




<b>Section 400:</b>	<b>Review of Research</b>
<b>Title:</b>	<b>Initial Review - Criteria for HSREB Ethical Clearance</b>
<b>SOP Code:</b>	<b>403.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

## Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015 May 22
	Name: Jennifer Couture	Date
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	Date
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015
	Name: Dr. Andrew Winterborn	Date

## 1.0 PURPOSE

This SOP describes the minimum requirements that research proposals involving human participants must meet in order to receive ethics clearance by the HSREB, independent of the review pathway (i.e., Full Board or delegated review).

## 2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

## 3.0 RESPONSIBILITIES

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

The HSREB members are responsible for determining whether the research meets the criteria for ethics clearance.

## 4.0 DEFINITIONS

See Glossary of Terms.

## **5.0 PROCEDURES**

All research involving human participants must meet certain criteria before HSREB ethics clearance may be granted. Initial HSREB ethics clearance of the research is based on assessment of a complete submission to the HSREB. The HSREB and/or HSREB Office Personnel may consult the Researcher for additional information as necessary.

Following initial review of the research, the HSREB should be prepared to make a determination as to the approvability of the research.

In addition to HSREB ethics clearance, the requirements of Queen's University and Affiliated Teaching Hospital(s), where the research will be conducted must also be met before the research can begin (e.g., department approvals, adequate resources, etc.).

Participant recruitment/registration, obtaining informed consent, access or collection of data and collection of biological materials cannot start prior to receiving written ethical clearance/favorable opinion of the trial by the HSREB.

### **5.1 Minimal Criteria for Ethical Clearance of Research**

In order for the research to receive HSREB ethics clearance, the HSREB will take the following into consideration:

- 5.1.1 The electronic application form has been submitted using the ROMEQ/TRAQ interface by the Researcher who is qualified to conduct the research, is entitled to provide health care under the applicable laws and that he/she is in good standing with his/her regulatory authority;
- 5.1.2 Suitability and feasibility of research facilities at the research site, and available care in the event of an emergency;
- 5.1.3 Disclosure of any financial interest or potential conflict of interest and a copy of the trials budget (including sources of funding) in sufficient detail to ensure any conflicts can be identified, minimized, or otherwise managed;
- 5.1.4 The protocol with the purpose of the study clearly defined and all supporting documentation attached, including a peer review, if applicable;
- 5.1.5 There is a state of clinical equipoise when there is a comparison of two or more treatment arms;
- 5.1.6 Justification for any plans to withhold or withdraw standard therapies of clinical management protocols;

- 5.1.7 Justification for the use of control arms, including choice of a placebo control arm as opposed to the other possible choices of a control group;
- 5.1.8 For all studies the nature and safety of the research intervention and for clinical trials, the design, type and phase of trial must be considered, as well as all associated ethical issues;
- 5.1.9 The methodology is scientifically sound and capable of answering the research question;
- 5.1.10 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, and
  - By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate;
- 5.1.11 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated to society as a whole. The HSREB should consider the research participants, concerned communities and other individuals with similar needs relevant to the study;
- 5.1.12 The selection of participants is equitable. In making this assessment, the HSREB will take into account the purpose of the research and the research setting. The HSREB will consider the scientific and ethical reasons for including/excluding vulnerable populations, if applicable;
- 5.1.13 When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research, and in the HSREB review process to protect the rights and welfare of these participants;
- 5.1.14 Time to conduct research/trial, including all initial, treatment and follow up schedules;
- 5.1.15 The sample size for participant recruitment is justified;
- 5.1.16 The participant recruitment methods must be outlined and copies of the recruitment materials must be submitted for review;
- 5.1.17 Participant inclusion/exclusion criteria;
- 5.1.18 All available safety information, including investigator brochures, product monographs and device manuals;
- 5.1.19 Any written information that will be provided to research participants (i.e. contact cards, patient diaries);
- 5.1.20 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. Payments to a participant should be prorated and not contingent on the full completion/participation;

