



SOP 402.003

Title	REB Review Decisions
SOP Code	402.003
Effective Date	8-Oct-2019

Site Approvals

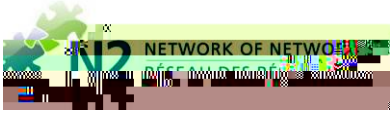
Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
Albert F Clark		06JAN2022
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1.0 PURPOSE

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

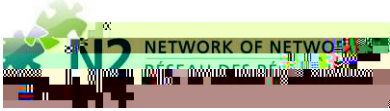


SOP 402.003

5.0 PROCEDURE

As a result of its review, an REB has the authority to approve, disapprove, or to require modifications to submitted research. If there are questions that must be addressed prior to a determination, the REB may defer its decision. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the REB members who are present at a Full Board meeting at which there is a quorum.

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.



SOP 402.003

modifications, or clarifications required are identified at the REB meeting 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 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,

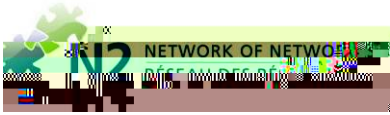
A sub-group of the REB members designated by the REB Chair or designee or by the REB,

A designated REB member or members with sufficient knowledge and experience regarding the research and the regulations.

- 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 straightforward, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone,
- Where the additional information/modification is technical (e.g., statistical clarifications), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s),
- If the Researcher's response is deemed complete and satisfactory, 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),
- 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 of the conditions for approval have been met.

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



SOP 402.003



