



Western Research

CONFERENCE • FALL 2018

**The Good, The Bad, The Ugly –
Improving your Human Ethics application
and minimizing recommendations**

Today's Agenda

- What We Do and Why
- How We Do It
- Tips for Success
- Who We Are

What We Do and Why

What We Do and Why

- The Office of Human Research Ethics (OHRE) facilitates Western's Research Ethics Boards (REBs) manage the approval and monitoring process for research involving human participants (incl. human biological materials).
- REBs are accountable to ensure any and all research involving humans (incl. human biological materials) conforms to the ethical standards set forth by federal (e.g., **TCPS2**, ICH GCP, HC, FDA), provincial regulations (e.g., PHIPA), and local institutions (e.g., Lawson).

1. Consider institutional requirements.

- In addition to ethical requirements, there are institutional requirements about data retention, confidentiality and privacy, participant approach, etc.
- Please consider these in your study design.

Our Responsibility

All research involving humans conducted by faculty, staff or students at Western University or its affiliated hospitals or research institutes must be reviewed by the REB.

- Western University: All Faculties
- Hospitals: University Hospital, Victoria Hospital, Children's Hospital, St. Joseph's Hospital, Parkwood Institute, etc.
- Research Institutes: Fowler Kennedy, Robarts, etc.

Multi-Centre Clinical Trials

- HSREB is a qualified REB by Clinical Trials Ontario

How We Do It

Our Boards

Health Science Research Ethics Board (HSREB)

Research that takes place inside a medical or health care environment or that involves medical patients or medical patient data

| | |
|--------------------------------|---|
| Full Board Review | Prospective research > minimal risk |
| Delegated Level 1 (DL1) Review | Retrospective Research =/< minimal risk |
| Delegated Level 2 (DL2) Review | Prospective research =/< minimal risk |

Non-Medical Research Ethics Board (NMREB)

Includes social, behavioral and cultural research in a non-clinical, non-patient-based population

| | |
|-------------------|---------------------------|
| Full Board Review | Research > minimal risk |
| Delegated Review | Research =/< minimal risk |

Minimal Risk: potential harms are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Note: Contact OHRE if unsure whether a study should be submitted to HSREB or NMREB.

The Review Process

Initial Reviews

New studies that have not yet been approved by an REB, and have not yet started.

Post Approval Events

Changes or updates to an REB submission that has previously received approval and may already be underway.

2. Response documents are important.

- Response documents need to include the question/recommendation posed and the text of your response in a clear and itemized fashion.
- Simply stating “done” or “complete” is insufficient.

IMPORTANT RESUBMISSION NOTES:

- Ensure that you change Q1.1 from "Initial Submission" to "Response to REB Recommendations". Consult the "Help" tab in WREM for a guidance document on submitting responses.
- In a separate document, include each REB question/recommendation and your specific response to each. DO NOT refer to other documents.
- Submit all revised documents (e.g. instruments, LOI etc.) in TRACKED and CLEAN copies. The TRACKED copies must only be uploaded when prompted (i.e., in the section called "Resubmission Information").
- When uploading the revised CLEAN copies, you MUST delete the old versions. Deleting the old versions will archive them and NOT permanently delete them.
- Ensure there is a version date (dd/mm/yyyy) in the footer of each revised document. This version date must be consistent with the version date entered when uploading the document.
- Please note that if a response is not received within 1 year of recommendations, this application will be considered stalled and be withdrawn.

If the above instructions are not followed, the file will be sent back until this is done. Please note that once we receive your response, further questions generated by your response may be asked.

DO NOT begin any study related activities until you receive final notification of approval from the Office of Human Research Ethics (OHRE). If this study involves Lawson, you must also ensure you have received Lawson's Institutional Approval (IA).

Response Documents

- Change 1.1 to “Response”.
- Include each REB question/recommendation and your specific response to each.
- TRACKED and CLEAN copies of all documents.
- MUST delete the old versions.
- Version date (dd/mm/yyyy) in footers that match WREM.

The Good,

Dear REB, thank you for the August 1 review of our submission. Please find our responses below.

Documents re-submitted include the LOI and survey.

1. **Q1.4 Please list all study team members.**

John Smith and Jane Doe have been added to Q1.4.

the Bad, and the Ugly.

1. 13.3 Complete.
2. 1.4.Add identifiers.Identifiers added.

1. Complete.

Tips for Success

3. Allow adequate time for review and responses.

Submissions almost always require recommendations; plan ahead long before you want to start your study.

- Determine the most appropriate board (HSREB or NMREB).
- If submitting for Full Board review, check the submission deadlines.
- If you know of specific time restrictions ahead of time, alert the REB and start early.