- 5.1.21 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 regulations and guidelines unless the conditions for a waiver of alteration of informed consent is met (refer to SOP 701.001 Informed Consent Form Requirements and Documentation section 5.8);
- 5.1.22 The informed consent form will accurately explain the research and contain the required elements of consent (refer to SOP 701 Informed Consent Form Requirements and Documentation);
- 5.1.23 A description of processes that will be used to provide participants with any new study information, and how ongoing consent will be obtained;
- 5.1.24 The informed consent process will be appropriately documented in accordance with the relevant regulations (refer to SOP 701 Informed Consent Form Requirements and Documentation);
- 5.1.25 Practices are in place to ensure no prospective or current participant will be coerced or unduly influenced to participate in the research;
- 5.1.26 Procedures for seeking the participants' consent to inform their primary health care provider about the proposed clinical trial if appropriate, and information about the health care that will be provided to them over the course of their participation;
- 5.1.27 Criteria for premature withdrawal of research participants, and the steps to be taken if research participants voluntarily withdraw or are withdrawn by the principal investigator;
- 5.1.28 There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research. The HSREB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;
- 5.1.29 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
- 5.1.30 There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate;
- 5.1.31 There will be adequate provisions for the timely publication and dissemination of the research results;

- 5.1.32 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 HSREB. If the research is not yet registered, the researcher shall provide the HSREB with the registration number upon registration;
- 5.1.33 All previous decisions, if known, by other REBs or regulatory authorities, an indication of any modifications made to the protocol on account of past reviews, and the reasons for previous negative decisions;
- 5.1.34 Any additional documentation which the HSREB or the research may deem necessary to be included in the ethics review.

## **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 for the full life-cycle of information (its collection, use, dissemination, retention and/or disposal);
- 5.2.2 Additional criteria for research involving Aboriginal peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations;
- 5.2.3 For research involving First Nations, Inuit or Metis participants, the process for engaging the relevant community or an exception must be described;
- 5.2.4 If the study involves optional tissue banking or genetic testing, a separate process for obtaining and documenting informed consent, and copies of applicable documents;
- 5.2.5 If data linkage is proposed, a description of how the data will be linked and the likelihood that identifiable data will be created through the linkage.

## **5.3 Additional Considerations for Collection of Personal Health Information**

- 5.3.1 A description of the personal health information (PHI) being collected and the potential sources, as well as copies of data collection forms as applicable;
- 5.3.2 A description of how the PHI will be used in the research and if it will be linked to other information, including a description of the other information and how it will be linked, and an explanation as to why the linkage is required;
- 5.3.3 An explanation as to why the research cannot be conducted without the PHI and any foreseeable harms and benefits that may arise

from the use of the PHI, and a plan on how to address these issues;

- 5.3.4 A description of all individuals that have access to the information and why access is necessary and any plans to address confidentiality;
- 5.3.5 Safeguards that will be imposed to protect the confidentiality and security of PHI, including how long the PHI will be maintained in identifiable form and why;
- 5.3.6 If PHI will be collected, procedures to de-identify information prior to the data being sent outside of Kingston;
- 5.3.7 Information as to when the PHI will be disposed of or returned to the Health Information Custodian (HIC), as well as an explanation as to why consent is not being sought from the individuals to who the information relates (as applicable).

#### **5.4 Duration of Ethics Clearance**

- 5.4.1 The HSREB shall review research at periods appropriate to the degree of risk and at least annually;
- 5.4.2 The HSREB may require review more often than annually when there is a high degree of risk to participants relative to the population;
- 5.4.3 The HSREB may consider reviewing the research more often than annually as required by the renewal review procedure.

#### **5.5 Submission Requirements for Clinical Trials and Regulated Biomedical Clinical Trials**

- 5.5.1 TCPS2 defines a clinical trial as any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, manual therapies and psychotherapies. Clinical trials may also include questions that are not directly related to therapeutic goals – for example, drug metabolism – in addition to those that directly evaluate the treatment of participants.
- 5.5.2 Biomedical Clinical Trials are an investigation in which a health product (drug, medical device or natural health product) is administered to or used by humans and that is intended to discover or verify the clinical, pharmacodynamic or pharmacokinetic effects of the product, or ascertain the safety or efficacy of the product;
- 5.5.3 Refer to HSREB Submission Requirements for Review of Biomedical Clinical Trials (Appendix 1) for submission requirements for a biomedical clinical trial application.

## 6.0 REFERENCES

See References.

## 7.0 APPENDICES

1. HSREB Submission Requirements for Biomedical Clinical Trials

## 8.0 REVISION HISTORY

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Initial Review - Criteria for HSREB Ethical Clearance	v.403.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.





