Research Ethics submissions

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Why is it important to talk about REB applications?

ocreb

- To avoid delays in approval → get studies approved ASAP
- To provide ON patients access to treatment options not available otherwise
- To ensure Sponsors see ON/Canada as a viable jurisdiction to conduct trials in

Review of REB applications and timeline to approval depends on :

- Quality of the applications:
  - Appropriateness of the responses to the questions
  - Completeness of the applications

- Content of the applications :
  - complexity of studies ; adaptive study designs, basket studies, master protocols, etc.

RESEARCH INVOLVING HUMANS CAN BE ETHICALLY JUSTIFIED WHEN:

- The research is scientifically sound; potential benefit significantly outweighs the potential for harm/risks ; there is an adequate process for informed consent, and /or assent ; there is justice or fairness in selection of participants.
- How would the REB assess :
  Methodology ; Selection and recruitment and Informed consent process; assessing potential harms and benefits ; ensuring Privacy and confidentiality

METHODOLOGY:

- describe how the research will be conducted ; describe the study design; objectives, end points ; explain what the study-required procedures are

SELECTION AND RECRUITMENT:

- study population ; how are participants recruited
- Are the groups unnecessarily excluded on the basis of culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, competency/capacity, sex, gender, age or other criteria?
- Are there specific groups of individual included (Indigenous populations)

INFORMED CONSENT PROCESS

- Will consent to participate be obtained
- Does the Consent form include all the required elements
- Consent review is often the bulk of the REB review
- Language is important
- OCREB consent template

POTENTIAL HARMS AND BENEFITS

- Potential risks and benefits should be disclosed
- Future risks ; short term and long term risks; reproductive risks
- How risks are minimized; safety committees ; safety monitoring plan ; DSMC/DSMB
- When is treatment discontinued ; what is the criteria for D/C

PRIVACY AND CONFIDENTIALITY

- What identifiers are being collected and why
- Privacy legislation (PHIPA)
- Data sharing

GENERAL TIPS FOR A SUCCESSFUL REB APPLICATION TO OCREB

- Ensure there is a CURRENT protocol that clearly outlines details of the study, including how it will be implemented or operationalized at the research sites ; particularly for Investigator-initiated studies .

- Consider regulatory requirements / guidance for the type of study you are submitting : keep in mind requirements/best practices about data retention, confidentiality and privacy, participant approach, which ideally , should also be considered in the study design.

- Think of all of your different participant groups ; not always patients; can include doctors, caregivers, etc. Anyone contributing data is considered a participant and needs to have their role explained in all pertinent sections of the application.

- Carefully read and respond to the application questions. Full study details are important for the REB to understand what participants will experience, and to assess risks and benefits. Ensure all appropriate sections are completed.

- Provide **consistent** responses between the protocol, application and consent documents. If there is contradictory information between these documents, then it will be difficult for the Board to determine what the researcher's intentions are.

- Ensure completeness by submitting ALL study documents and participant-facing materials used in the study ; describe how they will be provided in the relevant sections of the application; and upload them to the correct section of the application.

- Use OCREB consent templates and consult guidance documents. Use of the OCREB template is MANDATORY for all studies submitted to OCREB. Consult the ANNOTATED application forms available on our website . These forms provide instructions on the kind of responses OCREB expects in the application forms.

- Provide a complete response letter to the REB upon resubmission as this response letter is required to guide the REB in assessing the adequacy of researchers' responses to requirements and or recommendations, which in turn determines the approvability of your study.

- Contact /Consult with OCREB prior to submitting for any unusual or unclear situations with your submissions

Consider Using a Checklist:

REB Submission Checklist		Date	Initials
1. Understand Guidelines	☐ Reviewed all REB submission requirements and ethical guidelines.		
2. Complete Documentation	☐ Included all required forms (application form, consent forms, protocols). ☐ Attached supplementary documents (questionnaires, recruitment materials, etc.).		
3. Clear Research Objectives	☐ Clearly described the study's purpose and significance. ☐ Explained research methods in detail.		
4. Ethical Considerations	☐ Addressed risks and benefits to participants. ☐ Described procedures for obtaining informed consent. ☐ Explained confidentiality and data protection measures.		
5. Lay Language	☐ Used clear, simple language in participant-facing documents.		
6. Transparency	☐ Disclosed conflicts of interest and funding sources. ☐ Reported any potential ethical concerns upfront.		
7. Formatting and Instructions	☐ Followed formatting rules (font size, page limits). ☐ Submitted documents in correct file formats. ☐ Met submission deadlines.		
8. Early Consultation	☐ Consulted with REB or ethics experts if needed before submission.		
9. Review and Accuracy	☐ Double-checked all information for completeness and accuracy. ☐ Corrected any typos or errors.		
10. Timing	☐ Submitted application well in advance of research start date. ☐ Prepared to respond promptly to REB requests for additional info.		

FINAL WORDS:

- Submission, review and approval of a clinical trial is a collaborative effort

- Ensure that the application provides sufficient detail so that the REB can appropriately assess the proposal against the ethical criteria for approval

- Take the time to prepare for your submission; consider discussing the application with your PI
- Use available resources: www.ocreb.ca

QUESTIONS??

Thank you!