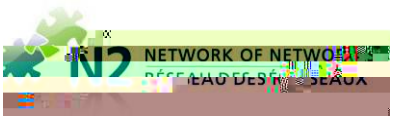

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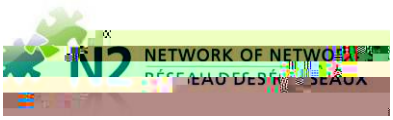
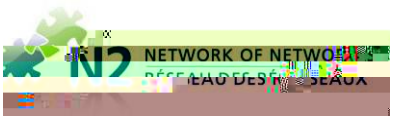

NETWORK OF NETWORKS
RÉSEAU DE RÉSEAUX


NETWORK OF NETWORKS
RÉSEAU DE RÉSEAUX

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 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 Reportable Events

5.2.1 The Researcher is responsible for submitting reportable events that meet the procedures;

5.2.2 Local AEs: The Researcher must report the following to the REB in a timely manner:

Any local adverse event that in the opinion of the Researcher meets the definition of an unanticipated problem,
All reports submitted to the REB must have all research participant identifiers removed (i.e., participant research number only),
Once a local SAE is acknowledged by the REB, subsequent important follow-up reports related to the SAE should be submitted when relevant information is available as a SAE update(s). All initial and subsequent follow-up reports will be retained with the reportable event;

5.2.3 Non-Local (External) Adverse Events: Upon receipt of an external adverse event (EAEv P7-8(h)-3(r)1-8btype/Fd0 61/8 721.32 Tm9[L)-3(o)-3(ca)-3(l)-39((Ex)10(te)-5(rna)-4(l))5

- An analysis of the significance of the current adverse event(s) in light of the previous reports, **and**
- The proposed research changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the event(s),

The individual AE reports or periodic safety updates or safety summary reports that meet the reporting criteria must be submitted to the REB in a timely manner;

5.2.4 Other Reportable Events: The Researcher is responsible for reporting to the REB other events or findings, such as:

would

Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity,
Any sponsor-approved waivers to the participant eligibility criteria,
Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented),
Any deviations that lead to an SAE,
Deviations must be reported within a timeframe specified by the REB;
deviations that lead to an SAE should be reported with a timely manner;

5.2.6 Privacy Breaches: The Researcher must report to the REB any unauthorized collection, use, or disclosure of personal information (PI) including, but not limited to:

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REB Chair or designee for review and final acknowledgement;

5.3.3. The REB Office Personnel may route the submission back to the Researcher to request clarifications, missing documents or additional information;

5.3.4. The REB Office Personnel will forward the submission to the designated REB reviewer(s);

5.3.5. The assigned REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

5.3.6. The assigned reviewer(s) may request further information from the Researcher;

5.3.7. When reviewing a reportable event, the REB should:

Assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or Researcher,
Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or 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

5.3.11. For reportable events 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,

SOP Code	Effective Date	Summary of Changes
		serious adverse event (SAE) form (if applicable), Fourth serious adverse event (SAE) form (if applicable), must be signed by the Researcher or medical local SAE is acknowledged by the REB, subsequent important follow-up reports related to the SAE should **relevant information is available'**