

	RESEARCH ETHICS BOARD STANDARD OPERATING PROCEDURES	
	SOP Number	301
	REB Submission Requirements	
	Date of Issue Date of Revision	2006 03 01 2010 08 23 2012 10 19 2018 03 30 2022 07 13
<p>Purpose: This standard operating procedure (SOP) describes the Research Ethics Board (REB) submission requirements. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to approved research and any new information.</p> <p>References: 2019 10 08 CAREB SOP 301.003, Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials), Part C, Division 5, The International Conference on Harmonization Guidelines for Good Clinical Practice E6(R2), Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 109, 110, US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.109, 56.110</p> <p>Responsibility: All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.</p>		

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.

1.0 Submission Requirements

- 1.1 Submission requirements for initial review and post-approval activities are outlined in the REB Application Forms and accompanying Guidance Notes, which are available on the REB website;

- 1.2 All applicable sections of the application forms, including all required accompanying documentation, must be completed. Signatures from the Principal Investigator and their Administrative Supervisor are required for the REB review of the submission;
- 1.3 REB Office Personnel will review each application for completeness. If there are elements missing, the investigator will be notified by REB Office Personnel, and applications will not be assigned for review or consideration at an REB meeting until all required documents are received;
- 1.4 The REB may request any additional documentation it deems necessary to the ethics review, or for research ethics oversight;
- 1.5 **Research Requirements:** The research question and methodology is written in sufficient detail to permit evaluation of the 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,
 - Treatment allocation (if applicable),
 - Primary and secondary outcome measures,
 - Assessment of safety,
 - Sample size justification,
 - Data analysis,
 - Data monitoring.

2.0 Administrative Review Procedures

- 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;
- 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 research coordinator to request the required information for inclusion with the submission;
- 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;
- 2.4 For submissions requiring Full Board review, the REB Office Personnel posts the submission to the agenda of the next Full Board meeting;

2.5 For submissions reviewed via delegated review procedures the REB Chair or designee assigns a reviewer(s) and send the research.