

Addenda to N2 Network of Networks CAREB/ACCER Standard Operating Procedures for the Research Ethics Board at St. Joseph's Care Group

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Introduction

This document contains the addenda to the N2 Network of Networks CAREB/ACCER Standard Operating Procedures (SOPs) made by the Research Ethics Board (REB) at St. Joseph's Care Group (SJCG). The changes and additions reflect the practices of the REB at SJCG and have been approved by the REB and Board of Directors at St. Joseph's Care Group.

The full SOP referenced for each addendum can be found on the SJCG REB website (<http://www.sjcg.net/departments/research-services-ethics/reb.aspx>). If there are any questions, please contact the Manager, Volunteers, Library & Research Services at sjcg_reo@tbh.net.

Glossary of Terms

N2 CAREB/ACCER	SJCG Addendum
Organizational Approver:	
	<p>Manager, director, vice president or president who signs the Organizational Impact Form agreeing for the research to take place at SJCG and indicating support for the resources required from SJCG.</p> <p><i>Addendum: Definition provided for this term used within the SOPs.</i></p>
Organizational Official:	
<p>A senior official who signs an organization's human participants' assurance, making a commitment on behalf of the organization to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human participants, and with Health Canada regulations.</p>	<p>A senior official who signs an organization's human participants' assurance, making a commitment on behalf of the organization to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human participants, and with Health Canada regulations. The President & CEO (or delegated official) who is a delegate of the Board of Directors of St. Joseph's Care Group and whose signature can bind the organization. While autonomous in its decision making role, the REB must be responsible and accountable to the Board of Directors. The Organizational Official has broad authority over research that takes place within the institution.</p> <p><i>Addendum: Sentence removed and modified. Explanation: The definition was changed to better fit the structure and function of the REB at SJCG.</i></p>
Timely:	
	<p>Defined as a period of two weeks.</p> <p><i>Addendum: Definition added. Explanation: This was done clarify the timeline regarding the distribution of the agenda and minutes outlined in SOP 302.004, 5.1.6.</i></p>

105A.004 Conflicts of Interest – REB Members and Office Personnel

N2 CAREB/ACCER	SJCG Addendum
5.3 Delegated Review	
5.3.2 REB members involved in the delegated review process are expected to disclose any conflicting interests.	5.3.2 REB members involved in the delegated review process are expected to disclose any conflicting interests. The conflict must be disclosed to the Manager – Volunteers, Library & Research Services as soon as it is known. <i>Addendum: Sentence added. Explanation: It indicates that REB members must report conflicts promptly.</i>

203.004 Duties of REB Members

N2 CAREB/ACCER	SJCG Addendum
5.1 Attendance	
<p>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.</p>	<p>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 one REB meetings per year.</p> <p><i>Addendum: Changed from two to one. Explanation: There are a limited number of full-board REB meetings each year making attendance at a minimum of two meetings onerous for alternate members.</i></p>
5.3 Duties	
<p>5.3.1 All members attending an REB meeting are expected or review the relevant materials 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.</p>	<p>5.3.1 All members attending an REB meeting are expected or review the relevant materials 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.</p> <p><i>Addendum: Phrase removed. Explanation: REB members are not required to submit comments in advance.</i></p>
5.4 Primary and Secondary Reviewers	
<p>5.4.1 REB members will act as primary and/or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the REB submission materials and provide an assessment of the soundness and safety of the research and recommends specific action to the REB. They lead the discussion of the research project during the REB meeting. The primary and secondary reviewers review additional material(s) as requested by the REB for the purpose of approval of the research.</p>	<p>5.4.1 REB members will act as primary and/or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the REB submission materials and provide an assessment of the soundness and safety of the research and recommends specific action to the REB. They lead the discussion of the research project during the REB meeting. The primary and secondary reviewers review additional material(s) as requested by the REB for the purpose of approval of the research.</p> <p><i>Addendum: Section removed. Explanation: The REB does not have primary and secondary reviewers.</i></p>

