

SOP 101.001

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| Title | Authority and Purpose |
| SOP Code | 101.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to:

1. State the organizational authority under which the Research Ethics Board (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 participants are protected;
4. State the authority of the REB.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

Organizational Official(s), all REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB receives its mandate from the highest level of the Organization and will fulfill this mandate by following all relevant ethical policies, standards, procedures and legal and regulatory requirements.

5.1 Statement of Organizational Authority

- 5.1.1 The REB is established and empowered under the authority of the organization to review ethical acceptability of all research involving human participants conducted under the auspices of the Organization (as per SOP 102);
- 5.1.2 The Organization requires that all research involving human participants be reviewed and approved by the REB prior to initiation of any research related activities.

5.2 Purpose of the REB

- 5.2.1 The REB's purpose is to protect the rights and welfare of human research participants;
- 5.2.2 The REB reviews and oversees the research to ensure that it meets ethical standards and that it complies with all applicable requirements pertaining to human research participant protection;
- 5.2.3 These include, but are not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and where applicable, the US Federal Policy for the Protection of Human Subjects (Final Common Rule).

5.3 Governing Principles

- 5.3.1 The REB is guided by ethical principles regarding all research involving human participants including:
 - Respect for Persons:
 - Recognize the intrinsic value of human beings and the respect and consideration they are due,
 - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

- Concern for Welfare:
 - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
 - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
 - Ensure that participants are not exposed to unnecessary risks.
- Justice:
 - Obligation to treat people fairly with equal respect and concern,
 - Vulnerable or marginalized people may need to be afforded special attention.

5.4 REB Authority

5.4.1 The REB is established to review all research involving human participants within its established jurisdiction;

5.4.2 The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

Specifically the REB has the authority to:

- establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
- approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
- ensure that the Researcher follows policies and procedures to protect the rights, safety and welfare of research participants,
- request, receive and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
- conduct ongoing and continuing ethics review to protect the rights and welfare of research participants,
- suspend or terminate ethics approval for the research,
- place restrictions on the research,
- take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB's jurisdiction.

5.5 Research Subject to US and International Regulations

The REB shall apply the requirements of the applicable US and International regulations to the extent that they vary from the protections set out in the applicable Canadian policies and guidelines, where required.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
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SOP 102.001

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|-----------------------|--------------------------------------|
| Title | Research Requiring REB Review |
| SOP Code | 102.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Research Ethics Board (REB) review, those that are exempt from review, and activities that are not defined as research requiring review.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

Researchers, REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants must be reviewed and approved by an REB prior to commencement of activities. No recruitment of or interaction with human participants in research may begin until an REB has reviewed and approved the ethics application and respective documents.

5.1 Research that Requires REB Review

5.1.1 The following requires ethics review and approval by an REB before the research commences:

- (a) Research involving living human participants,
- (b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

5.2 Research Exempt from REB Review

5.2.1 Research that relies exclusively on publicly available information does not require REB review when:

- (a) The information is legally accessible to the public and appropriately protected by law,
- (b) The information is publicly accessible and there is no reasonable expectation of privacy;

5.2.2 REB review is not required for research involving the observation of people in public places where:

- (a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,
- (b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
- (c) Any dissemination of research results does not allow identification of specific individuals;

5.2.3 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as

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the process of data linkage or recording or dissemination of results does not generate identifiable information;

5.2.4 The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

5.3 Activities Not Requiring REB Review

5.3.1 Activities outside the scope of research requiring REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB;

5.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review;

5.3.3 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
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| SOP 102.001 | | |
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SOP 103.001

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|-----------------------|-------------------------------|
| Title | Training and Education |
| SOP Code | 103.001 |
| Effective Date | |

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1.0 PURPOSE

This standard operating procedure (SOP) describes the training and education requirements for Research Ethics Board (REB) members and REB Office Personnel.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB members, REB Office Personnel and others charged with the responsibility for reviewing, approving, and overseeing human participant research should be well-versed in the ethical principles, policies, guidelines and other requirements applicable to human participant research. Adequate training and education in these areas is critical for the REB to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner.

5.1 Training and Education – REB Members

5.1.1 The REB Chair or designee will provide new REB members with a general overview of the policies and procedures pertinent to REB meeting functions and REB member expectations, as well as an orientation to the principles and guidelines for research ethics;

5.1.2 New REB members will receive an orientation before beginning their formal duties. REB members are required to complete the TCPS online tutorial or equivalent and are expected to participate in the orientation process which may include, but is not limited to:

- Background on the REB (e.g., Terms of Reference, governance structure, annual reports, process flowchart),
- Policies and Procedures (e.g., relevant SOPs and associated forms, consent form template, consent form checklist),
- Member information (e.g., meeting schedule, membership list, information and guidelines for members, reviewer guide),
- Regulatory and guidance documents,
- Other member-specific information (e.g., copy of signed confidentiality and conflict of interest agreement, membership appointment letter),
- Resource information (e.g., list of training and education references, relevant articles, etc.);

5.1.3 As part of their orientation, new REB members will be offered the opportunity to observe at least one REB meeting prior to commencing their REB member duties;

5.1.4 REB members are encouraged to participate in local, regional and national educational opportunities pertaining to human participant research protection. These may be in person or virtual. The REB Office will support such activities to the extent possible and as appropriate to the responsibilities of REB members. Attendance may be based on availability of funding and other practical considerations (e.g. timing, location);

- 5.1.5 Ongoing ethics education in areas germane to the REB members' responsibilities may be provided at REB meetings or as special meetings;
- 5.1.6 New or revised policies and SOPs will be disseminated to the new REB members;
- 5.1.7 REB members are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities.

5.2 Training and Education – REB Office Personnel

- 5.2.1 The REB Chair or designee will provide new REB Office Personnel with an overall orientation to the REB including a general overview of the policies and procedures pertinent to their role in support of the REB;
- 5.2.2 New REB Office Personnel will receive an orientation package. Before commencing their official duties in the REB office, REB Office Personnel are expected to read and become familiar with the information;
- 5.2.3 New REB Office Personnel will receive training on the REB SOPs and will be expected to be knowledgeable and compliant with the SOPs;
- 5.2.4 New REB Office Personnel are required to complete the TCPS online tutorial or equivalent, and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research;
- 5.2.5 REB Office Personnel are encouraged to participate in local, regional and national educational opportunities pertaining to human participant research protection. These may be in person or virtually. The REB Office will support such activities to the extent possible and as appropriate to the responsibilities of REB Office Personnel. Attendance may be based on availability of funding and other practical considerations (e.g. timing, location);

- 5.2.6 New or revised policies and SOPs will be disseminated to the REB Office Personnel;
- 5.2.7 REB Office Personnel are encouraged to engage in self-directed learning to enhance their ability to fulfill their responsibilities.

5.3 Documentation of Training and Education

- 5.3.1 The REB Office will retain copies of the CVs of all REB members and REB Office Personnel;
- 5.3.2 REB members and REB Office Personnel will record their relevant training and education and provide copies of their certificates of completion. Training records will be kept on file in the REB Office;
- 5.3.3 REB members and REB Office Personnel are encouraged to retain copies of agendas of relevant workshops, seminars and conferences attended;
- 5.3.4 REB agendas and minutes will record the distribution of any educational materials presented at the REB meetings.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP103.001 | | |
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SOP 104.001

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|-----------------------|---|
| Title | Management of REB Office Personnel |
| SOP Code | 104.001 |
| Effective Date | |

Site Approvals

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1.0 PURPOSE

This standard operating procedure (SOP) describes the overall management of Research Ethics Board (REB) Office Personnel.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

Organizational representatives, REB Chair or designee and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The Organization is responsible for providing sufficient resources to adequately support the functions of the REB.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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 vital to ensuring the efficient and effective administration and enforcement of REB decisions, thus the highest level of professionalism and integrity is expected.

5.1 Job Descriptions

5.1.1 Job descriptions will be developed to establish the role requirements for REB Office Personnel, in accordance with organizational policies and procedures;

5.1.2 Each REB Office Personnel will be provided with a copy of his or her job description, job expectations and access to all applicable organizational policies and procedures.

5.2 Responsibilities

5.2.1 REB Office Personnel responsibilities may include:

- screening and pre-review of submissions and requests to the REB,
- quality management activities,
- management of administrative issues involving REB oversight as described by applicable REB policies,
- the implementation of REB directives, and
- the provision of advice and information to the REB
- serving as a non-voting REB member (as per SOP 204).

5.3 Hiring and Terminating REB Office Personnel

5.3.1 The Organization will determine and assign responsibility for the recruitment, hiring, and termination of REB Office Personnel, in accordance with organizational policies and procedures.

5.4 Delegation of Authority or Responsibility

5.4.1 The REB Chair or designee may formally delegate appropriate tasks or responsibilities to an REB Office Personnel if the individual has the expertise to carry out the task(s), the task is compliant with the REB SOPs and the task delegation has been agreed to by both the REB Office Personnel and the organization.

5.5 Performance Evaluations and Documentation

- 5.5.1 Performance feedback will be provided on an ongoing basis;
- 5.5.2 The Organization will determine responsibility for conducting formal performance evaluations in accordance with organizational policies and procedures;
- 5.5.3 The Organization will determine responsibility for identifying, documenting and retaining formal REB Office Personnel interactions.

5.6 Periodic Evaluation of REB Office Resource Needs

- 5.6.1 A periodic evaluation of the adequacy of the REB resources will be conducted;
- 5.6.2 The evaluation will assess whether the REB Office Personnel, equipment, finances and space are adequate to carry out its function in support of the REB;
- 5.6.3 The assessment takes into consideration the volume, complexity and types of research projects administered by the REB Office Personnel and whether activities in support of the REB can be completed in a timely manner;
- 5.6.4 The need for additional resources will be discussed with the appropriate Organizational Official.

6.0 REFERENCES

Note: references will reflect the organizational policies and practices

7.0 REVISION HISTORY

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| SOP104.001 | | |
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SOP 105A.001

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|-----------------------|---|
| Title | Conflicts of Interest – REB Members and REB Office Personnel |
| SOP Code | 105A.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Research Ethics Board (REB) members (including the REB Chair and any ad hoc advisors) and REB Office Personnel, and describes the requirements and procedures for disclosure and management of COI.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for disclosing any real, potential or perceived COI and for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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.

REBs should identify and manage COI to maintain public confidence and trust and to maintain the independence and integrity of the ethics review process. 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 by sponsors or funders, Organizations, Researchers whose research is being reviewed, or by other professional and/or non-professional sources.

The standard that guides decisions about considering COI is whether an independent observer could reasonably question whether the individual's actions or decisions could be influenced by factors other than the rights, welfare and safety of research participants.

5.1 REB Reviewer Assignment

- 5.1.1 The REB Chair or designee reviews the agenda prior to the REB meeting to identify potential COI;
- 5.1.2 When the agenda is distributed, REB members are expected to disclose as soon as possible, any conflicting interest(s) for any of the projects on the agenda;
- 5.1.3 If a member is unclear as to whether a COI exists, he or she must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI and the member shall follow the REB's decision regarding any actions required to mitigate his/her real, potential or perceived COI;
- 5.1.4 If a COI is identified in the reviewer assignments, the project must be assigned to another REB member.

5.2 Full Board Meeting

- 5.2.1 At the beginning of the meeting, REB members are reminded of their obligation to verbally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the REB meeting minutes;

- 5.2.2 If a COI is declared and determined as such, the REB member may be asked to provide information about the research, but must be recused for the deliberation and decision;
- 5.2.3 The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum for the specific protocol for which they are conflicted.

5.3 Delegated Review

- 5.3.1 The REB Chair or designee will assess projects undergoing the delegated review process to determine potential COI;
- 5.3.2 REB members involved in the delegated review process are expected to disclose any conflicting interests;
- 5.3.3 If a COI is identified, the project will be assigned to another REB member.

5.4 REB Chair

- 5.4.1 In the event that the REB Chair declares a COI, the Vice-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s).

5.5 REB Office Personnel

- 5.5.1 All REB Office Personnel are expected to disclose any conflicts that may arise with a particular research project, including any implications to their job status or compensation. If a COI exists, they must recuse themselves from review of that research project;
- 5.5.2 Any disclosure of a COI by REB Office Personnel should be referred to the REB Chair or designee for the development of a management plan;
- 5.5.3 If REB Office Personnel are unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI.

5.6 External Ad Hoc Advisors

- 5.6.1 At his/her discretion, the REB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB;

- 5.6.2 All ad hoc advisors must sign agreement(s) addressing confidentiality of information and conflicts of interest prior to commencement of their consultation, and disclose any COI to the REB Chair.
- 5.6.3 Any disclosure of a COI by an ad hoc advisor should be referred to the REB Chair or designee for the development of a management plan, as applicable.
- 5.6.4 If ad hoc advisors are unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI.

5.7 Documentation

- 5.7.1 All REB members, guests and ad hoc advisors must sign agreement(s) addressing confidentiality of information and conflicts of interest and agree to abide by the REB COI and confidentiality policies;
- 5.7.2 The signed agreement(s) will be retained in the REB office;
- 5.7.3 The REB minutes will record any COI that are declared on any of the projects under review at the REB meeting, and the decision on the management of the conflict;
- 5.7.4 The REB minutes will also record the recusal of an REB member;
- 5.7.5 At the time of hire, REB Office Personnel may be required to sign agreement(s) addressing confidentiality of information and conflicts of interest as a condition of their employment, as per the Organization's hiring practices. Otherwise, this agreement should be considered implicit with conditions of their employment. REB Office Personnel must also comply with REB COI SOPs;
- 5.7.7 The signed agreement(s) will be retained;
- 5.7.8 The REB management plan for COI declarations will be documented in the appropriate files. Any discussion at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
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| SOP 105A.001 | | |
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SOP 105B.001

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| Title | Conflicts of Interest – Researcher |
| SOP Code | 105B.001 |
| Effective Date | |

Site Approvals

| Name | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Researchers and research team members engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REBs) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are responsible for disclosing any real, potential or perceived COI to the REB.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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 and research team members should identify and manage COI to maintain 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.