4. Ensure completeness.

- Sufficient detail regarding study procedures is required for the application to be reviewed.
- Incomplete submissions will be return un-reviewed.
- Please submit ALL study documents and instruments for review.
 - *E.g., data collection tools, interview guides, LOI/C, recruitment materials, etc.*
 - Note: These documents must be in their final form (i.e., no comments, tracked changes, etc.) to be approved.

5. Make use of our templates and guidance documents.

- Available on our website and under WREM “Help” tab.
- Explain local policies and provide examples of how to formulate key documents (e.g., Letters of Information and Consent documents, recruitment materials, etc.)
- *Note: Majority of recommendations pertaining to LOI/C are due to missing required details and statements for participants to provide informed consent. Following the relevant LOI/C Guidance Document is the best chance for minimizing recommendations.*

6. Develop a protocol.

- For clarity and consistency, prior to starting your WREM submission, write a stand-alone protocol and think about how you will operationalize your study.
- Remember that logistical issues exist even in minimal risk studies.
- The REB needs to understand the ‘who, what, where, when, and how’. This should be thought through and documented prior to submitting the WREM application.
- Check key terms – anonymous vs. de-identified, conflict of interest/commercialization.
- Ensure accurate translation of protocol to WREM.

7. Read the questions and follow the instructions.

- Full study details are important for the REB to understand what participants will experience, and to assess risks and benefits.
- Ensure questions are answered sequentially and accurately ('smart' forms).
- Read all help texts.
- Tip: Just because a study is low risk, doesn't mean the application can lack detail.

8. Consistency is key.

- It is impossible to discern the study activities if contradictory information is provided between questions or documents.
- Good = all information clear and consistent
- Bad = some inconsistencies, but minimal impact on ability to review; recommendations to confirm
- Ugly = so many inconsistencies, cannot determine what the researchers are doing
- Ensure all information is accurate.
- When a revision is made in one part of the application, update all relevant information elsewhere.

HSREB and NMREB

- *Are there any additional study team members (from Western and/or its affiliate institutions) who are working on this study?*
- All team members
- All contact information
- Day to day activities (ROLES and DUTIES....never responsibilities)

HSREB only

- *Has the study undergone a formal scientific or peer review (i.e., internal peer review or external review (e.g., CIHR, NSERC, NIH, etc.))?*
- Not an internal review or expert panel. Not looking for funding letters, looking for review documents.

HSREB only

- *Provide a brief lay/non-scientific summary of the study (max 250 words)*
- LAY LAY LAY
- Grade 8 reading level
- Please do not copy and paste or simply repeat the title.
- Facilitates amendments and confirms to Board that you can explain the study to participants.

HSREB only

- *Hypothesis and rationale*
- *Study design*
- Generally well done for clinical trials and those with protocols.
- Main error is providing detailed methodology/procedures

9. Think about all of your different participant groups.

- It is very common to recognize only patients or only those receiving an intervention as participants.
- *Will this study include the following population(s): (select all that apply):*
- Anyone who will complete study procedures or have their data collected are considered to be a participant and needs to have their role explained in all pertinent sections of WREM.

NMREB only

- *Describe your study procedures (i.e., how are you are doing it?):*
 - *Help Text: If there are multiple sessions/procedures, ensure to describe each. Remember to include details such as...*
 - Study locations
 - Anticipated time commitments
 - Use of audio/video
 - Optional vs. mandatory procedures
 - Evolving study procedures
- *Explain in full*

HSREB only

- *If a patient population is included, will any procedures be carried out in this study that are not considered the usual diagnostic, therapeutic "routine" or standard of care?*
- Everything a patient participant will experience from first contact to study end.
- Even if a procedure/test would be used in standard of care, if it is being administered for study purposes, it's a procedure.

HSREB only

- *If a patient population is included, describe the usual diagnostic, therapeutic “routine” or standard of care at this trial site for this population (including frequency of follow up visits). If there is no diagnostic, therapeutic “routine” or standard of care state this clearly.*
- Explain in full. Best answers give overview of options, frequency of visits, current drugs, context, options.
- Allows Board to have a context for your intervention and assess appropriateness of placebo.

HSREB and NMREB

- *Indicate your data collection tools/forms by selecting the relevant option(s) below*
- *Website/Electronic*
- Version dates.
- Names instead of Study IDs
- As they will appear to participants.
- Need to see live version

HSREB only

- *Provide the inclusion criteria*
- *What is the primary objective*
- Local
- Check symbols
- Pilots - feasibility

HSREB only

- *Describe the circumstances under which a participant may be withdrawn from the study.*
- Withdrawal BY INVESTIGATORS. Should be reflected in LOI as well.

