at least an annual basis, of the status of the approved study.
4	Procedure:	The REBs conduct continuing review of approved research taking place within their jurisdiction at intervals appropriate to the degree of risk to which participants are exposed, but not less than once per year. The UBC REBs make the determination concerning the duration of the approval period and the interval by which continuing review must occur at the time of initial review and approval.

4	Specific Procedures:	4.1 Continuing Review by the Full Board 4.2 Continuing Review by Delegated Review Procedures 4.3 REB Determinations 4.4 Required Information and Documentation 4.5 Continuing Review Applications not Received by the Expiry Date 4.6 U.S. Federally Funded Research
406: Research Completion		
1	Purpose:	This purpose of this standard operating procedure (SOP) is to describe the procedure for the closure of a research project with the Research Ethics Board (REB).
4	Procedure:	The Completion of research is a change in activity and must be reported to the REB. Although participants will no longer be "at risk" under the study, a final report/notice to the REB allows it to close its files as well as providing information that may be used by the REB in the evaluation and approval of related studies.
4	Specific Procedures:	4.1 Determining when Research can be Closed 4.2 Content of Notification of Study Closure Report
407: Administrative Holds, Terminations and Suspensions of Approval		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the procedures associated with the suspension or termination of the Research Ethics Board's (REB) approval of research (including the suspension or termination of approval, and administrative holds requested by the Sponsor or the Researcher).
4	Procedure:	As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Researcher is not conducting the research in compliance with applicable regulations and guidelines. The REB also has the authority to suspend new enrollment while additional information is requested. A decision to suspend or to terminate the REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place. The REB has the authority to suspend or to terminate the REB's approval of the research. The REB Chair or designee has the authority to suspend ethics approval. Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board. For studies funded by the U.S. Federal Government, applicable regulations require that the REB have the authority to suspend or terminate research. A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.
4	Specific Procedures:	4.1 Suspension or Terminations of Research by the Sponsor 4.2 Suspension or Termination of REB Approval 4.3 Reporting Suspensions or Terminations
408: Reportable Events and Reporting		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to build upon the policies described in SOPs 409 and 903, and details the procedures for supplementary reporting of unanticipated problems, serious and continuing non-compliance, and suspension and termination of REB approval.

3	Procedure:	It is UBC's policy to require that investigators report as soon as reasonably possible (within 7 days) any unanticipated problems involving risk to participants or others to the relevant UBC REB. Once reported, the REB will make determinations about the reported problems and direct appropriate follow-up with the investigative team. The REB then has the responsibility to promptly report the unanticipated problems or instances of serious or continuing non-compliance, with the resulting determinations (including suspension or termination of REB approval) to all appropriate study contacts (including the study Sponsor/Contract Research Organization (CRO) and institutional officials, when appropriate), and the appropriate government agencies (OHRP, FDA) when applicable.
3	Specific Procedures:	3.1 Reportable Events 3.2 Reporting Procedures 3.3 Unanticipated Problems Involving Risk to Participants or Others 3.4 Serious or Continuing Non-Compliance 3.5 Suspension or Termination of Approved Research by the REB
409: Reconsideration of REB Decisions and Appeal Process		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the process by which a Researcher may seek reconsideration of an REB decision, and ultimately, appeal the REB decision to the Research Ethics Appeal Committee.
3	Procedure:	The UBC REBs are guided by the principles of natural justice in their decision-making. In fulfilling their mandate, UBC REBs shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions.
3	Specific Procedures:	3.1 Reconsideration 3.2 Notice of Appeal 3.3 Composition of the Research Ethics Appeal Committee 3.4 The Appeal

Section 500: Reviews Requiring Special Consideration		
501: REB Review During Publicly Declared Emergencies		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the research ethics review procedures during a publicly declared emergency.
3	Procedure:	A publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. Potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so. During publicly declared emergencies, the REB must have established procedures to continue to provide the necessary research ethics oversight. Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, REBs might not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to current ongoing research. The existence of an emergency does not override established procedures to protect the welfare of research participants. Any relaxation of the usual procedural requirements for review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified.
3	Specific Procedures:	3.1 Determining the Level of Impact 3.2 Emergency Preparedness Procedures 3.3 Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency 3.4 Review of New Research NOT Related to or Arising from the Publicly Declared Emergency 3.5 Review of Research Related to or Arising from the Publicly Declared Emergency
502: Special Categories of Research		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe review of specific types of research, some of which may require additional considerations by the REB.
3	Procedure:	Certain categories of research involve either methodologies that might require additional considerations, or for which there are federally mandated determinations that REBs are required to make and document.
3	Specific Procedures:	3.1 Research in Emergency Health Situations 3.2 Secondary Use of Identifiable Information for Research Purposes, including Health Records and Medical Chart Review 3.3 Collection of Human Biological Materials 3.4 Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes 3.5 Use of Tissue and/or Data Obtained from Tissue and Data Banks

Section 600: REB Communication and Notification		
601: Communication - Researcher		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the REB actions that must be communicated to the Researcher and the importance of open communications among REBs, researchers, staff, and university committees and officials.
3	Procedure:	In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Researcher, research staff, and organizational representatives. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies and procedures. All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research. Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the REB office procedures. In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures.
3	Specific Procedures:	3.1 Notifications of REB Decisions 3.2 Research Appeal of REB Decision 3.3 Communications Concerning Non-compliance
602: Communication – Research Participants		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the REB actions that must be communicated to various parties involved in the research program.
3	Procedure:	The REB is required to communicate certain actions to entities that may have an interest in the status of the research being conducted. Procedures should be in place for prompt reporting to the REB, institutional officials, and, where applicable, funding agencies and Sponsors (including department and agency heads) of: • Serious Adverse Events and other unanticipated problems; • Serious or Continuing non-compliance with policies, protocols, or REB requirements; and, • Suspension or termination of research. The specific procedures for investigating and making determinations concerning these situations are addressed in SOPs 407 and 408.
3	Specific Procedures:	3.1 Communication with Research Participants 3.2 Communication to Others