The standard that guides decisions about considering COI is whether an independent observer could reasonably question whether the individual's actions or decisions could be influenced by factors other than the rights, welfare and safety of research participants.

5.1 Researcher Disclosure of Conflicts of Interest

5.1.1 Researchers submitting research applications to the REB are required to declare any COI including those of his/her sub/co-Researcher(s), research team members, and immediate family members (which includes spouse, domestic partners and dependent child), and close relationships;

5.1.3 Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;

5.1.4 The Researcher shall disclose any conflicts to the REB at the following times:

- With the initial REB application,
- At each continuing review of the project,
- Whenever a COI arises, such as changes in responsibilities or financial circumstances;

5.1.5 The Researcher shall cooperate with the REB and with other Organizational representatives involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and with his/her organizational COI policies to eliminate and/or to manage the conflict;

5.1.6 The Researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

5.2 REB Review of Researcher Conflict of Interest

5.2.1 The REB will review each application for disclosure of COI;

5.2.2 If the Researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;

5.2.3 The REB review shall focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks;

5.2.4 In determining the appropriate action, the REB may take into consideration information presented by the Researcher such as:

- The nature of the research,
- The magnitude of the interest or the degree to which the conflict is related to the research,
- The extent to which the interest could affect the research,
- Whether a specific individual is unique in his/her clinical or scientific qualifications to conduct the research,
- The degree of risk to human participants involved in the research that is inherent in the research, and/or
- The management plan for the COI already developed by the Researcher;

5.2.5 The REB may approve the research and may require a management plan, which may include changes at the Researcher's or sponsor's/funder's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interests,
- Mandating Researcher recusal from research,
- Modifying or limiting the participation of the Researcher in all or in a portion of the research,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data)),
- Monitoring the consent process, and/or
- Disclosure of the conflict to organizational committees, research participants, and journals;

- 5.2.6 The REB has the final authority to determine whether a COI has been eliminated or managed appropriately;
- 5.2.7 Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes;
- 5.2.8 After review by the REB and input by the appropriate Organizational Official, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

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SOP 105C.001

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| Title | Conflicts of Interest - Organization |
| SOP Code | 105C.001 |
| Effective Date | |

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1.0 PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) in the relationship between the Organization 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.

2.0 SCOPE

The SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Organizational Officials are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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 sponsors and funders, the Organization and 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 the Organization under whose authority they were established and given their mandate, and avoid or manage real, potential or perceived 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 Organization's actions or decisions could be influenced by factors other than the rights, welfare and safety of research participants.

5.1 Disclosure of Conflict of Interest

- 5.1.1 All Organizational employees must be familiar with their respective Conflict of Interest Policy (if applicable) and must complete a Disclosure of Conflict of Interest Form(s) (if applicable) at the time of hire and annually thereafter, or as per organizational policy;
- 5.1.2 Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;
- 5.1.3 REB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the REB and the Organization. The actions of the REB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;
- 5.1.4 REB meetings are closed to employees of the organization unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place;
- 5.1.5 Organizational senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.

5.2 Management of Conflicts of Interest

- 5.2.1 The REB Chair or designee must be notified if an organizational COI relating to the REB is declared or discovered;
- 5.2.2 The REB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the ethics review process or to obtain preferential treatment;
- 5.2.3 The REB Chair or designee will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human research participant protection;
- 5.2.4 The REB Chair or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
 - Divestiture or termination of relevant interest,
 - Recusal of REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB,
 - If Organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation;
- 5.2.5 If the REB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Chair or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP105C.001 | | |
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SOP 106.001

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|-----------------------|----------------------------|
| Title | Signatory Authority |
| SOP Code | 106.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) specifies who has the signatory authority on behalf of the Research Ethics Board (REB) and describes the responsibilities of such individuals, and the circumstances under which signatory authority may be delegated.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for authorizing documents and decisions related to REB review and approval of research. If authority is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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 authorized by a person or persons having the appropriate authority to do so. Documentation includes both hard copy and electronic formats. Signing may be done with ink, e-signature or scanned signature, as per REB/organizational policies and procedures.

5.1 Delegation of Signing Authority

- 5.1.1 The REB Chair or designee may delegate signatory authority for documents related to REB review and approval;
- 5.1.2 The REB Chair or designee may only delegate signing authority to REB members or REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority;
- 5.1.3 The REB Chair or designee may not delegate his/her signing authority to ad hoc advisors or to independent contractors;
- 5.1.4 The REB Chair or designee should clearly define the parameters of the delegated authority;
- 5.1.5 The REB Chair or designee may delegate signing authority indefinitely or for defined periods of time (e.g., for absences);
- 5.1.6 Delegation of signing authority must be documented and retained.

5.2 REB Reviews, Decisions and Other Correspondence with the Researcher

- 5.2.1 For each submission reviewed at a Full Board meeting, the responsible REB Office Personnel records the decision made by the Full Board;
- 5.2.2 Communication of the REB decision made at a Full Board meeting must be reviewed and authorized by the REB Chair or designee or as otherwise delegated by the REB Chair or designee;
- 5.2.3 For each submission that undergoes delegated review, the reviewer's decision is documented;

- 5.2.4 Once a final decision is documented by the REB Chair or designee, the responsible REB Office Personnel may issue the decision or letter;
- 5.2.5 All activities are documented in the research file, which may be physical or electronic;
- 5.2.6 Any letters, memos, or emails between the REB and Researchers that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information), may be issued as per delegated signing authority;
- 5.2.7 All reviews, actions, decisions and signatures (where applicable) are filed within the research file;
- 5.2.8 All correspondence is retained in the research file.

5.3 Correspondence with External Agencies

- 5.3.1 The responsible Organizational Official or the REB Chair or designee signs all correspondence with all governmental or funding agencies and/or sponsors.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP106.001 | | Original version |
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SOP 107.001

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|-----------------------|---|
| Title | Use and Disclosure of Personal Information |
| SOP Code | 107.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the Research Ethics Board (REB) and REB Office personnel in the protection of the Personal Information (PI) of research participants.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

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 project, including the manner in which it is identified, collected, accessed, used, disclosed, retained, disposed of and protected.

The REB Chair, REB members and the REB Office Personnel are responsible for ensuring that the plan to protect confidentiality of participants' PI is appropriate, while ensuring that any PI received or accessed by the REB office, whether in the process of ethics review, inadvertently, or for other purposes is protected.

The Organization's privacy office is responsible for providing Researchers and research team members with guidance on privacy policies and regulations.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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.

PI may be obtained directly from research participants or through data stewards or custodians.

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 research community is in appropriately protecting 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.

5.1 REB Review of Privacy Concerns

5.1.1 The REB shall review the research submitted to determine if the Researcher has access to and/or is using PI and whether appropriate privacy legislation is adhered to;

5.1.2 In reviewing the research, the REB will include such privacy considerations as:

- The type of PI to be collected,
- The research objectives and justification for the requested personal data needed to fulfill these objectives,
- The purpose for which the personal data will be used,
- How the personal data will be controlled, accessed, disclosed, and de-identified,
- Limits on the use, disclosure and retention of the personal data,
- Any anticipated secondary uses of identifiable data from the research,
- Any anticipated linkage of personal data gathered in the research with other data about research participants, whether those data are contained in public or in personal records,

- Whether consent for access to, or the collection of personal data from participants is required,
- How consent is managed and documented,
- If and how prospective research participants will be informed of the research,
- How prospective research participants will be recruited,
- The administrative, technical and physical safeguards and practices in place to protect the personal data including de-identification strategies and managed linkages to identifiable data,
- How accountability and transparency in the management of personal data will be ensured;

5.1.3 The REB must find that there are adequate provisions to protect the privacy interests of participants before approving the research.

5.2 Receipt, Use and Disclosure of PI by the REB Office

5.2.1 The REB Chair, REB members and the REB Office Personnel are bound by confidentiality agreements signed or implicitly understood as a condition of employment prior to commencement of their duties;

5.2.2 The REB does not intentionally collect participant PI;

5.2.3 Subject to consent, as applicable, the REB is permitted to access PI for the purposes of the review, the approval, the ongoing monitoring/auditing, and/or other Quality Assurance activities;

5.2.4 The REB office must adopt reasonable safeguards and ensure that there is training for REB Office Personnel to protect PI from unauthorized access;

5.2.5 REB members or REB Office Personnel may consult with the REB Chair or designee if they are uncertain about the appropriate use or disclosure of PI;

5.2.6 If any PI is received inadvertently in the REB Office (e.g. disclosed by a Researcher), appropriate notification must take place and any corrective action that is required including, if applicable, notification to the appropriate Organizational representative. The facts surrounding the breach, the appropriate steps taken to manage the breach, remedial activities to address the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per Organizational policies and procedures;

5.2.7 If there is an internal breach involving the use or dissemination of PI, the REB Chair or designee will be notified, and if applicable, notification of the appropriate Organizational representative, and a determination will be made in a timely manner regarding a corrective action plan. This process may include notification, containment, investigation and remediation, and strategies for prevention. The

SOP 107.001

facts surrounding the breach, the appropriate steps taken to manage the breach and the outcome will be documented. The PI will be destroyed in a secure manner as per Organizational policies and procedures;

5.2.8 At the discretion of the REB Chair or designee, in consultation with the Organization, the provincial privacy office (or equivalent) may be notified.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP107.001 | | |
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SOP 108.001

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|-----------------------|--|
| Title | Standard Operating Procedures Maintenance |
| SOP Code | 108.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1 Development, Review, Revision and Approval of Policies & Procedures

- 5.1.1 Designated REB Office Personnel will review the SOPs at least bi-annually (once every second year). SOPs will be reviewed sooner if changes to policies, guidelines, or standard practice warrant revisions or the creation of new SOPs;
- 5.1.2 SOPs may be revised for reasons including, but not limited to: changes to policies, regulations or guidelines, new policies, or changes to REB or administrative practices;
- 5.1.3 Designated REB Office Personnel will make the necessary modifications to existing SOPs, or draft a new SOP(s). SOPs are controlled documents and new drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”;
- 5.1.4 The revised SOP(s) will be circulated to REB Office Personnel and REB Chair or designee, as well as REB members and Organizational personnel (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;
- 5.1.5 Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the “Final Version Date”. The history of revisions will be recorded in the ‘SOP History’ section of each SOP;
- 5.1.6 Signatures on the SOP as determined by organizational policy will denote SOP approval. A new final version of the SOP supersedes any previous versions.

5.2 Distribution and Communication

- 5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all individuals identified in the ‘Responsibilities’ section of each SOP;
- 5.2.2 The SOPs will be available to Researchers and research teams, Organizational personnel, sponsors and funders as required;
- 5.2.3 Designated REB Office Personnel will train members of the REB and other REB Office Personnel on any new or revised policy and or relevant procedure, as applicable;

- 5.2.4 Each new REB member must review the applicable policies and procedures prior to undertaking his/her responsibilities as an REB member;
- 5.2.5 Each new REB Office Personnel must review the applicable policies and procedures prior to undertaking his/her responsibilities with the REB office;
- 5.2.6 Evidence of training must be documented;
- 5.2.7 The REB office shall maintain all documentation of SOP training.

5.3 Forms, Memos and Guidance Documents

- 5.3.1 Forms such as checklists and worksheets may be developed to facilitate compliance with the SOPs and to ensure that policies are integrated into daily operations. Forms may be either controlled or non-controlled;
- 5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;
- 5.3.3 Memos and guidance documents will be made available to the Researchers as applicable;
- 5.3.4 Designated REB Office Personnel and/or REB Chair or designee will evaluate the need for new or revised forms, memos or guidance documents.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP108.001 | | Original version |
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SOP 109.001

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|-----------------------|---|
| Title | Requirements for US Regulated Research |
| SOP Code | 109.001 |
| Effective Date | |

Site Approvals

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1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the necessary changes to REB processes, procedures and composition required for review of human participant research that falls under the jurisdiction of US federal regulations (45CFR46).

2.0 SCOPE

This SOP pertains to REBs that review a proportion of human participant research in compliance with US federal regulations.

3.0 RESPONSIBILITIES

Organizational Official(s), all REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB must review human research that falls under the jurisdiction of US federal agencies in compliance with US federal regulations. These requirements may differ from the policies and guidelines governing Canadian REBs and therefore necessitate changes to REB processes, procedures and composition.

5.1 Determination of Research under US Federal Regulations

5.1.1 Human participant research that is conducted, funded or supported by a US government agency and falls under the US Office of Human Research Protections' (OHRP) definition of "human subjects research" must comply with US regulations 45CFR46, otherwise known as the "Common Rule";

5.2 REB Composition and Quorum

5.2.1 In addition to the TCPS requirements for membership, the following REB composition requirements apply:

- If the REB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these groups.
- Membership may not consist entirely of members of one profession.
- At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

5.2.2 Quorum must additionally include 50% + 1 of the voting membership including a nonscientist.

5.3 REB Procedures

5.3.1 The REB Chair or designee shall determine if the project is defined as "human subjects research";

5.3.2 For research determined to fall under the definition of "human subjects research", the REB may only use expedited (delegated) review procedure for the initial and ongoing review of research that appears on the Secretary, Health and Human Services' (HHS) list of categories for expedited review and is

determined to involve no more than minimal risk and/or minor changes in previously approved research during the period for which approval is authorized;

5.3.3 At the time of continuing review, the REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving vulnerable populations,
- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or Research Staff complaints,
- Any other situation that the REB deems appropriate;

5.3.4 The REB has the authority to observe or have a third party observe the consent process and the research.

5.4 Research involving prisoners as participants

5.4.1 When reviewing research involving prisoners, the REB must additionally comply with the requirements outlined in 45CFR46 Subpart C, including:

- A majority of the REB members shall have no association with the prison(s) involved, apart from their membership on the REB;
- At least one member of the REB shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity;
- The research under review represents one of the categories of research permissible under 45CFR46.306(a)(2);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making

decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;

- Where the REB finds there may be a need for follow-up with participants after the end of their participation, adequate provision has been made for such activities, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

5.5 Reporting to the Organization

5.5.1 The Chair or designee will report any serious or continuing non-compliance with the Common Rule requirements and any suspension or termination of REB approval to the appropriate Organizational Official(s) and has the authority to notify the regulatory authorities (as applicable). The REB may delegate regulatory authority reporting to the organization.