## HSREB Submission Requirements for Biomedical Clinical Trials (Appendix 1)

The following will be taken into consideration when submitting a HSREB application for Biomedical Clinical Trials:

- The electronic application form has been submitted using the ROMEO/TRAQ interface by the Researcher who is qualified to conduct the research, is entitled to provide health care under the applicable laws and that he/she is in good standing with his/her regulatory authority, as applicable
- Confirmation of the suitability and feasibility of research facilities at the research site, and available care in the event of an emergency
- Disclosure of any financial interest or potential conflict of interest and a copy of the trials budget (including sources of funding) in sufficient detail to ensure any conflicts can identified, minimized, or otherwise managed
- The protocol with the purpose of the study clearly defined and all supporting documentation attached, including a peer review, if applicable
- Justification for any plans to withhold or withdraw standard therapies of clinical management protocols
- Justification for the use of control arms, including choice of a placebo control arm as opposed to the other possible choices of a control group
- The nature and safety of the research intervention and for clinical trials, the design, type and phase of trial must be considered, as well as all associated ethical issues
- The methodology is scientifically sound and capable of answering the research question
- The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated to society as a whole
- The selection of participants is equitable
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research to protect the rights and welfare of these participants
- Time to conduct research/trial, including all initial, treatment and follow up schedules
- The sample size for participant recruitment is justified
- The participant recruitment methods must be outlined and copies of the recruitment materials must be submitted for review
- Participant inclusion/exclusion criteria
- All available safety information, including investigator brochures, product monographs and device manuals
- Any written information that will be provided to research participants (i.e. contact cards, patient diaries)

- 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. Payments to a participant should be prorated and not contingent on the full completion/participation
- 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 regulations and guidelines unless the conditions for a waiver of alteration of informed consent is met (TCPS 2 - 2014 – Section 5)
- The informed consent form will accurately explain the research and contain the required elements of consent (refer to Informed Consent Form Required Elements for Biomedical Clinical Trials)
- A description of processes that will be used to provide participants with any new study information, and how ongoing consent will be obtained
- The informed consent process will be appropriately documented in accordance with the relevant regulations
- Practices are in place to ensure no prospective or current participant will be coerced or unduly influenced to participate in the research
- Procedures for seeking the participants' consent to inform their primary health care provider about the proposed clinical trial if appropriate, and information about the health care that will be provided to them over the course of their participation
- Criteria for premature withdrawal of research participants, and the steps to be taken if research participants voluntarily withdraw or are withdrawn by the principal investigator
- There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research (i.e. use of a Data and Safety Monitoring Board (DSMB))
- There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data
- There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate
- There will be adequate provisions for the timely publication and dissemination of the research results
- 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 HSREB. If the research is not yet registered, the researcher shall provide the HSREB with the registration number upon registration
- All previous decisions, if known, by other REBs or regulatory authorities, an indication of any modifications made to the protocol on account of past reviews, and the reasons for previous negative decisions

- Any additional documentation which the HSREB or the research may deem necessary to be included in the ethics review

### **Additional Criteria**

- 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 for the full life-cycle of information (its collection, use, dissemination, retention and/or disposal)
- Additional criteria for research involving Aboriginal peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or Regulations
- For research involving First Nations, Inuit or Metis participants, the process for engaging the relevant community or an exception must be described
- If the study involves optional tissue banking or genetic testing, a separate process for obtaining and documenting informed consent, and copies of applicable documents
- If data linkage is proposed, a description of how the data will be linked and the likelihood that identifiable data will be created through the linkage

### **Additional Considerations for Collection of Personal Health Information**

- A description of the personal health information (PHI) being collected and the potential sources, as well as copies of data collection forms as applicable
- A description of how the PHI will be used in the research and if it will be linked to other information, including a description of the other information and how it will be linked, and an explanation as to why the linkage is required
- An explanation as to why the research cannot be conducted without the PHI and any foreseeable harms and benefits that may arise from the use of the PHI, and a plan on how to address these issues
- A description of all individuals that have access to the information and why access is necessary and any plans to address confidentiality
- Safeguards that will be imposed to protect the confidentiality and security of PHI, including how long the PHI will be maintained in identifiable form and why
- Procedures to de-identify PHI prior to the data being sent outside of Kingston
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