301.004 REB Submission Requirements and Administrative Review

N2 CAREB/ACCER	SJCG Addendum
5.2 Administrative Review Procedures	
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.	5.2.4 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. <i>Addendum: Sentence removed.</i> <i>Explanation: The REB does not have primary and secondary reviewers.</i>

302.004 REB Meeting Administration

N2 CAREB/ACCER	Addendum
5.1 Agenda Preparation	
<p>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.</p>	<p>5.1.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, and confirms REB meeting attendance and assigns the reviewers.</p> <p><i>Addendum: Phrase removed.</i> <i>Explanation: Reviewers are not assigned by the REB Office Personnel.</i></p>
<p>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.</p>	<p>5.1.6 The reviewer assignment and the agenda are is 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.</p> <p><i>Addendum: Phrase removed.</i> <i>Explanation: The REB Office Personnel do not assign reviewers.</i></p>
5.2 Primary and Secondary Reviewers	
<p>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;</p> <p>5.2.2 No REB member will be assigned as a reviewer on a submission in which he or she is a Researcher or co-Researcher or in which there is a declared conflict of interest;</p> <p>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;</p> <p>5.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.</p>	<p>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;</p> <p>5.2.2 No REB member will be assigned as a reviewer on a submission in which he or she is a Researcher or co-Researcher or in which there is a declared conflict of interest;</p> <p>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;</p> <p>5.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.</p> <p><i>Addendum: Section removed.</i> <i>Explanation: The REB Office Personnel do not assign reviewers.</i></p>
5.3 Prior to the REB Meeting	
<p>5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of</p>	<p>5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of</p>

<p>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;</p>	<p>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;</p> <p><i>Addendum: Section removed.</i> <i>Explanation: The REB does not have primary and secondary reviewers.</i></p>
<p>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</p>	<p>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</p> <p><i>Addendum: Sentence removed.</i> <i>Explanation: The REB does not have primary and secondary reviewers and members are not required to submit comments in advance.</i></p>

401.004 Delegated Review

N2 CAREB/ACCER	SJCG Addendum
5.2 Delegated Review Process	
5.2.3 The REB Chair or designee reviewing the research under delegated review must not have a conflict of interest.	<p>5.2.3 The REB Chair or designee reviewing the research under delegated review must not have a conflict of interest. If the Chair or designee does have a conflict of interest, this must be reported to the Manager – Volunteers, Library & Research Services as soon as it is known.</p> <p><i>Addendum: Phrase added.</i> <i>Explanation: Indicates what must be done when a conflict of interest exists.</i></p>

402.004 REB Review Decisions

N2 CAREB/ACCER	SJCG Addendum
5.1 REB Decisions	
<p>5.1.2 ... Disapproval:</p> <ul style="list-style-type: none"> • 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. 	<p>5.1.2 ... Disapproval:</p> <ul style="list-style-type: none"> • 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, • The REB at SJCG can disapprove the research when it fails to meet the Mission, Vision and Core Values of St. Joseph's Care Group and the most current edition of the <i>Health Ethics Guide (Chapter 6: Research Involving Humans)</i> by the Catholic Health Alliance of Canada, • 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. <p><i>Addendum: Sentence added. Explanation: The Mission, Vision and Core Values guide all undertakings at SJCG including research conducted within the organization.</i></p>
5.2 Reconsiderations and Appeal of REB Decisions	
<p>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</p>	<p>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</p>

<p>case-by-case basis by the REB in consultation with the Researcher (and his/her affiliated organization);</p>	<p>case-by-case basis by the REB in consultation with the Researcher (and his/her affiliated organization). <i>The appeal process shall follow the Letter of Agreement between: St. Joseph's Care Group Research Ethics Board and Thunder Bay Regional Health Sciences Centre Research Ethics Board Regarding Appeals to Research Ethics Boards Decisions dated November 19, 2020.</i></p> <p><i>Addendum: Sentence added.</i> <i>Explanation: This document provides the details about the appeal process for a researcher to follow when appealing an REB decision.</i></p>
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403.004 Initial Review – Criteria for REB Approval