5.6 Informed Consent Form

5.6.1 The informed consent form, when applicable, must additionally comply with the requirements set out in 45CFR50. For observational research, this includes, as appropriate/applicable to the research:

- The approximate number of research participants,
- The process involved for participation withdrawal,
- The effects of a participant choosing to withdraw,
- A statement identifying those with the authority to modify the research subjects participation (such as the Researcher or Sponsor).

5.8 REB Records

5.8.1 The REB Chair or designee will maintain the REB membership roster which includes: name, degree(s), area(s) of expertise and organizational affiliation(s), role on the REB (e.g. scientific, nonscientific), sex, and sufficient detail to describe each member's chief anticipated contribution to REB deliberations (as applicable);

5.8.2 A vote will be held for each submission requiring a decision; the REB minutes will reflect the number of members voting for, against or abstaining for each submission.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP 109.001 | | |
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| Title | Composition of the REB |
| SOP Code | 201.001 |
| Effective Date | |

Site Approvals

| Name and Title (typed or printed) | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the membership composition requirements of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for ensuring that the composition of the REB meets the applicable requirements.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Individual members of an REB must have the appropriate training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles, and applicable policies, guidelines and regulations pertaining to human research participant protection.

To ensure thoughtful and proportional review it is important that the REB is composed of members with expertise in the disciplines and methods that match with the research submitted to them. Representatives of the communities from which research participants are recruited must also sit on the REB as members.

5.1 Selection of REB Members

- 5.1.1 In selection of REB members, equal consideration shall be given to qualified persons of both sexes. No appointment shall be made solely on the basis of sex;
- 5.1.2 The REB will make every effort to foster diversity as it reflects the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions;
- 5.1.3 REB members will be selected based on the needs of the REB as outlined below and per applicable policies, guidelines and regulatory and other requirements.

5.2 Composition of the REB

- 5.2.1 The membership of the REB will be in compliance with *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
- 5.2.2 The REB Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions;
- 5.2.3 The REB will include at least five members represented by the following categories:

- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the REB,
- At least one member who is knowledgeable in ethics,
- At least one member who is knowledgeable in the relevant law. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research, and
- At least one community member who has no affiliation with the organization;

5.2.4 A member may not fulfill more than two representative capacities or disciplines;

5.2.5 Members will include men and women;

5.2.6 At least one member, when possible, who is from an identifiable Indigenous community, when the REB reviews research that recruits participants from that community;

5.2.7 Additional membership as required by applicable legislation or guidelines.

5.3 Alternate Members

5.3.1 The REB Chair or designee may ask an alternate REB member to attend an REB meeting to draw on his/her expertise in an area that may be relevant to that meeting's deliberations, or to establish a quorum for that meeting in the absence of the regular REB member;

5.3.2 Only alternate REB members of comparable qualifications may substitute for an REB member;

5.3.3 The minutes shall document when an alternate REB member replaces a primary REB member.

5.4 REB Chair

- 5.4.1 Whenever possible and practicable, the REB Chair will be selected from experienced REB members who are familiar with the applicable policies and guidance documents;
- 5.4.2 The REB Office Personnel updates the REB membership roster to reflect this change.

5.5 Ad Hoc Advisors

- 5.5.1 At his/her discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB;
- 5.5.2 The ad hoc advisor may be asked to participate in the REB meeting to lend his/her expertise to the discussions;
- 5.5.3 All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement*;
- 5.5.4 The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum;
- 5.5.5 Documentation of key information provided by the ad hoc advisor shall be summarized in the REB minutes and if available, the written report shall be placed in the REB files.

5.6 Observers at REB Meetings

- 5.6.1 The REB may allow observers to attend its meetings;
- 5.6.2 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the REB conflict of interest and confidentiality policies;
- 5.6.3 Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion;
- 5.6.4 Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application;

5.6.5 The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP201.001 | | Original version |
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SOP 202.001

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|-----------------------|-------------------------------------|
| Title | Management of REB Membership |
| SOP Code | 202.001 |
| Effective Date | |

Site Approvals

| Name and Title (typed or printed) | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the management of the membership of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

The REB Chair and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for monitoring and managing the REB membership.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB membership (e.g., appointment, terms) must be adequately managed to continue to meet composition requirements and to maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed.

5.1 Appointments – Regular Members and Alternates

- 5.1.1 REB members are appointed as per the organization's REB terms of reference;
- 5.1.2 Community members (meeting membership requirements) are solicited from the greater local community;
- 5.1.3 Each REB member selected is approved by the REB Chair or designee or as determined by the organizational REB terms of reference;
- 5.1.4 Candidates selected to serve on the REB will be asked to sign a letter of appointment and a *Confidentiality of Information and Conflict of Interest Agreement*.

5.2 Appointments – REB Chair and Vice-Chair

- 5.2.1 The REB Chair is appointed as per the Organization's REB terms of reference;
- 5.2.2 The REB Vice-Chair is appointed as per the Organization's REB terms of reference;
- 5.2.3 The REB Chair and Vice-Chair will be asked to sign a *Confidentiality of Information and Conflict of Interest Agreement*.

5.3 Ad hoc Advisors

- 5.3.1 At his/her discretion, the REB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

5.4 Terms of Appointment

- 5.4.1 Each REB member will serve for a term specified by the organization;
- 5.4.2 Re-appointment of an REB member for (an) additional term(s) is allowed, by mutual agreement of the REB member and the REB Chair or designee;
- 5.4.3 The REB Chair and Vice-Chair will serve for a term specified by the organization;

5.4.4 Terms will be overlapping to preserve the experience level, expertise, and continuity of the REB.

5.5 Qualifications and Training of REB Members

5.5.1 Each member of the REB will follow qualification and training procedures.

5.6 Resignations and Removals

5.6.1 An REB member may resign before the conclusion of his/her term upon provision of notice to the REB Chair or designee;

5.6.2 An REB member may be asked to step down if they consistently miss a specified percentage of the scheduled Full Board meetings in their term;

5.6.3 The REB Chair or designee may otherwise remove an REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner;

5.6.4 An REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other relevant behavior that could be perceived as compromising his/her ethical judgment;

5.6.5 Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve the level of experience and expertise and to ensure the continuity of the functions of the REB.

5.7 Compensation

5.7.1 Compensation and reimbursement of expenses for REB members will be according to Organizational policies.

5.8 Liability and Coverage

5.8.1 All REB members are insured for their research ethics review-related work by the Organization's insurance policy, subject to the terms and conditions of that policy.

5.9 Documentation

5.9.1 The REB Office Personnel will maintain an updated electronic REB membership list;

5.9.2 The REB membership list is reviewed and updated as required, or with the initiation of new or conclusion/termination of existing terms;

- 5.9.3 The current REB membership list and archived lists are maintained by the REB Office;
- 5.9.4 CVs, other supporting documents related to education and expertise, signed members' letters of appointment and confidentiality agreements for all current and past REB members will be maintained in the REB office;
- 5.9.5 The REB Chair or designee will maintain the REB membership roster which may include: name, degree(s), area(s) of expertise, role on the REB (e.g. faculty member, community member, legal member), gender, and indications of experience sufficient to describe each member's anticipated contribution to REB deliberations (as applicable);
- 5.9.6 A detailed membership list will be kept in the REB Office. This list will contain REB member contact information and additional information on areas of expertise for the purposes of communication and reviewer assignment. It will be kept confidential for access only by REB members and the REB Office Personnel;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP202.001 | | Original version |
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|-----------------------|------------------------------|
| Title | Duties of REB Members |
| SOP Code | 203.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of the members of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for clearly articulating all required duties associated with membership to the REB to potential and current REB members.

REB members and alternates are responsible for fulfilling their duties as specified in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Each REB member's primary duty is the protection of the rights and welfare of humans who are serving or will serve as participants in research. In order to fulfill their duties, REB members must be dedicated to meeting the REB's responsibilities to its research community and must be knowledgeable in the policies and guidelines germane to human research participant protection.

5.1 Attendance

5.1.1 Regular REB members are expected to attend the regularly scheduled REB meetings. REB Members may be asked to step down if they miss a specified percentage of the scheduled REB meetings;

5.1.2 REB members must notify the REB Office if they will be absent for an REB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place;

5.1.3 Alternate REB members are expected to attend the identified REB meetings for which they have confirmed their availability to replace a regular REB member, and/or a minimum of two REB meetings per year;

5.1.4 REB members are expected to be available for the entire REB meeting, not just the sections for which they have been assigned as reviewers.

5.2 Terms of Duty

5.2.1 All members of the REB, including the REB Chair and Vice-Chair, will be appointed for a term as specified by Organizational policy.

5.3 Duties

5.3.1 All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to submit comments in advance of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;

5.3.2 Each REB member is expected to fulfill specific duties based on the role as outlined below. More than one REB member may fulfill each role;

- 5.3.3 **Members with relevant expertise in research disciplines, fields and methodologies:** are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits and standards of practice. These members should also advise the REB if additional expertise is required to assess whether the research adequately protects the rights and welfare of human participants;
- 5.3.4 **Community member(s):** are expected to reflect the perspective of the participant, where relevant provide input regarding their knowledge about the respective community, and be able to discuss issues and research from that perspective; they must be at arms-length from the institution and it is preferable that they are not currently engaged in research or legal work as their principal activities;
- 5.3.5 **Member(s) knowledgeable in relevant law:** are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the REB;
- 5.3.6 **Member(s) knowledgeable in ethics:** are expected to guide the REB in identifying and addressing ethics issues related to the research under review;
- 5.3.7 **Ad hoc advisors:** individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend his/her expertise to the discussions;
- 5.3.8 **REB Chair:** The REB Chair or designee provides overall leadership to the REB:
- The REB Chair can delegate any of his/her responsibilities, as appropriate to a Vice-Chair or other qualified individual(s),
 - Any responsibilities that are delegated by the REB Chair must be documented,
 - The REB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The REB Chair or designee determines the level of risk of each research project. The REB Chair or designee monitors the REB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
 - The REB Chair or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Chair or designee can ask a substitute REB member to attend an REB meeting in order to draw his/her expertise in an area that may be relevant to the REB's review and deliberations of the research,
 - The REB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
 - The REB Chair or designee performs or delegates authority to (an) REB

member(s) to perform a delegated review,

- The REB Chair or designee authorizes approval on all REB decisions, confirmed through signature, electronic signature or official letter,
- The REB Chair or designee will report on the activities of the REB to the Organization on an annual basis,
- The REB Chair or designee, in conjunction with the REB Office Personnel and other Organizational representatives as applicable, ensures the REB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the Organization on policies and procedures related to research conduct,
- The REB chair or designee, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and Office Personnel, and will address any gaps identified,
- The REB Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards.

5.3.10 **REB Vice-Chair:** The REB Vice-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so:

- The REB Vice-Chair performs all responsibilities assigned by the REB Chair,
- The REB Vice-Chair assists with the overall operation of the REB.

5.4 Primary and Secondary Reviewers

5.4.1 The REB may assign reviewers for studies reviewed at a full board meeting or for delegated reviews.

5.4.2 For delegated review: assigned reviewers present their findings resulting from review of the REB submission materials and provide an assessment of these materials, recommending specific action to the REB Chair or designee.

5.4.2 For full board review: Assigned reviewers must conduct in-depth reviews of their assigned submissions and submit comments prior to the REB meeting. Reviewers may lead the discussion of the research project during the REB meeting.

5.4.3 Assigned reviewers may review additional material(s) as requested by the REB.

5.5 Training and Education

5.5.1 REB members are expected to follow training and education procedures.

5.6 Conflict of Interest

5.6.1 REB members are expected to follow conflict of interest procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP203.001 | | Original version |
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SOP 204.001

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|-----------------------|--|
| Title | REB Office Personnel Serving as REB Members |
| SOP Code | 204.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the duties of REB Office Personnel serving as members of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

The REB Chair, REB Office Personnel and Organizational Official(s) are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for ensuring that the REB Office Personnel serving as members have the requirements for fulfilling this role and clearly articulating all required duties associated with their duties as members of the REB.

REB Office Personnel are responsible for understanding and fulfilling their roles as REB members and as REB staff and managing real, potential or perceived COI appropriately.

The Organizational Official(s) is responsible for ensuring that the REB Office Personnel serving as members of the REB understand and execute their functions appropriately.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Each REB member's primary duty is the protection of the rights and welfare of humans who are serving or will serve as participants in research. In order to fulfill their duties, REB members must be dedicated to meeting the REB's responsibilities to its research community and must be knowledgeable in the policies and guidelines germane to human research participant protection. REB Office Personnel who serve as REB members must meet the same standard as other REB members (as per SOP 203).

5.1 Duties

- 5.1.1 REB Office Personnel who are designated as Board members should attend convened meetings and participate in discussions, but they shall not be counted in determining a quorum and shall not participate in any votes;
- 5.1.2 REB Office Personnel that have been appointed to serve as REB members may perform delegated review in accordance with the delegated review procedure;
- 5.1.2 The assignment of these tasks to REB Office Personnel will be documented.

5.2 Appointment Criteria

- 5.2.1 REB Office Personnel serving as REB members shall have knowledge, experience, and training comparable to what is expected of REB members. The REB shall ensure that Office Personnel can fulfill their responsibilities as REB members independently from their responsibilities as members of their Organization.

5.4 Training and Education

- 5.4.1 REB Office Personnel serving as REB members are expected to follow training and education procedures for REB members in addition to any professional training requirements for organizational personnel.

5.5 Conflict of Interest

- 5.5.1 REB Office Personnel serving as REB members are expected to follow conflict of interest procedures for REB members in addition to conflict of interest procedures for organizational personnel.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP204.001 | | Original version |
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SOP 301.001

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|-----------------------|--|
| Title | REB Submission Requirements and Document Review |
| SOP Code | 301.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes Research Ethics Board (REB) submission requirements and document review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research, renewal applications for ongoing research and completion reports.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REB members must rely on the documentation provided by the Researcher for initial and continuing review. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

The REB is supported by administrative procedures that ensure that REB members not only have adequate time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB approval.