Section 700: Informed Consent		
701: Informed Consent Form Requirements and Documentation		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the requirements for the informed consent form and the process for waiving or obtaining and documenting initial and ongoing informed consent.
4	Procedures:	4.1 REB Review of Required Elements of Informed Consent 4.2 Translation of Informed Consent Documents 4.3 Consent Update for Ongoing and Completed Research Participants 4.4 Recruitment Methods 4.5 Recruitment Materials 4.6 Documentation of Informed Consent 4.7 Consent Monitoring 4.8 Waiver or Alteration of Informed Consent 4.9 Consent for Research Involving Individuals who Lack Capacity 4.10 Inappropriate Inclusion and Exclusion of Participants 4.11 Consent for Research in Health Emergencies 4.12 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes 4.13 Incidental Findings

Section 800: Responsibilities of Investigators		
801: Researcher Qualifications and Responsibilities		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the qualifications and responsibilities of the Researcher who engages in research involving human participants.
3	Procedure:	Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB must have assurance that the qualifications of new Researchers, for the conduct of research, are appropriate. Researchers are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all REB policies.
3	Specific Procedures:	3.1 Researcher Qualifications 3.2 Researcher Responsibilities

Section 900: Quality Management		
901: Quality Assurance Inspections		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to: • Describe the processes for monitoring, evaluating and improving the effectiveness of the human research enterprise; • Define the policy regarding the compliance auditing of research studies under the oversight of the Research Ethics Boards (REBs) operating under the direct authority of the University of British Columbia (UBC); • Define and promote Researcher, Institution, and REB compliance with national and international policies, regulations, and guidance, plus UBC Policy and Standard Operating Procedures (SOPs), in the conduct of research; • Assure that research study participants' rights, safety, and welfare are protected; • Ensure research study data integrity and control of bias; • Foster a culture of responsible research conduct and review.
3	Procedure:	The University of British Columbia is responsible for conducting ongoing oversight/continuing review of approved protocols of human participants research based on applicable regulations and policy. The designated REB Office Personnel, within the Office of Research Ethics at UBC, conducts the resultant compliance oversight activities including routine and directed/for-cause inspections of REB approved protocols. The process of Quality Assurance Inspections is meant to accomplish several important purposes. First, it is intended to assure that human participants are properly protected, and that the procedures used to accomplish this goal are carefully documented. Second, the process is intended to assist Researchers in complying with the current regulatory standards for protecting human participants and in avoiding any external sanctions that may result from non-compliance with the standard of practice. Finally, this process is intended to assure that the University of British Columbia and its affiliated institutions remain in good standing with federal agencies having oversight of human participant's research activities. Quality Management programs, Quality Assurance (QA), and Quality Control (QC) activities, such as inspections of the REB and of Researchers, allow for a continuous evaluation and subsequent assurance of the human research protection enterprise. Findings are measured against established policies and procedures and all of the applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.
3	Specific Procedures:	3.1 REB Quality Assurance Inspections (Internal) 3.2 Researcher Quality Assurance Inspections 3.3 Corrective Action 3.4 Documentation
902: External Inspections or Audits		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the procedures to be followed before, during and following an external inspection or audit.

3	Procedure:	Health Canada has the authority to inspect Researcher sites conducting clinical trials that fall under the Regulations to assess compliance with relevant regulations and guidelines. For external audits involving Health Canada, the following must be notified immediately: • Vice-President, Research & Innovation • Relevant REB Chair • Hospital Administration, if applicable • Health Records, if applicable. The U.S. Food and Drug Administration (FDA) has the authority to audit Researcher sites involved in studies conducted under a U.S. Investigated New Drug Application (IND) or Investigational Device Exemption (IDE) to assess compliance with relevant regulations and guidelines. The U.S. Office for Human Research Protection (OHRP) has the authority to audit Canadian REBs that oversee studies that are supported by the U.S. federal government. Sponsors, funding entities, or others authorized by regulations or agreements with the organizations may have the authority to audit or inspect research-related documents and procedures. These entities include the Canadian federal granting agencies (CIHR, NSERC and SSHRC). These audits or inspections may involve the REB; therefore, the REB must have policies in place for dealing with external audits or inspections. Quality assurance and quality control of the daily operations of the REB ensure that they effectively support the REB's mandate. The Researcher is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.
3	Specific Procedures:	3.1 Preparing for an Inspection or Audit 3.2 Participating in an Inspection or Audit 3.3 Follow-up after an Inspection or Audit
903: Non-Compliance		
1	Purpose:	The purpose of this standard operating procedure (SOP) is to describe the Research Ethics Board's (REB) process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance.
4	Procedure:	Reports of non-compliance may come from any source including the REB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.
4	Specific Procedures:	4.1 Reports of Non-compliance 4.2 Evaluating Allegations of Non-compliance 4.3 Managing Non-compliance 4.4 REB Response to Reports of Non-compliance 4.5 Documenting Non-compliance