N2 CAREB/ACCER	SJCG Addendum
5.1 Minimal Criteria for Approval of Research	
5.1.1 The application has been signed by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the qualifications to conduct the research	<p>5.1.1 The application has been signed by the Researcher and, if applicable, by a designated Organizational Official, indicating that the Researcher has the qualifications to conduct the research the Organization Impact Form has been completed and signed by the appropriate manager/director or other party in a reporting relationship at SJCG.</p> <p><i>Addendum: Phrase removed. Sentence added.</i> <i>Explanation: There is no designated Organization Official in this role at SJCG but approval must be sought from the appropriate manager/director and the signed Organizational Impact Form submitted with the REB application.</i></p>
5.2.2 Additional Criteria	
	<p>5.2.3 All research must meet the Mission, Vision and Core Values of St. Joseph's Care Group and the most current edition of the Health Ethics Guide (Chapter 6: Research Involving Humans) by the Catholic Health Alliance of Canada.</p> <p><i>Addendum: Phrase added.</i> <i>Explanation: These are additional criteria for research within the organization.</i></p>

404.004 Ongoing REB Review Activities

N2 CAREB/ACCER	SJCG Addendum
5.2 Reportable Events	
5.2.2 Local AE's: The Research must report the following to the REB within a time frame specified by the REB:...	5.2.2 Local AE's: The Research must report the following to the REB in a timely manner immediately. <i>Addendum: Phrase removed.</i> <i>Explanation: Time frame for reporting to the REB is specified.</i>

407.004 Suspension or Termination of REB Approval

N2 CAREB/ACCER	SJCG Addendum
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) and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting to the organization.	<p>The REB Chair or designee will report any suspension or termination of REB approval to the appropriate Organizational Official(s) and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting to the organization.</p> <p>Until the Researcher addresses the reason(s) for the suspension or termination, the Researcher will be ineligible to submit future applications to the REB as a principal investigator or co-investigator.</p> <p><i>Addendum: Phrase added.</i> <i>Explanation: Indicates the result of non-compliance with completing REB documentation.</i></p>

501.004 Review During Publicly Declared Emergencies

N2 CAREB/ACCER	SJCG Addendum
5.0 Procedure	
	<p>5.5.5 In the event that the REB Chair or designee has a conflict of interest in materials that are reviewed during a publicly declared emergency, the conflict will be reported to the Manager – Volunteers, Library & Research Services as soon as it is known and an alternate member will complete the review.</p> <p><i>Addendum: Phrase added.</i> <i>Explanation: Provides instruction so that the Chair or designee is not in conflict.</i></p>

801.004 Researcher Qualifications and Responsibilities

N2 CAREB/ACCER	SJCG Addendum
5.1 Researcher Qualifications	
<p>5.1.1 The organizational approver's signature attests that:</p> <ul style="list-style-type: none"> • 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 to conduct this research, • The Researcher has sufficient space and resources to conduct this research. 	<p>5.1.1 The organizational approver's signature attests that:</p> <ul style="list-style-type: none"> • 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 to conduct this research, • The Researcher has sufficient space and resources to conduct this research at SJCG. <p><i>Addendum: Sentence removed and phrase added.</i> <i>Explanation: The organizational approver may not be able to attest to the Researcher's experience.</i> <i>Additional details indicate that the organizational approver is aware that there is sufficient space at SJCG.</i></p>
<p>5.2.2 The organization is responsible for maintaining current CVs and medical licenses (if appropriate) for each of its Researchers.</p>	<p>5.2.2 The organization is responsible for maintaining current CVs and medical licenses (if appropriate) for each of its Researchers.</p> <p><i>Addendum: Sentence removed.</i> <i>Explanation: SJCG does not currently have a formal central repository of CVs and medical licenses of Researchers doing work within the organization.</i></p>