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.

5.1 Submission Requirements

5.1.1 The required documents, format and submission procedures are outlined on the REB's website. These may include:

- REB application form,
- Continuing Review form,
- Amendment and/or Administrative Change form,
- Unanticipated and Adverse Event Reporting form,
- Research Completion form.

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

5.1.3 The research question and methodology is written in sufficient detail to permit evaluation of the scientific or scholarly 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,
- Primary and secondary outcomes,
- Sample size justification,
- Data analysis.

5.2 Document Review Procedures

- 5.2.1 A unique number is assigned to each submission at the time of the receipt of the application. REB Office Personnel screens the submission for overall completeness;
- 5.2.2 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the REB Office Personnel will follow up with the Researcher and/or alternate contact to request the required information for inclusion with the submission;
- 5.2.3 Upon receipt of a complete submission, the responsible REB Office Personnel identifies any outstanding items that will be required to issue approval, as applicable;
- 5.2.4 For submissions requiring Full Board review, the REB Office Personnel posts the submission to the agenda of the next Full Board meeting. Primary and secondary reviewers are assigned once the agenda is complete, if applicable;
- 5.2.5 For submissions reviewed via delegated review procedures, the REB Chair or designee assigns a reviewer(s) and sends the research to that (those) reviewer(s).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP301.001 | | Original version |
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|-----------------------|-----------------------------------|
| Title | REB Meeting Administration |
| SOP Code | 302.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the required activities for the preparation, management and documentation of Full Board meetings of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

The REB Chair and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Except when a delegated review procedure is used, the REB must review proposed research at Full Board meetings at which a quorum is present and maintained.

The REB meeting agenda provides structure and order for meeting. Agenda items normally include review and approval of minutes from the previous meeting, declarations of conflict of interest, an overview of all items that have been reviewed and approved through the delegated review procedure, new information pertinent to REB review such as new policies or guidelines, 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 discussions and 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.

5.1 Agenda Preparation

- 5.1.1 Following a document review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the REB Office Personnel and the determination of the review type by the REB Chair or designee, the responsible REB Office Personnel adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;
- 5.1.2 For submissions that were reviewed and approved via delegated review procedures, the list of approvals is appended to the next Full Board meeting agenda;
- 5.1.3 The REB Office Personnel attaches to the agenda any previous REB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 5.1.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns the reviewers;
- 5.1.5 The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 5.1.6 The reviewer assignment and the agenda are issued in a timely manner prior to the REB meeting date. The REB members attending the REB meeting will receive a copy of the REB meeting agenda;
- 5.1.7 Ad hoc advisors will receive copies of relevant submissions;

5.1.8 Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Office Personnel or designee also may issue an updated agenda notice depending on the nature of the changes.

5.2 Primary and Secondary Reviewers

5.2.1 Prior to the meeting, the REB Office Personnel, in consultation with the REB Chair or designee as necessary, will assign a primary and may assign one or more secondary reviewers for each new research project and at least one reviewer for each amendment;

5.2.2 No REB member will be assigned as a reviewer on a submission in which he or she is a Researcher or Supervisor or in which there is a declared conflict of interest;

5.2.3 The REB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda;

5.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

5.3 Prior to the REB Meeting

5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the REB meeting. The primary reviewer should be prepared to lead the discussion at the Full Board meeting;

5.3.2 All REB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous REB meeting minutes on the agenda and any attachments to the agenda for review or discussion;

5.3.3 REB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting;

5.3.4 All REB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.

5.4 During the REB Meeting

5.4.1 A quorum must be present to proceed with a Full Board meeting;

5.4.2 Should quorum fail during a Full Board meeting (e.g., through recusal of REB members with conflicts of interest or early departures), the REB may not make further decisions unless quorum can be restored;

- 5.4.3 An alternate REB member may attend in the place of a regular REB member to meet quorum requirements. When a REB member and his/her alternate both attend the REB meeting, only one is allowed to participate in the deliberations and final decisions regarding approval;
- 5.4.4 Should a REB member not be physically present during a Full Board meeting, he/she may participate via videoconference or teleconference. REB members participating by videoconference or teleconference count towards quorum;
- 5.4.5 Ad hoc advisors will not be used to establish a quorum;
- 5.4.6 REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 5.4.7 REB Office Personnel serving as REB members are not counted toward quorum.
- 5.4.8 Under unusual circumstances (e.g., public health alerts and quarantines) the REB Chair or designee may, at his/her discretion, conduct an REB meeting with all REB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met;
- 5.4.9 Only those REB members present (i.e., in person, or via videoconference or teleconference) at the Full Board meeting may participate in the deliberation and final decision regarding approval;
- 5.4.10 Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Observers must disclose any vested interest in, or responsibility for, any applications being considered at the REB meeting;
- 5.4.11 If requested, Researchers may (in person or via teleconference) attend the REB meeting to present their research and respond directly to any comments or questions raised by the REB, subject to the agreement of the REB;
- 5.4.12 Any individual not listed on the official REB membership roster may not participate in the decisions of the REB.

5.5 Meeting Minute Preparation

- 5.5.1 The REB Office Personnel will draft the REB meeting minutes including key discussions, decisions and votes;
- 5.5.2 The key REB discussions and decisions for submissions are recorded;

- 5.5.3 The REB's concerns, clarifications and recommendations to the Researcher as discussed at the REB meeting are included in the REB reviewer comments that are sent to the Researcher. The information documented is included in the REB meeting minutes;
- 5.5.4 The meeting may be audio recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
- 5.5.5 The minutes are intended to reflect what the REB discussed, how it resolved controverted issues, and the decisions made;
- 5.5.6 The draft minutes should be completed prior to the next REB meeting.

5.6 Meeting Minute Approval

- 5.6.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;
- 5.6.2 The REB approval on the previous REB meeting minutes are recorded in the current REB meeting minutes;
- 5.6.3 If the previous REB meeting minutes are approved pending revisions, the REB Office Personnel makes the required changes, and unless the REB requests further review of the minutes prior to approval, the REB Office Personnel records the minutes as "approved by the REB."

5.7 Documentation

- 5.7.1 The REB meeting minutes include the following items:
 - Date, place, and time the REB meeting commenced and adjourned,
 - Names of REB members in attendance (present, teleconference, videoconference),
 - Names of REB members absent,
 - Names of REB Office Personnel present at the meeting,
 - Presence of observers,
 - Use of ad hoc advisors and their specialty,
 - List of declared conflicts of interest, a summary of any discussions, and the decision taken by the REB to address them (as applicable) or a note that none were declared,
 - A summary of key discussions and controverted issues and their resolution for each submission, as applicable,

- The decisions taken by the REB regarding approval for each submission, as applicable,
- The basis for requiring changes or for disapproving submissions,
- Number of REB members in attendance for the review of each submission requiring a decision,
- REB member(s) recused related to conflicts of interest for each submission requiring a decision,
- Number(s) voting for, against or abstaining in the rare event of a vote,
- Reference to any attachments to the agenda;

5.7.2 All REB meeting agendas and minutes are retained in the REB records;

5.7.3 The agendas, REB meeting minutes and review documents are confidential and will not be released or made available unless required for compliance purposes.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP302.001 | | Original version |
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SOP 303.001

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| Title | Document Management |
| SOP Code | 303.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the Research Ethics Board (REB) for initial or for continuing review, as well as to all REB administrative documents.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB office must retain all relevant records (e.g., documents reviewed and approved or disapproved, REB meeting minutes, correspondence with Researchers, written SOPs, REB membership rosters) to provide a complete history of all actions

related to the REB review and approval of submitted research. Such records must be retained for the length of time required by applicable policies, regulations and guidelines.

Relevant records must be made accessible to authorized organization personnel, Researchers and funding agencies within a reasonable time upon request.

5.1 Research-Related Documents

5.1.1 The REB office retains the submission materials for all research that have been submitted for REB review and have been either approved, acknowledged or disapproved;

5.1.2 Research-related documents include, but are not limited to, the following (as applicable):

- Initial REB application form and all associated attachments;
- Correspondence between the REB and the Researcher, including REB approval letters, requests for modifications, etc.;
- Records of ongoing review activities such as:
 - Modifications to the application including amendments to the research application and respective documents (recruitment and consent materials, research tools),
 - Protocol deviations, adverse and unanticipated event reports,
 - Audit, quality assurance reports
- Continuing review applications;
- Reports of any complaints received by the REB and their resolution.

5.2 REB Administrative Documents

5.2.1 The REB office retains all administrative records related to the REB review activities;

5.2.2 REB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all REB meetings;
- Submitted REB member reviews;

- REB member records:
 - Current and obsolete REB membership rosters, including alternate REB members,
 - CVs and training/qualification documentation of current and past REB members;
- Copies of appointment letters;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions;

5.3 Document Access, Storage and Archiving

5.3.1 Access to individual research projects and related documents, and to Researcher profiles is role-based to ensure that users only have access to documents and activities that are required by their role;

5.3.2 The REB records are housed in a physically and electronically secure location with back-up, disaster and recovery systems in place.

5.4 Confidentiality and Document Destruction

5.4.1 All submissions received by the REB are considered confidential and are accessible only to REB members (including the REB Chair and Vice-Chair), as well as to Organizational Official(s) and REB Office Personnel;

5.4.2 Relevant research projects and associated documents may be made accessible to other parties, by the Researcher submitting a request for guest access to the research;

5.4.3 Relevant research projects and associated documents may be made accessible for quality assurance and compliance purposes;

5.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) as per organizational policy or for a minimum of 3 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable requirement;

5.4.5 Any confidential materials in paper format in excess of the required documentation will be shredded.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP303.001 | | Original version |
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SOP 401.001

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|-----------------------|-------------------------|
| Title | Delegated Review |
| SOP Code | 401.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for determining if research is eligible for delegated review. The REB Chair or designee may delegate this task to REB Office Personnel; however, the responsibility for oversight remains with the REB Chair or designee.

The REB Chair or designee or REB member(s) is responsible for conducting the delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full Board 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.

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typical used by REBs are Full Board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.

5.1 Determination of Qualification for Delegated Review

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

5.1.2 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 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, and where the REB Chair has determined that delegated review is appropriate.

5.1.3 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 ethics guidance and requirements as applicable.

5.2 Delegated Review Process

- 5.2.1 REB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review (see Section 5.1.2) may be sent 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;
- 5.2.2 For research that meets the criteria, delegated review may be conducted by the REB Chair, designee or by one or more REB members as designated by the REB Chair or designee;
- 5.2.3 The REB Chair, designee or REB member(s) reviewing research under delegated review must not have a Conflict of Interest in the research;
- 5.2.4 In reviewing the research under delegated procedures, the REB Chair, REB member(s) or designee may exercise all of the authorities of the REB, except that they may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;
- 5.2.5 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;
- 5.2.6 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;
- 5.2.7 The decision regarding the designation of the research (i.e., either requiring Full Board or delegated review) and the outcome of the review will be recorded. The REB Office Personnel may issue the review or decision letter.

5.3 Notification of the REB

- 5.3.1 The REB will be informed of research that was reviewed and approved using delegated review procedures in a timely and appropriate manner.

5.4 Documentation

- 5.4.1 The type of REB review conducted (i.e., Full Board or delegated) will be documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;
- 5.4.2 The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP401.001 | | |
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SOP 402.001

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|-----------------------|-----------------------------|
| Title | REB Review Decisions |
| SOP Code | 402.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research for ethical acceptability.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly stated and agreed upon.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

As a result of its review, an REB has the authority to approve, disapprove, or to require modifications to submitted research. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the REB members with voting rights who are present at a Full Board meeting at which there is a quorum. When a vote is used, dissenting opinions shall be documented (see SOP 302).

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 (see SOP 105A).

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

5.1 REB Decisions

5.1.1 REB decisions are made either by consensus or, if consensus cannot be reached, by a majority vote of REB members with voting rights who are present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies.

5.1.2 The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

Approval:

- When initial review criteria required for approval are satisfied, the research may be approved,
- The approval date is defined according to the REB's procedures,
- The expiry date of the REB approval is calculated from this date.

Approval with Modifications/Clarifications*:

- When initial review criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may recommend "Approval with Modifications/Clarifications",
- When the REB recommends "Approval with Modifications/Clarifications",

the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified (at the REB meeting for Full Board review or by designated reviewers for delegated review) and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:

- The REB Chair or designee alone,
 - The REB Chair and one or more named REB members that were present at the REB meeting or who submitted written comments on the application,
 - A sub-group of the REB members designated by the REB Chair or designee or by the REB,
 - A designated REB member or members with sufficient knowledge and experience regarding the research and ethical requirements.
- In deciding the procedures to be followed, the REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it.
 - Where the information or modifications are administrative, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone,
 - Where the additional information/modification is substantive (e.g. clarification on inclusion criteria), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the assigned reviewer(s) or relevant expert member(s),
 - If the Researcher's response is deemed complete and satisfactory by the REB Chair, designee or REB (as determined above), approval can be issued,
 - If the Researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the Researcher,
 - The reviewers may decide upon reviewing the Researcher's response that the decision should be deferred and that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below),

*It is recognized that not all REBs utilize this category as a review decision.

Deferral (defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):

- The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met,
- The REB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting,

- The revised protocol and the Researcher's response materials shall be reviewed at a Full Board meeting,
- Upon consideration of the research along with the response from the Researcher, at the Full Board meeting, the REB should issue its final decision (approved, approved with modifications, deferral or disapproved),
- Researcher responses must be received and reviewed at a Full Board meeting. The approval date is defined according to local REB procedures. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all the conditions for approval have been met.