HSREB and NMREB

- *Describe any direct benefits to the study participants.*
- DIRECT
- OK for there to be no benefit.
- OK to acknowledge may become worse.
- Not benefits = Joy of participating in research, compensation, or getting “extra” care

HSREB and NMREB

- *List and describe the known risks/harms/inconveniences of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only (including approximate rates of occurrence, severity and reversibility). This information must be included in the informed consent documentation.*
- For all tests and procedures.
- Even if SOC, if being performed exclusively for study purposes, list risks.
- List for all study groups.
- Privacy breach is always a risk.
- Please quantify, other than for the most common (benign) risks, provide a range.
- Emotional discomforts, etc.
- *Measures in place to mitigate?

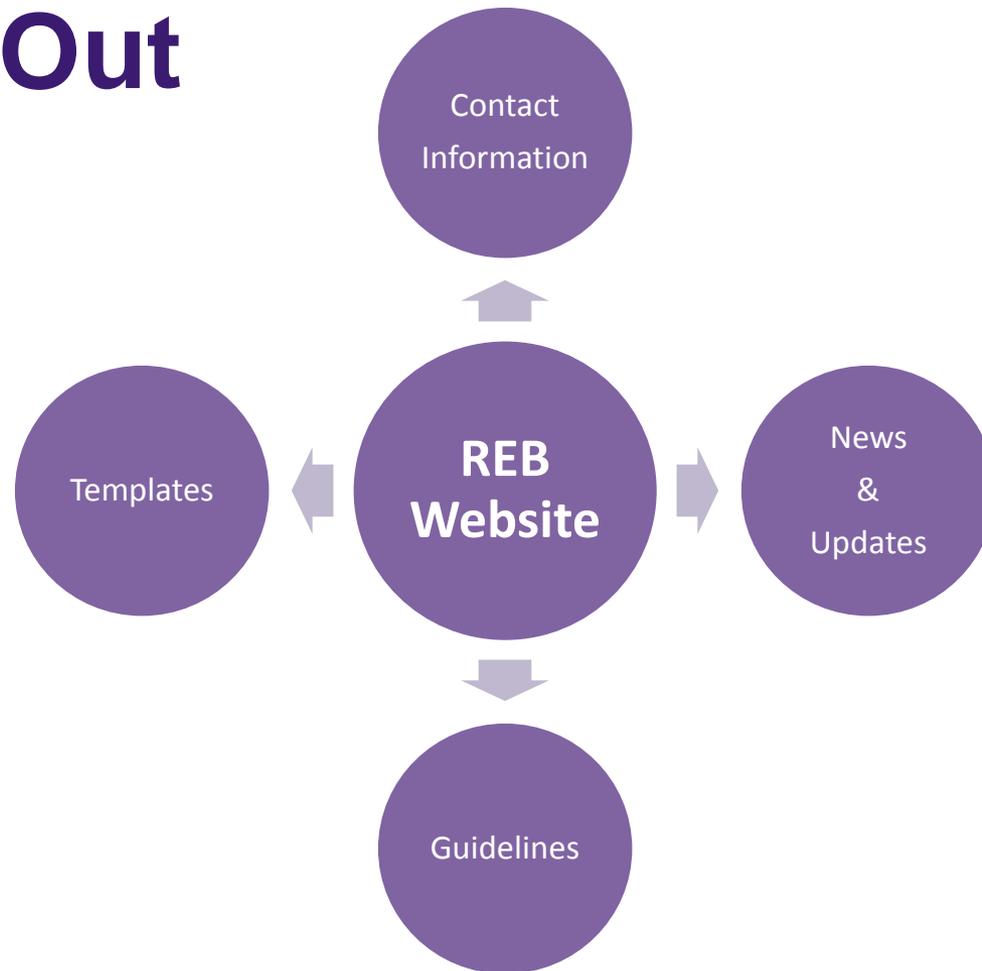
HSREB and NMREB

- *LOI/Cs*
 - Must meet local guidelines (Lawson and HSREB/NMREB)
 - Must have optional studies separate
 - SDM statement
 - Grade 8 reading level

HSREB and NMREB

- *Identify any personal identifiers collected for this study. Select all that apply.*
- *Data storage and destruction*
- Think about ALL identifiers.
- Names on LOI/Cs, family physicians, full vs/ partial DOB, contact information
- Storage location for each (master list? eCRF platform?)
- Clear and consistent
- PI retains study records
- Follow institutional policies

10. Use Your Resources & Reach Out



Who We Are

Our Staff

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