901.004 Quality Assurance Inspections

N2 CAREB/ACCER	SJCG Addendum
901.004 Quality Assurance Inspections	
Quality Assurance (QA) Officer	<p>The Manager, Volunteers, Library & Research Services, will perform the role of Quality Assurance (QA) Officer.</p> <p><i>Addendum: Role re-defined.</i> <i>Explanation: The REB at SJCG does not have a Quality Assurance Officer to perform this role.</i></p>

903.004 Non-Compliance

N2 CAREB/ACCER	SJCG Addendum
5.3 Managing Non-compliance	
<p>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 and refer the matter to the next Full Board meeting of the REB, and will inform the Organizational Official.</p>	<p>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 and refer the matter to the next Full Board meeting of the REB, and will inform the Organizational Official. In the event that the Researcher has not received REB approval for the study, the Chair will contact the Researcher immediately and request that the Researcher cease non-compliant actions at SJCG and will inform the Organizational Official and other relevant parties/stakeholders if appropriate;</p> <p><i>Addendum: Sentence added. Explanation: This is included to deal with situations where a Researcher conducts research at SJCG without REB approval.</i></p>
<p>5.3.6 Corrective actions are based upon the nature and the degree of the noncompliance. In evaluating the non-compliance, the REB may consider one or more of the following actions:</p> <ul style="list-style-type: none"> • Request modification of the protocol, • Request modification of the informed consent document, • 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 the new enrollment 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 entities (e.g., legal counsel, risk management), 	<p>5.3.6 Corrective actions are based upon the nature and the degree of the noncompliance. In evaluating the non-compliance, the REB may consider one or more of the following actions, or any other action deemed reasonable by the REB:</p> <ul style="list-style-type: none"> • Request submission or re-submission of the REB application, • Request modification of the protocol, • Request modification of the informed consent document, • 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 the new enrollment of participants, • Suspend REB approval of the research, • Suspend Researcher involvement in the research, • Terminate REB approval of the research,

<ul style="list-style-type: none"> • Ensure that all other regulatory reporting requirements are met, as required, • Any other action deemed appropriate by the REB. 	<ul style="list-style-type: none"> • Require the Researcher and/or staff to complete a training program, • Notify organizational entities (e.g., legal counsel, risk management), • Ensure that all other regulatory reporting requirements are met, as required, • Any other action deemed appropriate by the REB. <p><i>In response to any instance of non-compliance, the REB may also consider suspending the Researcher from conducting research at SJCG for a period of time deemed reasonable by the REB.</i></p> <p><i>The Researcher can appeal this decision through the appeal processes outlined in SOP 402.004, Section 5.2 and the Letter of Agreement between: St. Joseph's Care Group Research Ethics Board & Thunder Bay Regional Health Sciences Centre Regarding Appeals to Research Ethics Boards Decisions dated November 19, 2020.</i></p> <p><i>Addendum: Sentences added.</i> <i>Explanation: This is included to provide the REB with the option of sanctioning Researchers in the case of serious and/or repeated instances of non-compliance and provides instructions for Researcher appeal.</i></p>
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In addition, the following also has been added to the SOPs of the REB:

The REB at SJCG regards the following to be examples of non-compliance and subject to review, corrective action, and possible suspension of research privileges by the REB:

- Failing to obtain SJCG REB approval prior to commencing research involving human participants;
- Failing to comply with corrective actions set in place by the REB;
- Failing to follow the approved research ethics protocol;
- Failing to report an Adverse Event;
- Failing to submit an Amendment to a previously Approved Ethics Application should a procedure or research instrument be revised;
- Failing to fulfill the continuing research ethics review requirements of the SJCG REB, including Annual Reports and Final Report.

The instances of non-compliance above are examples and not an exhaustive list. Violations may be a one-time, minor or serious, incident or may be repeated incidents indicating a more chronic issue of compliance.