Disapproval:

- The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination,
- Disapproval cannot be decided through the delegated review mechanism.
 - If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting,
- The REB Chair or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the Researcher,
- If the research is disapproved, the reasons for disapproval will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

5.1.3 **Delegated Reviews:** When the research qualifies for delegated review, the reviewer(s) has the authority to make the final decision, i.e., approve the application, require modifications to any aspect of the application, or request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting,

5.1.4 When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair, designee or assigned reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date. The approval letter is not issued until all of the conditions for approval have been met,

5.2 Reconsideration and Appeal of REB Decisions

- 5.2.1 A Researcher may appeal the decision of the REB if the disagreement between the Researcher/applicant and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the Researcher/applicant shall have the right to be heard;
- 5.2.2 The Researcher must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons. A final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process;
- 5.2.3 Appeals are conducted in accordance with the established organizational policy. The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the Researcher (and his/her affiliated organization);
- 5.2.4 The appeal committee shall have the authority to review the basis of the decisions made by the REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the Researcher and the REB in writing.

5.3 Documenting REB Decisions

- 5.3.1 The REB meetings minutes will satisfy the applicable policy/ies;
- 5.3.2 The REB shall notify the Researcher in writing of its decision to approve or disapprove the proposed research, or of modifications/clarifications required to secure approval of the research;
- 5.3.3 If the REB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;
- 5.3.4 The final approval letter should include standard conditions of approval to which the Researcher must adhere (e.g. requirement to submit amendments prior to implementing changes to the protocol);
- 5.3.5 Notification or correspondence to the Researcher may be issued by the REB Office Personnel.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP402.001 | | |
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SOP 403.001

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| Title | Initial Review – Criteria for REB Approval |
| SOP Code | 403.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants 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).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

REB members are responsible for determining whether the research meets the criteria for approval.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants must meet 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.

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, the requirements of the organization where the research will be conducted must also be met before the research can begin (e.g., department approvals, adequate resources, etc.).

5.1 Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration:

- 5.1.1 The application has been authorized by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the authority to conduct the research;
- 5.1.2 Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;
- 5.1.3 The research will generate knowledge that could lead to improvements in health or well-being of individuals or society;
- 5.1.4 The methodology is appropriate with respect to the discipline and capable of answering the research question;
- 5.1.5 The risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;
- 5.1.6 The risks to participants (if any) are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;
- 5.1.7 The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research setting. The REB will consider vulnerability of participant populations with respect to ethical reasons for their inclusion, as appropriate;
- 5.1.8 There are sound methodological and ethical reasons for excluding classes of persons who might benefit from the research;

- 5.1.9 When some or all of the participants may be in situations or circumstances that make them vulnerable in the context of the research, additional safeguards have been included in the research, and in the REB review process, to protect the rights and welfare of these participants;
- 5.1.10 The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule, is provided to participants when applicable;
- 5.1.11 Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable policies and guidelines;
- 5.1.12 The informed consent process will ensure the research and the required elements of consent are accurately explained to participants;
- 5.1.13 The informed consent process will be appropriately documented in accordance with the relevant policy;
- 5.1.14 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
- 5.1.15 There will be adequate provisions for the timely publication or dissemination of the research results, unless there is an ethically acceptable reason for withholding publication or dissemination (e.g., Indigenous community control);
- 5.1.16 If applicable, the research has been or will be registered via an internationally recognized clinical trial registry and a registration number has been/will be submitted to the REB. If the research is not yet registered, the researcher shall provide the REB with the registration number upon registration.

5.2 Additional Criteria

- 5.2.1 Studies proposing access to, or collection of, personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to;
- 5.2.2 Additional criteria for research involving Indigenous peoples in Canada, or research on materials related to human reproduction, or genetic research shall be applied when applicable in accordance with policies and/or Regulations.

5.3 Length of Approval Period

- 5.3.1 The REB shall establish the length of approval in relation to the degree of risk to participants, up to a maximum of one year;

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP403.001 | | Original version |
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SOP 404.001

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|-----------------------|--------------------------------------|
| Title | Ongoing REB Review Activities |
| SOP Code | 404.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for REB review of ongoing research activities that occur after the initial Research Ethics Board (REB) approval of a research project and before the next scheduled continuing review of the research project.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for reporting to the REB any unanticipated issues or events that may arise or proposed changes that are needed through the course of the research that might affect the rights, safety and well-being of research participants.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Circumstances may arise during the course of research that may need to be reported to the REB and/or require that changes be made to the project. 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 information may include:

- Proposed amendments to the previously approved research,
- Reports of unanticipated issues and events involving risks to participants or others,
- Deviations from the previously approved research,
- Any other new information that may adversely affect 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.

5.1 Amendments to the Approved Research

- 5.1.1 The Researcher is responsible for submitting to the REB any proposed changes to the approved research in the form of an amendment request. Changes to the approved research include modifications to the research, to the consent form, changes in participant materials (e.g., recruitment materials), a change in the Researcher or research team, etc.;
- 5.1.2 When the amendment includes a change to the consent document(s), the Researcher must indicate his/her recommendation for the provision of the new information to current and/or past research participants;
- 5.1.3 The Researcher should indicate the new level of risk the research poses by incorporating the change. Supporting correspondence documentation and/or background information may be appended to the amendment submission;
- 5.1.4 The REB Chair or designee reviews the amendment to determine the appropriate level of REB review required (i.e., Full Board or delegated review);
- 5.1.5 The REB Chair or designee also may use delegated review procedures for review of amendments when the conditions are met (see SOP 401);

- 5.1.6 If the proposed change represents more than minimal risk, it must be reviewed by the REB at a Full Board meeting.
- 5.1.7 For amendments requiring Full Board review, the responsible REB Office Personnel assigns the amendment to the next available Full Board meeting. For amendments that meet the criteria for delegated review, the responsible REB Office Personnel will forward the amendment to the designated reviewer;
- 5.1.8 When an amendment involves a revised consent, the REB will consider the recommendations of the Researcher in determining if, how and when the new information should be provided to the research participants and whether re-consent is required;
- 5.1.9 The REB must find that the criteria for approval of the overall project are still met in order to approve the amendment;
- 5.1.10 The amended research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants.

5.2 Unanticipated Issues

- 5.2.1 The Researcher is responsible for reporting any unanticipated issue or event that may increase the level of risk to participants, or have other ethical implications for participants.
- 5.2.2 Any unanticipated issue that may increase the level of risk to participants or may impact participants' welfare should be reported immediately to the REB.
- 5.2.3 The researcher should indicate whether the unanticipated issue was directly related to the research and whether changes to the protocol are necessary to reduce the chance of recurrence.
- 5.2.4 If changes are necessary, an amendment request should be submitted in addition to the unanticipated event report.

5.3 Deviations to Previously Approved Research

- 5.3.1 Deviations from the approved protocol that are necessary to eliminate an immediate risk(s) to the participants may be implemented immediately, but must be reported to the REB at the earliest opportunity.
- 5.3.2 Deviations that occur through the course of research that may impact the risk assessment of the research or have other ethical implications must be reported to the REB. If a permanent change is required, an amendment request should be submitted.
- 5.3.3 Minor deviations (e.g. typographical corrections of consent form, changes of wording on questionnaires) from the research that do not impact risk or have ethical implications may be summarized in annual status reports.

5.4 Review of Unanticipated Event and Deviation Reports by the REB

- 5.4.1 The responsible REB Office Personnel will screen the submission form for completeness;
- 5.4.2 Privacy breaches are reviewed by the REB Chair or designee, and any recommendations including remedial action are determined in consultation with the organization's privacy office and/or legal counsel. The privacy breach report is forwarded to the REB Chair or designee for review and final acknowledgement;
- 5.4.3 The REB Office Personnel may route the submission back to the Researcher to request clarifications, missing documents or additional information;
- 5.4.4 The REB Office Personnel will forward the submission to the designated REB reviewer(s);
- 5.4.5 The assigned REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;
- 5.4.6 The assigned reviewer(s) may request further information from the Researcher;
- 5.4.7 When reviewing the report, the REB should:
 - Assess the appropriateness of any proposed corrective or preventative measures by the Researcher,
 - Consider any additional appropriate measures that may or may not have been identified or proposed by the Researcher,

- Consider whether the affected research still satisfies the requirements for REB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

5.4.8 If the event does not raise concerns and does not appear to involve risks to research participants or others, the REB Chair or designee acknowledges the report, and no further action is required;

5.4.9 If the REB Chair or designee determines that immediate action is required to protect the safety of research participants, he/she may suspend ethics approval of the research pending review by the Full Board, providing the justification for such action is documented;

5.4.10 If the event raises concerns or involves risk to research participants such that REB action may be required, the item is added to the agenda of the next Full Board meeting;

5.4.11 For reports reviewed at a Full Board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent documents or process,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants' willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- Allegation of non-compliance or breach of responsible conduct of research in accordance with the Organization's policy and procedures.

5.4.13 When action is taken by the REB to ensure the protection of the rights, safety, and well-being of participants, the REB chair or designee is responsible for reporting to the Researcher and the Organizational Official(s).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP404.001 | | Original version |
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| Title | Continuing Review |
| SOP Code | 405.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the continuing review of research that is overseen by the Research Ethics Board (REB), and the criteria for continued REB approval.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee and the REB members are responsible for reviewing continuing review submissions and respective materials as appropriate for Full Board or delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REBs must establish procedures for conducting the continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

5.1 Continuing Review by the Full Board

- 5.1.1 The Researcher is required to submit an application for continuing review of research at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;
- 5.1.2 At a minimum, the REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB;
- 5.1.3 The REB may determine that the research requires continuing review more frequently than once per year. Considerations may include:
 - The nature of any risks posed by the research,
 - The degree of uncertainty regarding the risks involved,
 - The vulnerability of the participant population;
- 5.1.4 Continuing review applications must be submitted with sufficient time to be reviewed and approved prior to the date of expiry, regardless of the type of review they may undergo;
- 5.1.5 To assist the Researchers in submitting on time, a courtesy reminder(s) prior to the expiry date may be generated;
- 5.1.6 REB Office Personnel will review the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable;
- 5.1.7 REB Office Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review;
- 5.1.8 A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda;
- 5.1.9 For research that meets the criteria for Full Board review, the REB will discuss the research at a Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

5.2 Continuing Review by Delegated Review Procedures

- 5.2.1 When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;
- 5.2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met (see SOP 401);
- 5.2.3 REB Office Personnel will review the continuing review application for completeness, including verification of which, if any, documents have been changed, and request any clarifications, missing documents or other information as applicable;
- 5.2.4 REB Office Personnel will forward the application to the appropriate REB reviewer;
- 5.2.5 The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;
- 5.2.6 Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

5.3 REB Determinations

- 5.3.1 To grant a continuation of the approval of the research the REB must determine that Criteria for REB Approval, as described in SOP 403, are still met.
- 5.3.2 The REB may also make additional determinations, as per SOP 402, REB Review Decisions.

5.4 Continuing Review Applications not Received by the Expiry Date

- 5.4.1 If an application for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Researcher. When suspended, the Researcher must suspend all research activities as specified by the REB.
- 5.4.2 If the REB approval lapses and the Researcher wants to continue with the research, the REB may allow the Researcher to submit an application for continuing review after the expiry date. The REB will complete the review of the research as soon as possible and the Researcher may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented.

- 5.4.3 The REB may define a reasonable length of time for which a Researcher may submit an application for continuing review, beyond which the research is

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closed and a renewal application will not be accepted. A new submission will be required.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP405.001 | | Original version |
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SOP 406.001

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|-----------------------|----------------------------|
| Title | Research Completion |
| SOP Code | 406.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the completion of research with the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The Completion of research is a change in activity that must be reported to the REB.

SOP 406.001

A final report allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

5.1 Determining when Research is complete

- 5.1.1 The Researcher may submit a research completion report to the REB when there is no further recruitment, all new data collection is complete, no further contact with participants is expected, and the research objectives have been met. Other criteria may be determined as per Organizational policy;
- 5.1.2 The responsible REB Office Personnel will review the research completion application and request any outstanding information, clarification or documentation from the Researcher, if needed;
- 5.1.3 The REB Chair or designee will review the submission and acknowledge to the Researcher that the protocol file is “complete”;
- 5.1.4 Once a protocol file is “complete” with the REB, no further ethics review submissions for that research are required; however, the Researcher may submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB, (e.g. adverse event reports, changes to data management plan);

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP406.001 | | Original version |
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| Title | Suspension or Termination of REB Approval |
| SOP Code | 407.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures to be undertaken in determining and executing the suspension or termination of the Research Ethics Board's (REB) approval of research.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.

The Researcher is responsible for notifying the REB and the organization of any suspensions or terminations of the research and for providing a detailed explanation for the action.

The REB Chair or designee is not authorized to terminate REB approval; however, the REB Chair or designee is authorized to suspend REB approval, which must be reported

to the REB at its next Full Board meeting. The REB is authorized to terminate REB approval following its review at a Full Board meeting.

The REB Chair or designee is responsible for notifying the Researcher, and the Organizational Official(s), of any suspension or termination of REB approval of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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; or when there is evidence that the Researcher is not conducting the research in compliance with applicable policies and guidelines. The REB also has the authority to suspend recruitment while additional information is requested.

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.

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.

5.1 Suspension or Terminations of Research Activities

- 5.1.1 Research may be suspended or terminated by the REB or by the researcher (?) for a variety of reasons, e.g., following results of interim analyses, in response to a safety or privacy concern, due to pre-planned stopping criteria, etc.;
- 5.1.2 The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;
- 5.1.3 Reports of suspensions or terminations will be forwarded to the REB Chair or designee for review;

5.2 Suspension or Termination of REB Approval

- 5.2.1 If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include but are not limited to:
- The research not being conducted in accordance with the REB-approved protocol or REB requirements,
 - The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events)
 - Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
 - Repeated or deliberate failure to properly obtain or document consent from research participants,
 - Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
 - Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;
 - In accordance with an ongoing allegation or finding of a breach of responsible conduct of research, as determined through the Organization's policy and procedures.
- 5.2.2 The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, he/she must notify the REB at its next Full Board meeting;
- 5.2.3 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;
- 5.2.4 Prior to suspending or terminating REB approval, the REB must consider:
- Risks to current participants,
 - Actions to protect the safety, rights and well-being of currently enrolled participants,
 - Whether participants should be informed of the termination or suspension,
 - Whether adverse events or outcomes should be reported to the REB,
 - Identification of a time frame in which the corrective measures are to be implemented;
- 5.2.5 The REB Chair or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision;
- 5.2.6 Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;
- 5.2.7 If the research is suspended or terminated, the REB Chair or designee will issue

SOP 407.001

a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB (if any);

5.2.8 Suspensions may be lifted after corrective actions are completed to the REB's satisfaction.

5.3 Reporting Suspensions or Terminations

The REB Chair or designee will report any suspension or termination of REB approval to the appropriate Organizational Official(s).

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP407.001 | | Original version |
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SOP 408.001

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|-----------------------|----------------------------|
| Title | Course-based Review |
| SOP Code | 408.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the review procedure for research that will be conducted for pedagogical purposes as part of a student's course.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) and non-REB reviewers that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and non-REB reviewers are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee or REB member(s) or non-REB reviewer(s) is responsible for conducting the course-based delegated review.

The REB Chair or designee is responsible for oversight of the research undergoing course-based delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

REBs should adopt a proportionate approach to ethics review based on the general principle that the more invasive or risky the proposed and ongoing research, the greater the care in its assessment. Full Board review by the REB shall be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on foreseeable risks of harm anticipated to arise from the research. While all research must be reviewed adequately, provisions for proportionate review allow the REB to reserve a higher level of scrutiny, and correspondingly more protection, for more ethically challenging research.

When research will be conducted by a student as part of a course, for pedagogical purposes only (e.g., to learn how to conduct research), the institution may decide that ethics review can be conducted through the delegated review procedure by an REB member or by a non-REB reviewer at the institution's department or equivalent level.

In delegating ethics review of course-based research, the REB should carefully select REB member(s) or non-REB reviewer(s) and ensure that they have the appropriate experience, expertise, training and resources required to review the ethical acceptability of all aspects of the proposal in accordance with this Policy.

Research undergoing the course-based review procedure must meet the criteria for delegated review. Greater than minimal risk course-based research cannot use the course-based review procedure and must be reviewed by the Full Board.

5.1 Course-Based Review Process

5.2.1 REB Office Personnel will perform an initial screening of the submission. If the submission covers research activity within a recognized course (with valid course code) for a pedagogical purpose, the submission is then screened against a pre-defined set of criteria for delegated review as determined by the REB. If the submission meets the delegated review criteria, it may be forwarded for course-based review.

5.2.2 For research that meets the criteria, course-based review may be conducted by an REB member or a non-REB reviewer who has the appropriate experience, expertise, training and resources as an REB member;

5.2.3 The non-REB reviewer reviewing research under course-based review must not have a conflict of interest in the research;

- 5.2.4 In reviewing the research under course-based procedures, the non-REB reviewer may exercise all of the authorities of the REB, except that he/she may not disapprove the research; the research may be disapproved only by the REB at a Full Board meeting;
- 5.2.5 If the non-REB reviewer 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;
- 5.2.6 The decision regarding the designation of the research (i.e., course-based or FB review) and the outcome of the review will be recorded. The responsible REB Office Personnel may issue the review letter or decision.

5.3 Reporting to the REB

- 5.3.1 At minimum once per year, the REB will be informed of research that was reviewed and approved using course-based review procedures.

5.4 Documentation

- 5.4.1 The type of REB review conducted (i.e., course-based or FB review) is documented in the REB records and noted in the decision issued to the Researcher, where appropriate;
- 5.4.2 The REB annual report will include a list of submissions that were reviewed and approved using delegated review procedures.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP408.001 | | Original version |
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SOP 501.001

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|-----------------------|--|
| Title | REB Review During Publicly Declared Emergencies |
| SOP Code | 501.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the research ethics review procedures during a publicly declared emergency.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Organizational Official(s) are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 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.

5.1 Determining Scope of Emergency

5.1.1 Subsequent to an officially publicly declared emergency, the REB Chair or designee will assess the scope of the emergency with respect to:

- potential and current participants as individuals and communities,
- Researchers,
- REB members,
- Organizational infrastructure, and
- research ethics review procedures;

5.1.2 Determining the scope of the emergency may involve consultation with Organizational Officials and other Organizational representatives, Researchers, REB members and REB Office personnel;

5.1.3 Scope of the emergency may assist the REB Chair or designee in determining the level of impact;

5.2 Determining the Level of Impact

5.2.1 Subsequent to a publicly declared emergency, the REB Chair or designee will assess the level of impact on the research ethics review procedures. The assessment will consider factors including (but not limited to):

- Whether the publicly declared emergency affects some or all of the research reviewed by the REB, including:

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- The review of ongoing research that is unrelated to or not arising from the publicly declared emergency,
- The review of new research that is unrelated to or not arising from the publicly declared emergency, and
- The review of research that arises from or is related to the publicly declared emergency,
- The nature of the risks imposed by the publicly declared emergency on research participants, communities, the REB, REB Office personnel and the Organization,
- Potential impact on Organizational resources or infrastructure (e.g. online systems, electricity, access to buildings),
- What research is considered “essential” during the emergency, and
- The potential duration of any alterations in review procedures, if predictable;

5.2.2 There are three levels of impact that may influence how ethics review will be conducted during the publicly declared emergency:

- **Mild** – little or no impact,
- **Moderate** – some impact; decisions to proceed at the discretion of the Chair or designee, in consultation with the Researcher, as necessary,
- **Severe** – extremely debilitating to normal research ethics review procedures;

5.2.3 The REB Chair or designee will use the scope of emergency and level of impact to guide the review of research submissions during the publicly declared emergency;

5.2.4 Pending the determination of the level of impact on the review of ongoing or new research, the currently established ethics review procedures should be followed.

5.3 Emergency Preparedness Procedures

5.3.1 Subsequent to an officially publicly declared emergency, the ability for standard ethics review procedures will be evaluated by the REB Chair or designee and REB Office personnel. Temporary ethics review procedures may be instituted, if necessary;

5.3.2 When the impact on ethics review procedures is deemed to be severe and the scope to include members of the REB, teleconferences or videoconferences may be used to conduct REB meetings;

5.3.3 When the impact on the ethics review processes is deemed to be severe, the REB Office Personnel may conduct their activities remotely, if it is possible to do so (via online access, remote access to email, mobile phone, etc.), with minimal

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disruption of services;

- 5.3.4 If the impact is deemed severe, the scope includes members of the REB and teleconferencing, videoconferencing or online access are not available, an REB subcommittee may be established for the duration of the publicly declared emergency;
- 5.3.5 The REB subcommittee composition should be in accordance with the standard REB membership requirements and should include at least five members drawn from the existing REB membership;
- 5.3.6 The current REB Chair or designee should serve as the Chair of the REB subcommittee;
- 5.3.7 At his/her discretion, the REB subcommittee Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available to the REB subcommittee; however, ad hoc advisors may not contribute directly to the subcommittee's decision and their presence shall not be used in establishing a quorum;
- 5.2.8 When the impact is deemed to be severe, the REB Chair or designee may defer the ethics review and research oversight of new and ongoing research to another REB, subject to the applicable policies and agreements;
- 5.3.9 Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the REB Chair or subcommittee Chair or designee will use his/her judgement in determining the type of review required (delegated or Full Board), taking into account the scope and severity of the impact of the emergency and the complexity and urgency of the submission;
- 5.3.10 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;
- 5.3.11 The REB Chair or designee should periodically assess the impact of the emergency on the ethics review procedures and adjust any temporary ethics review procedures accordingly;
- 5.3.12 Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency will cease as soon as is feasible after the emergency has officially ended (i.e., as declared by an authorized public official). The REB Chair or designee will determine when to resume routine ethics review procedures;
- 5.3.13 All delegated approvals of research following a publicly declared emergency must be assessed to determine if subsequent Full Board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency;

~~5.3.14 At the conclusion of the publicly declared emergency, the REB Chair or designee~~

and the REB Office Personnel should work with the REB subcommittee members to evaluate the effectiveness of its declared emergency procedures and to make recommendations for improvements.

5.4 Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency

5.4.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the following will apply to the review of ongoing research:

- The REB Chair or designee will determine if the scope of the emergency may include the research participants as individuals or as part of a community,
- The REB Chair or designee will determine if the research needs to continue, or if it can be postponed until after the emergency is over,
- The research may continue at the discretion of the REB Chair or designee in consultation with the Researcher, as necessary,
- Researcher's response to REB reviews, major amendments, and unanticipated and adverse events will be prioritized for review,
- Continuing reviews will receive the next priority for review, followed by research completion reports,
- Other submissions will be reviewed as time allows;

5.4.2 When the impact of the publicly declared emergency on ethics review is determined to be severe, the following will apply to the review of ongoing research:

- Research activities not involving, or no longer involving, recruitment or direct contact with participants may continue,
- Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety,
- Major amendments and unanticipated or adverse event reports related to these studies will be reviewed by the REB subcommittee or the REB subcommittee Chair or designee, as appropriate;

5.4.3 At the REB Chair or designee's discretion, and subject to applicable policies, review procedures may be delayed or temporarily suspended depending upon volume. In such cases, research shall be deemed to have continuing approval until such time that the REB is able to conduct its review.

5.5 Review of New Research NOT Related to or Arising from the Publicly Declared Emergency

5.5.1 When the scope of the emergency is contained and impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the REB Chair or designee will determine whether review of any new research not related to the publicly declared emergency may proceed or will be postponed until after the emergency is over;

5.5.2 When the scope of the emergency is large or uncontained and the impact of the publicly declared emergency on ethics review procedures is determined to be severe, any new research not related to the publicly declared emergency will not be reviewed until the emergency is declared to be over.

5.6 Review of Research RELATED to or Arising from the Publicly Declared Emergency

5.6.1 Researchers whose research focuses on publicly declared emergencies are encouraged to submit general protocols for conditional approval prior to emergencies to facilitate time-imperative REB approval;

5.6.2 If a request to review research related to a publicly declared emergency is received, it will be directed to the REB Chair or REB subcommittee Chair or designee, as applicable;

5.6.3 The REB Chair or designee will assess the risks associated with the proposed research, as well as aspects of the research that might require enhanced scrutiny or diligence, taking into account the scope of the emergency and severity of the impact on ethics review procedures;

5.6.4 When the impact of the publicly declared emergency on ethics reviews is determined to be mild to moderate, research related to the publicly declared emergency has priority for review;

5.6.5 When the impact of the publicly declared emergency on ethics review is determined to be severe, time-sensitive review processes may be followed, such as delegated review as appropriate, review by an REB subcommittee, and/or meetings conducted via teleconference or videoconference. These alterations may be limited to the review of the research related to the publicly declared emergency;

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5.6.6 The REB may implement any/all of the emergency preparedness procedures as deemed appropriate to the research/emergency.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP501.001 | | Original version |
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SOP 601.001

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| Title | Communication – Researcher |
| SOP Code | 601.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes routine communication procedures between the Research Ethics Board (REB) and the Researcher and his/her research team.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

For effective human research participant protection, it is important that the REB and Researcher and research team maintain open communication. This applies not only to

a specific research project, but also with respect to questions, concerns, ethical issues and REB processes, policies and procedures. 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. All REB decisions regarding specific research projects shall be documented in writing. Informal communications between the Researcher or research team and REB Chair or REB Office personnel may occur through email, over the phone or in person. Documentation should be created to ensure accurate reflection of discussions for future reference.

5.1 Notification of REB Decisions

- 5.1.1 The REB will notify the Researcher and/or research staff of the REB's decision within a time frame specified by the REB, following the review (REB meeting or delegated review) date of new research, modifications, or amendments to currently approved research, applications for continuing review or unanticipated event reports;
- 5.1.2 The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);
- 5.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Chair or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;
- 5.1.4 The REB Chair or designee will review the draft REB review comments, make revisions as necessary, and will indicate his/her approval;
- 5.1.5 The REB review comments will be sent to the Researcher(s);
- 5.1.6 The Researcher may be asked to identify the protocol by REB number or title in correspondence with the REB regarding the research project;

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- 5.1.7 Upon receipt of the Researcher's response to the REB review comments, the REB or REB Office personnel will follow-up with the Researcher and/or research staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewer(s);
- 5.1.8 Once all of the REB conditions are satisfied, the REB will issue an approval letter or notification of acknowledgement, as determined by submission type.

5.2 Researcher Consultation

- 5.2.1 A Researcher and/or research team may request advice, guidance or clarification with the REB Chair, designee or REB Office personnel for current or future research projects. Such consultations may involve communications through email, phone or in person.
- 5.2.2 REB Chair, designee or REB Office Personnel should document such consultations in writing, including date, who was present and brief description of what the concerns were and how they were addressed. Such documentation should be kept by the REB Office for future reference, if needed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP601.001 | | Original version |
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SOP 602.001

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| Title | Communication – Research Participants and Members of the Public |
| SOP Code | 602.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with research participants and members of the public.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Research participants and members of the public should be able to voice their concerns, questions and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the REB or in the REB Office.

5.1 Communication with Research Participants

- 5.1.1 Research participants are encouraged to contact the REB Office with questions and concerns, using the contact information provided in the informed consent document(s) or recruitment materials, or through the Organization's website or directory. If requested to remain anonymous, REB Office personnel will try to grant this request, or explain why this is not possible.
- 5.1.2 All communication with the research participant must be documented and a de-identified record of this communication maintained securely and in the relevant research file;
- 5.1.3 The REB Office Personnel will communicate participant concerns to the REB Chair or designee, where appropriate;
- 5.1.4 The REB Chair or designee will work to answer or resolve participant questions or concerns, which may include a follow-up with the Researcher or the Researcher's supervisor or other organizational representative, or with appropriate federal agencies, as applicable;

5.2 Communication with Members of the Public

- 5.2.1 Members of the public may contact the REB Office with questions or concerns with respect to a research project, a Researcher or field of research they may become aware of through recruitment procedures, social networks or the media.
- 5.2.2 REB Office Personnel should actively listen and prompt the individual for sufficient information to understand the nature of the question or concern, who should be involved in answering or resolving it, and in the case of a complaint, what the person considers to be an acceptable answer or resolution;
- 5.2.3 The REB Office Personnel will communicate the individual's questions or concerns to the REB Chair or designee, as appropriate;
- 5.2.4 The REB Chair or designee will consult with Organizational representatives on an appropriate response as appropriate. The organization's public relations department may be contacted if a formal response is required.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP602.001 | | Original version |
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SOP 701.001

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|-----------------------|----------------------------------|
| Title | Free and Informed Consent |
| SOP Code | 701.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the necessary components for free and informed consent throughout the life cycle of the research project.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the REB with a detailed description of the consent process and method for documenting consent and ensuring that prospective participants have sufficient information to make a free and informed decision on whether to participate in the research and whether to remain through its duration.

The REB is responsible for verifying that the consent process will provide sufficient information to enable individuals (and/or authorized third parties) to make a free and informed decision regarding their prospective participation and continued participation throughout the duration of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 REB Review of Required Elements of Informed Consent

- 5.1.1 The REB members will review the proposed consent process to ensure that prospective participants shall be able to make a free and informed decision on whether to participate in the research;
- 5.1.2 The Researcher will propose the method for consent (written or verbal or implied (e.g. returning a questionnaire)) and documentation with a rationale if written informed consent (i.e., informed consent form signed by participant and/or authorized third party) is not to be used.
- 5.1.3 The REB may approve a process that allows the informed consent document to be delivered by regular mail, fax or email to the potential participant, and to conduct a consent interview by telephone when the participant can read the consent document as it is discussed;
- 5.1.4 In some types of research the REB may approve the process of verbal consent, a verbal agreement or a handshake, e.g., where written consent is impossible to obtain or for some groups or individuals written signed consent may be felt by the participants as mistrust on the part of the Researcher,;
- 5.1.5 The REB will review the proposed consent documents to ensure that they contains adequate information to safeguard the privacy and confidentiality of research participants;
- 5.1.6 The REB may require a separate consent document for optional procedures or sub-studies (e.g., tissue, blood, genetic testing or specimen banking, recording);
- 5.1.7 Following the review, the REB may approve the consent document(s) as submitted or require changes;

5.2 Incidental Findings

- 5.2.1 Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research, unless it is impracticable to do so.
- 5.2.2 The Researcher's plan to identify and to disclose incidental findings must be submitted to the REB and approved prior to implementation;
- 5.2.3 For Research where material incidental findings are likely, participants may be provided with the choice to opt out of being notified.

5.3 Consent Must Precede Collection of, or Access to Data

- 5.3.1 Consent must be obtained from the participant or their authorized third party, before research may commence, unless a departure from the general consent requirements is approved by the REB. This includes interaction, intervention or access to the participant's information.

5.4 Departures from General Consent

- 5.4.1 The Researcher may propose an alteration to the consent process for consideration by the REB. This may include:
 - Partial disclosure or deception
 - Exception to the requirement for prior consent;
- 5.4.2 In considering these alterations, the REB shall ensure that:
 - The research involves no more than minimal risk to participants;
 - The alteration is unlikely to adversely affect the welfare of participants;
 - The research would be impossible or impracticable to be carried out if prior consent of participants is required;
 - The precise nature and extent of any proposed alteration is defined;
 - There is a described plan to debrief, and an offer to participants to refuse consent and/or withdraw data and biological materials, unless it is deemed impossible, impracticable or inappropriate to do so;

5.5 Consent for Research in Health Emergencies

- 5.5.1 The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research. The Researcher must justify to the REB the reasons why an exception to obtaining informed consent from participants is required;

5.5.2 The REB allows research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:

- A serious threat to the prospective participant requires immediate intervention,
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care,
- Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant,
- The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research project,
- Third-party authorization cannot be secured in sufficient time, despite diligent, and documented efforts to do so, and
- No relevant prior directive by the participant is known to exist;

5.5.3 When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

5.6 Decision-making Capacity

5.6.1 For research involving individuals who lack capacity to provide consent, either temporarily or permanently, the REB shall ensure that:

- Participants will be involved as much as possible in the decision-making process;
- Consent will be sought and maintained from an authorized third party, who is not the Researcher, nor a member of the research team;
- The research will be carried out for the participant's direct benefit or for the benefit of others in the same category;
- The research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the benefit is only for others in the same category, exposure to the individual must be minimal and the participant's welfare must be protected throughout;

5.6.2 If the participant lacking legal decision-making capacity has some ability to understand the significance of research, they shall be given the opportunity to provide assent or dissent to participation. Dissent shall preclude participation;

5.6.3 Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:

- Those whose capacity is in the process of development, such as children, whose capacity for judgment and self-direction is maturing,
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and

- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment;

5.6.4 If assent for research is required, the Researcher must submit to the REB the proposed procedures for obtaining consent from the authorized third party and assent from the research participant. The Researcher must submit an assent form or summary of the assent process to the REB for approval;

5.6.5 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation;

5.6.6 If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

5.7 Documentation of Informed Consent

5.7.1 The REB typically requires documentation of informed consent which may include:

- A consent form signed and dated by the participant or their authorized third party;
- Field notes/notation in participant record to document verbal consent;
- Actions of the participant i.e., completion of a paper-based or online questionnaire;
- Audio-recording or video-recording prior to the recording of an interview;
- Other strategies approved by the REB.

5.7.2 Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented;

5.7.3 A copy of the consent form or an information sheet will typically be provided to the research participant, unless doing so may compromise participant safety or confidentiality or is inappropriate in the research setting;

5.8 Consent Monitoring

5.8.1 In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer;

5.8.2 Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided;

5.8.3 Monitoring may also be appropriate as a corrective action when the REB has identified problems associated with a particular Researcher or a research project.

5.9 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

5.9.1 The REB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the Researcher is able to satisfy the following conditions:

- Identifiable information/materials is essential to the research,
- The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- The Researcher will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
- The Researcher will comply with any known preferences previously expressed by individuals about any use of their information/materials,
- It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and
- The Researcher has obtained any other necessary permission for secondary use of information/materials for research purposes;

5.9.2 In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the REB, if the Researcher proposes to contact individuals for additional information and/or materials, REB approval must be obtained prior to contact.

5.10 Consent by Head of Family or Community

5.10.1 In cultures where consent to participate in research must be obtained by the participant's family head or community head, the Researcher should propose a consent process to the REB that will include free and informed consent of the family or community head as well as of the prospective participant;

5.10.2 The Researcher must ensure that the prospective participant is able to provide free and informed consent to participate without coercion or undue influence by the family or community head;

5.10.3 Consent by the family or community head alone is insufficient for the research to proceed.

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6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP701.001 | | Original version |
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SOP 801.001

| | |
|-----------------------|---|
| Title | Researcher Qualifications and Responsibilities |
| SOP Code | 801.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the qualifications and responsibilities of the Researcher who engages in research involving human participants.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All Researchers, REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Research involving human participants must be conducted by individuals with the appropriate education, training, and experience required 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 Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with applicable policies and guidelines, and to comply with all REB requirements.

5.1 Researcher Qualifications

- 5.1.1 The Researcher should make available to the REB his/her current CV which should include his/her relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the Researcher's qualifications, if necessary;
- 5.1.2 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research and should have sufficient expertise in the discipline and methods of the proposed research;
- 5.1.3 If applicable (i.e. is part of the institution's policy or procedures), all specified Organizational Officials must approve the application to the REB;
- 5.1.4 The organizational approver's signature attests that:
 - He/she is aware of the proposal and supports its submission for REB review,
 - The application is considered to be feasible and appropriate,
 - Any internal requirements have been met,
 - The Researcher is qualified and has the experience and expertise to conduct this research,
 - The Researcher has sufficient space and resources to conduct this research;
- 5.1.5 Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to REB approval of the application.

5.2 Researcher Responsibilities

- 5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Researcher's responsibility to comply with all applicable requirements and ensure that (if applicable):
 - He/she and his/her staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,
 - He/she has adequate resources to properly conduct the research and conduct the research following acceptable practices,
 - All real, potential, or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise,

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- The REB review and approval is obtained before engaging in research involving human participants,
- All necessary documentation is signed by the responsible Researcher, as applicable,
- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the REB (as applicable),
- He/she personally conducts or supervises the execution of the described research,
- The research is conducted in compliance with the approved protocol and applicable reporting criteria are reported to the REB, including deviations, unanticipated adverse events and privacy breaches,
- Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s),
- Premature termination or suspension of the research is reported to the REB;
- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the REB at least annually, or more frequently if required by the REB, and an application for continuing review is submitted to the REB prior to the expiration of REB approval,
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the REB,
- The REB is notified if there is a change in Researcher or research team,
- The REB is notified when the research is complete.

5.2.2 The organization is responsible for maintaining current CVs for each of its Researchers. The organization is responsible for immediately advising the REB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate.

6.0 REFERENCES

See References.

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7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP801.001 | | Original version |
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SOP 901.001

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| Title | Quality Assurance Visits |
| SOP Code | 901.001 |
| Effective Date | |

Site Approvals

| Name and Title | Signature | Date dd/mm/yyyy |
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1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for evaluating and improving the effectiveness of the human research protection program.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and the QA Officer, if separate from the REB Office Personnel, are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Quality Assurance (QA) activities, such as periodic assessments of REB and research activities, 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.

5.1 Quality Assurance Assessments of the REB

5.1.1 The QA Officer will develop a schedule for routine QA assessments of the REB and REB Office in response to requests from the REB, Researcher or Organizational representatives;

5.1.2 QA assessments may be conducted by members of the REB Office, or by other organizational personnel. REB members may be directly or indirectly involved;

5.1.3 When the QA Officer conducts a QA assessment of the REB and the REB Office the evaluation may including the following:

- An assessment of the SOPs and compliance with applicable policies, guidelines and regulatory requirements,
- A review of research files, REB membership rosters, REB attendance records, and REB agendas and minutes,
- A review of workload, performance metrics and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with REB members, REB Office Personnel and Researchers,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from the Organization's policies, and whether the deviations require remediation,
- An assessment of compliance with all applicable requirements;

5.1.4 The QA Officer compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

5.1.5 The QA Officer prepares a written summary of the assessment, including areas requiring improvement;

- 5.1.6 The QA Officer reports the findings to the REB Chair or designee, and to the REB and/or to the appropriate Organizational Official as required;
- 5.1.7 The QA Officer works with the REB Chair or designee to implement improvements (e.g. new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

5.2 Researcher Quality Assurance Visits

- 5.2.1 The QA Officer will develop a schedule for routine QA visits and implement visits in response to Researcher requests;
- 5.2.2 The QA Officer will work with the REB and the Organization at which the research is being conducted to determine if and when a for-cause visit of a Researcher is warranted;
- 5.2.3 The REB may direct the QA Officer to conduct for-cause visits;
- 5.2.4 The QA Officer or designee may request that a pre-visit questionnaire is completed by the Researcher;
- 5.2.5 The criteria for selecting Researchers or research projects for visit may include:
- The results of a previous QA visit,
 - Studies that involve a potentially high risk to participants,
 - Studies that involve vulnerable populations,
 - Studies in which Researchers are enrolling large numbers of participants,
 - Suspected non-compliance,
 - Unanticipated problems involving risks to participants or others,
 - Suspected or reported protocol deviations,
 - Participant complaints,
 - Research Staff complaints,
 - Any other situation that the REB deems appropriate;
- 5.2.6 The QA Officer or designee will notify the Researcher of the visit to review the research project and a mutually acceptable time will be scheduled. It may be necessary to schedule a visit without first obtaining the formal consent of a Researcher (e.g., participant safety or suspected non-compliance);

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5.2.7 The QA Officer or designee will conduct a review of the research project using designated/appropriate evaluation tools;

5.2.8 When the QA Officer conducts a review of the research project, the review may include some or all of the following (as applicable):

- An assessment of the SOPs and compliance with applicable policies and guidance,
- A review of REB approved documentation,
- Interviews with the Researcher and research team,
- A review of specimens and associated collection processes,
- A review of computer hardware and/or software associated with the research,
- A review of the consent documents and/or processes including eligibility requirements,
- A review of data collection mechanisms,
- A review of appropriate source material (e.g., participant medical records), and
- A review of other documentation, as relevant and available;

5.2.9 The REB or the QA Officer may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;

5.2.10 At the conclusion of the evaluation, the QA Officer or designee will discuss the findings with the Researcher;

5.2.11 The QA Officer or designee will draft a report or provide a summary of the inspection including positive findings, areas for improvement and recommendations for corrective action, and submit the report to the REB Chair or designee for review;

5.2.12 The Researcher will be given an opportunity to respond to the report with responses and/or corrective action plans within a time specified by the REB;

5.2.13 The QA Officer or designee will send a copy of the final report to the Researcher and the REB. When applicable, the REB Chair or designee will provide the findings to the local Organizational Official.

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5.3 Corrective Action

- 5.3.1 The QA Officer may recommend corrective action based on the findings;
- 5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;
- 5.3.3 The QA Officer will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;
- 5.3.4 The QA Officer will follow-up with the Researcher in a timely manner to determine if the corrective actions have been implemented by the Researcher following a research project QA visit.

5.4 Documentation

- 5.4.1 The QA Officer or designee files all reports and correspondence concerning QA visits in the appropriate QA Files.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|------------|----------------|--------------------|
| SOP901.001 | | Original version |
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SOP 902.001

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Site Approvals

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1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) process for investigating potential incidents of non-compliance and the actions that the REB may take as a result of determining serious and/or continuing non-compliance. Non-compliance is defined as a failure to follow applicable guidelines and regulations governing human participant research and/or failure to follow the protocol approved by the Research Ethics Board (REB), or stipulations imposed by the REB as a condition of approval.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are required to comply with all of the applicable policies, guidelines and other requirements governing the conduct of human research, as well as with the required conditions of approval of the REB.

The REB Office Personnel and the REB members are responsible for acting on information of potential incidents of non-compliance received from any source.

The REB Chair or designee is responsible for the initial investigation of potential incidents of non-compliance.

If intentional, serious or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions, as pertains to the ethical review of the research.

The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Organizational Official(s). The REB may direct the report to the Organizational Official as an allegation of breach of responsible conduct of research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Information of potential incidents of non-compliance may come from any source including 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 information of potential incidents of non-compliance, to investigate quickly and to act on all credible allegations of non-compliance.

5.1 Reports of Non-compliance

5.1.1 Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance;

5.2 Evaluating Allegations of Non-compliance

5.2.1 When an allegation of non-compliance is referred to the REB, the REB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the REB Chair or designee;

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- 5.2.2 The REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;
- 5.2.3 The REB Chair or designee will conduct an initial review of all allegations to determine whether further investigation is necessary and may involve other Organizational personnel as required to make this determination;
- 5.2.4 The REB Chair or designee will obtain as much information as possible from the individual reporting the incident. The REB Chair or designee will obtain as much information as possible, or verification from other sources by one or more of the following means:
- Contacting the Researcher,
 - Consulting with other relevant Organizational personnel,
 - Collecting relevant documentation,
 - Reviewing any written materials,
 - Interviewing knowledgeable sources;
- 5.2.5 If the REB Chair or designee determines that there is evidence of non-compliance, he/she will then assess whether the non-compliance was intentional, serious and/or repeated;
- 5.2.6 If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

5.3 Managing Non-compliance

- 5.3.1 The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;
- 5.3.2 If the REB Chair or designee determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance and took appropriate corrective actions, no further action may be required;
- 5.3.3 If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research team did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance visit, and/or refer the matter to the REB at a Full Board meeting;

5.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately, as per SOP 407, and refer the matter to the next Full Board meeting of the REB, and will inform the Organizational Official responsible for receiving allegations of breaches of responsible conduct of research;

5.3.5 The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions that fall within its mandate;

5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB may consider one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent documents,
- Require that additional information be provided to past participants,
- Require that current participants be notified,
- Require that current participants re-consent to participation,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend recruitment of participants,
- Suspend REB approval of the research,

- Suspend Researcher involvement in the research,
- Terminate REB approval of the research,
- Require the Researcher and/or staff to complete a training program,
- Notify Organizational personnel (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Other actions, as deemed appropriate by the REB.

5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Chair or designee will notify the Researcher in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The REB Chair or designee will report any serious or continuing non-compliance to the Researcher as well as to the appropriate Organizational Official(s);

5.4.3 The REB may submit an allegation of breach of responsible conduct of research to the Organization Official as appropriate;

5.4.4 The REB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

- 5.4.5 The Researcher’s response may be reviewed using a delegated REB review procedure or the review may be referred to the REB for a decision from the Full Board;
- 5.4.6 The REB Chair or designee will follow-up to assess any corrective measures implemented by the Researcher.

5.5 Documenting Non-compliance

- 5.5.1 The REB Chair or designee will document the findings of reports of non-compliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the REB’s decision and actions taken (if applicable), and the Researcher’s response;
- 5.5.2 For those incidents of non-compliance referred to the Full Board, the REB Office Personnel will document the following in the REB meeting minutes: a description of the incident and findings, verification of the non-compliance, the REB’s decision, the remedial action required by the REB, the Researcher’s response and actions implemented and plans for further follow-up.
- 5.5.3 The REB Chair or designee will document cases where the non-compliance was referred to the Organizational Official responsible for allegations of breaches of responsible conduct of research and will follow-up with the official to ensure that they have received information on outcomes of an inquiry or investigation that could be relevant to the REB’s decision-making on the Research.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

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|-----------------|-----------------------|---------------------------|
| SOP902.001 | | Original version |
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Glossary of Terms

Ad hoc advisor: a person with relevant and competent knowledge and expertise consulted by an Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review, in the event that the REB members lack specific expertise or knowledge to review with competence the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the REB and is not counted in the quorum or allowed to vote on REB decisions.

Adverse event (AE): any untoward medical occurrence in a research participant, administered investigational product, including an occurrence which does not have a causal relationship with this product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.

Local adverse event: those adverse events experienced by research participants enrolled by the Researcher at the centre(s) under the jurisdiction of the Research Ethics Board (REB).

Non-local (external) adverse event (EAE): those adverse events experienced by research participants enrolled by Researchers at other centres/organizations outside the REB's jurisdiction.

Alternate member: a formally appointed voting member of the Research Ethics Board (REB) who may substitute for a regular member of the REB but who is not expected to attend every REB meeting. An alternate REB member's presence at the REB meeting in the place of an absent regular REB member is used to establish quorum.

Amendment: a written description of a modification or change(s) to the previously approved research study. Amendments include any changes to the protocol or related research documents, such as changes to the consent form, revisions to the Investigator Brochure, updated participant material, etc.

Assent: affirmative agreement to participate in research by an individual unable to provide consent.

Authorized signatory: individual(s) authorized to sign documents on behalf of an organization.

Authorized third party: Any person with the necessary authority to make decisions on behalf of the prospective participant who lacks the capacity to consent to participate, or to continue to participate, in a particular research project. (Also known as a "legally acceptable representative" or "substitute decision-maker").

Compensation: anything offered to research participants, monetary or otherwise, to encourage participation in research. Also referred to as **incentive** (see below).

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Confidentiality: refers to the agreement between the Researcher and the participant as to how personal data will be managed and used, and an ethical and/or legal responsibility to safeguard information from unauthorized use, disclosure, modification, loss or theft. The term also refers to the REB's ethical and/or legal responsibility to safeguard information in its custody from unauthorized use, disclosure, modification, loss or theft.

Conflict of Interest (COI): circumstance of a person (e.g., Researcher or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

COI may occur when an individual's judgments and actions or an organization's actions in relation to research are, or could be, affected by personal, organizational or other interests, including, but not limited to, business, commercial or financial interests, whether of individuals, their family members, their friends, or their former, current or prospective professional associations or of the organization itself.

Examples of secondary interests for a Researcher include the following:

- Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;
- Acts as an officer, director, or agent of the sponsor;
- His/her job status or compensation is impacted by the research (e.g., payment for speaking or leading study groups on behalf of the sponsor);
- Is receiving a finder's fee for the recruitment of research participants;
- Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;
- Has (or family, spouse, close relationships) any equity interest in the sponsor; Receives payments of other sorts, which are made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);
- Is intending to recruit his/her own patients as research participants;
- Has identified him or herself for any other reason as having a conflicting interest (i.e., organizational conflict that may impact the research).

Examples of secondary interests for an REB member include the following:

- Is a Researcher or sub-Researcher on the protocol;
- Is directly involved in the conduct of the research;
- His/her job status or compensation is impacted by the research (e.g. research coordinator, payment for speaking/leading study groups on behalf of the sponsor);
- Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;
- Acts as an officer, director, or agent of the sponsor;

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- Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;
- Has any equity interest in the sponsor that when aggregated for the member and the member's spouse and dependent children;
- Any equity interest in the sponsor (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices);
- Significant payments of other sorts, which are payments made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);
- Is in direct competition with the Researcher of the research project for limited resources, funding, sponsorship, or research participants; acts as a consultant for the sponsor; is considered a personal or professional adversary of the Researcher;
- Has identified him or herself for any other reason as having a conflicting interest.

Conflict of Interest (COI) disclosure: Formal acknowledgement of the Researcher's or REB member's COI to the REB.

Conflict of Interest (COI) management plan: Formally proposed and approved plan to address the COI, thereby resolving or removing it. The plan may be approved by the Researcher's one-up supervisor, COI committee or REB, as per Organizational policy.

Continuing research ethics review (also referred to as "continuing review"): any review of ongoing research conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.

Controlled forms: documents that require formal change control, and that form part of the permanent record of Research Ethics Board (REB) operations and processes.

Course-based research: Research involving human participants undertaken by students as part of an educational institution-recognized course for a pedagogical purpose. This does not include research undertaken by graduate students for a research thesis.

Data and Safety Monitoring Board (DSMB): a multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of research procedures, and monitoring the overall conduct of the research.

Delegated review: the level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from among the REB membership to conduct the review.

Designee: person to whom a duty has been delegated may refer to a member of the Research Ethics Board (REB) or to the REB Office Personnel depending on the context of the statement and the accompanying requirements of the organization.

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Expiry date: the first day that the Research Ethics Board (REB) approval of the research is no longer valid without further review and approval by the REB. When the REB determines that review more than annually is required, the expiration date will be determined by the REB (e.g., six months from the date of the approval).

Full Research Ethics Board (REB) review: the level of Research Ethics Board (REB) review assigned to above minimal risk research studies. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving human participants.

Human genetic research: the study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.

Impartial: without prejudice or bias, fair; a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person over another.

Impracticable: incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

Incentive: anything offered to research participants, monetary or otherwise, to encourage participation in research.

Incidental findings: unanticipated discoveries made in the course of research that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are discovered, Researchers have an obligation to inform the participant.

Inspection: a systematic examination and evaluation of study-related activities and documents in comparison to specified requirements and standards.

Institutional conflicts of interest: an incompatibility between two or more substantial institutional obligations that cannot be adequately fulfilled without compromising one or another of the obligations

Investigational product: refers to new or new uses of drugs, biologics, medical devices or natural health products.

Mature minor: is an individual who demonstrates adequate understanding and decision-making capacity.

Medical device trials: clinical trials that test the safety and/or efficacy of one or more instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition or the restoration, correction or modification of body function or structure.

Minimal risk: research in which the probability and magnitude of possible harms implied

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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.

Minor change: any change that would not materially affect an assessment of the risks and benefits of the research or the integrity of the data, and does not substantially change the specific aims or design of the study.

Multi-centred: multi-centre means that the research is reasonably expected to be conducted at more than one centre.

Natural health product (NHP) trial: a clinical trial testing the safety and/or efficacy of one or more natural health products (NHP). The term NHP is used to describe substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines.

Non-compliance: failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.

Non-controlled forms: documents that are not part of the permanent record of Research Ethics Board (REB) operations and processes. Non-controlled forms also will contain version dates.

Non-REB reviewer: a reviewer for a course-based research protocol that is not a member of the REB.

Ongoing research: research that has received Research Ethics Board (REB) approval and has not yet been completed.

Organizational Official: a senior official ultimately responsible for ensuring that the institution or organization complies with all required laws, regulations and standards for research involving human participants. This may include signing memoranda of agreements or other documentation on behalf of the organization to formalize assurance of compliance.

Participant: an individual whose data or responses to interventions, stimuli, or questions by a Researcher are relevant to answering a research question; also referred to as “human participant” and in other policies/guidance as “subject” or “research subject.”

Periodic safety update or summary report: a summary report, created by the sponsor, listing all of the reported unexpected serious adverse events that have occurred in a given reporting period, and which includes any significant areas of concern and the evolving safety profile of the investigational product.

Personal health information: Personal health information (PHI), is a subset of **Personal information** which is identifiable information about an individual. (See “Identifiable information” which also is “personal information”)

Personal health information is identifying information about an individual in either an oral or in a recorded form, if the information:

- Relates to the individual’s physical or mental health, including family health history;

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- Relates to the provision of health care, including the identification of persons providing care;
- Is a plan of service for an individual requiring long-term care; Relates to payment or eligibility for health care;
- Relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances;
- Is the individual's health number; or
- Identifies an individual's substitute decision-maker.

Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

Personal information (also referred to as “identifiable information”): information that identifies an individual and/or for which it is foreseeable that may reasonably be expected to identify an individual, alone or in combination with other available information.

- **Directly identifying information:** the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- **Indirectly identifying information:** the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic).
- **Coded information:** direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Researcher retains a list that links the participant's code name with their actual name so data can be re-linked if necessary).
- **Anonymized/de-identified information:** the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous information:** the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Privacy: an individual's right to be free from intrusion or interference by others.

Privacy refers to persons and their interest in controlling the access of others to themselves (their personal information).

Privacy breach: the unauthorized collection, use, or disclosure of personal information or personal health information (PHI) in the custody and control of an individual or a Health Information Custodian (HIC) or in the custody and control of the organization or its affiliated partners.

Privacy regulations: Laws and rules created at the federal or provincial/territorial level outlining measures that must be taken to ensure that person's privacy is maintained when collecting, using, sharing or storing their personal information.

Proportionate approach to research ethics review: the assessment of foreseeable risk to determine the level of scrutiny the research will receive (i.e., delegated review for minimal risk

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research or full Research Ethics Board (REB) review for research above minimal risk), as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.

Protocol deviation: any unplanned or unforeseen change in the execution of research that differs from the Research Ethics Board (REB) approved protocol or protocol procedures.

Publicly-declared emergency: An emergency situation which, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public office

Quorum: An REB meeting shall include at least five (5) voting members, including (at minimum):

- two (2) members with expertise in the relevant disciplines, fields and methodologies covered by the REB,
- one (1) member knowledgeable in ethics
- one (1) member from the community who has no affiliation with the organization(s) and who is not part of the immediate family of a person who is affiliated with the organization
- one (1) member knowledgeable in the relevant law (for biomedical research)
- additional representation as required by applicable legislation or guidelines

For research subject to the US Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.

Reportable event: includes anything that could significantly impact the conduct of the research or alter the Research Ethics Board's (REB) approval or favourable opinion to continue the research.

Research: an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Researcher: the leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. May also be known as Principal Investigator or PI.

Research Ethics Board (REB): a body of Researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an organization to review the ethical acceptability of all research involving humans conducted within the organization's jurisdiction or under its auspices.

Research Ethics Board (REB) Office: the unit, whether independent or part of a larger unit dedicated to providing administrative support to the REB.

Research Ethics Board (REB) Office Personnel: (an) administrative staff member(s) of the REB office.

Research Ethics Board (REB) of record: the Research Ethics Board (REB) that has been granted ultimate authority for the ethics review and oversight of a research study.

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Research Misconduct: any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community.

Risk: the possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.

Suspension: a temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor and/or by the Researcher.

Termination: a permanent halt by the Research Ethics Board (REB), by the sponsor and/or by the Researcher to all or some research activities.

Unanticipated issues: issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the Researcher in the research proposal submitted for research ethics review.