Western

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Research Ethics Considerations in the Research on Teaching and Learning: REB Review at Western University

Centre for Teaching and Learning

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Western

Disclaimer

The information provided in this presentation is consistent with the current policies and guidelines laid out within the Office of Human Research Ethics (OHRE), Western University's Research Ethics Boards (REBs), the University, and the Tri-Council Policy Statement (TCPS2, 2018), which are *subject to change*.

Overview

- **Introduction** to research ethics requirements
- **Submitting REB applications** at Western University
- Key **tips and tricks** for successfully and promptly receiving REB approval
- **Special considerations** within Teaching and Learning
- **Q&A**

Legal, Ethical and Institutional Considerations

- Privacy Legislation (e.g., FIPPA, PIPEDA, PHIPA)
- Tri-Council Policy Statement 2 (2018); Health Canada; OCAP; ICH-GCP
- Western University:
  - MAPP 1.13, MAPP 1.23, MAPP 7.0, MAPP 7.14
  - Western Technology Services' Information Governance, Data Classification, and Data Handling Standards
  - REB Data Security and Confidentiality Guidance Document
- Lawson Health Research Institute's Standard Operating Procedures

REB Exemptions (see TCPS2 Chapter 2)

The following examples **MAY** be exempt from REB review:

- Research relying on publicly available information
- Research on organizations, not involving personal/professional data/opinions
- Secondary use of anonymous information
- Naturalistic observation of people in public places
- Quality Assurance/Quality Improvement/Program Evaluation (QA/QI/PE)
- Creative practices

Research Ethics Oversight at Western

- Office of Human Research Ethics (OHRE) – Administrative unit facilitating REB operations.
- Non-Medical Research Ethics Board (NMREB) & Health Sciences Research Ethics Board (HSREB)

Location: *Support Services Building, 5th Floor (Rm 5150)*

Phone: *519.661.3036*

Email: *ethics@uwo.ca*

Research Ethics & Integrity

- Human Ethics
  - WesternREM
  - Workshops and Seminars
  - Guidelines & Templates
  - Board Deadlines
  - Contact Us
- Animal Ethics
- Policies
- Procedures
- Forms
- Research Integrity
- US Funding Requirements
- CRC Equity & Inclusion

Romeo Login

WesternREM Login

Human Research Ethics

The Office of Human Research Ethics (OHRE), on behalf of Western's Research Ethics Boards (REB), manages the approval and monitoring process for the use of humans in research at the University and its affiliated hospitals and research institutes. All research involving humans conducted by faculty, staff or students at Western or its affiliated hospitals or research institutes must be approved by a Western-sanctioned review board.

Getting Started

- Workshops & Seminars
- Which ethics board should I use?
- Submitting Protocols:
  - HSREB Full Board
  - HSREB Delegated Board
  - NMREB
- Coordinated Review
- Guidelines & Templates
- FAQs
- Post-Approval Events

Administrative Information

- Board Information
- Board Deadlines
- SOPs
- REB Fees
- External Resources
- Contact Us

Our Staff

Director

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Ethics Officers/Coordinator

Health Science Ethics Officers

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Western's REB Review Procedures

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.

Western's REB Review Procedures

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.

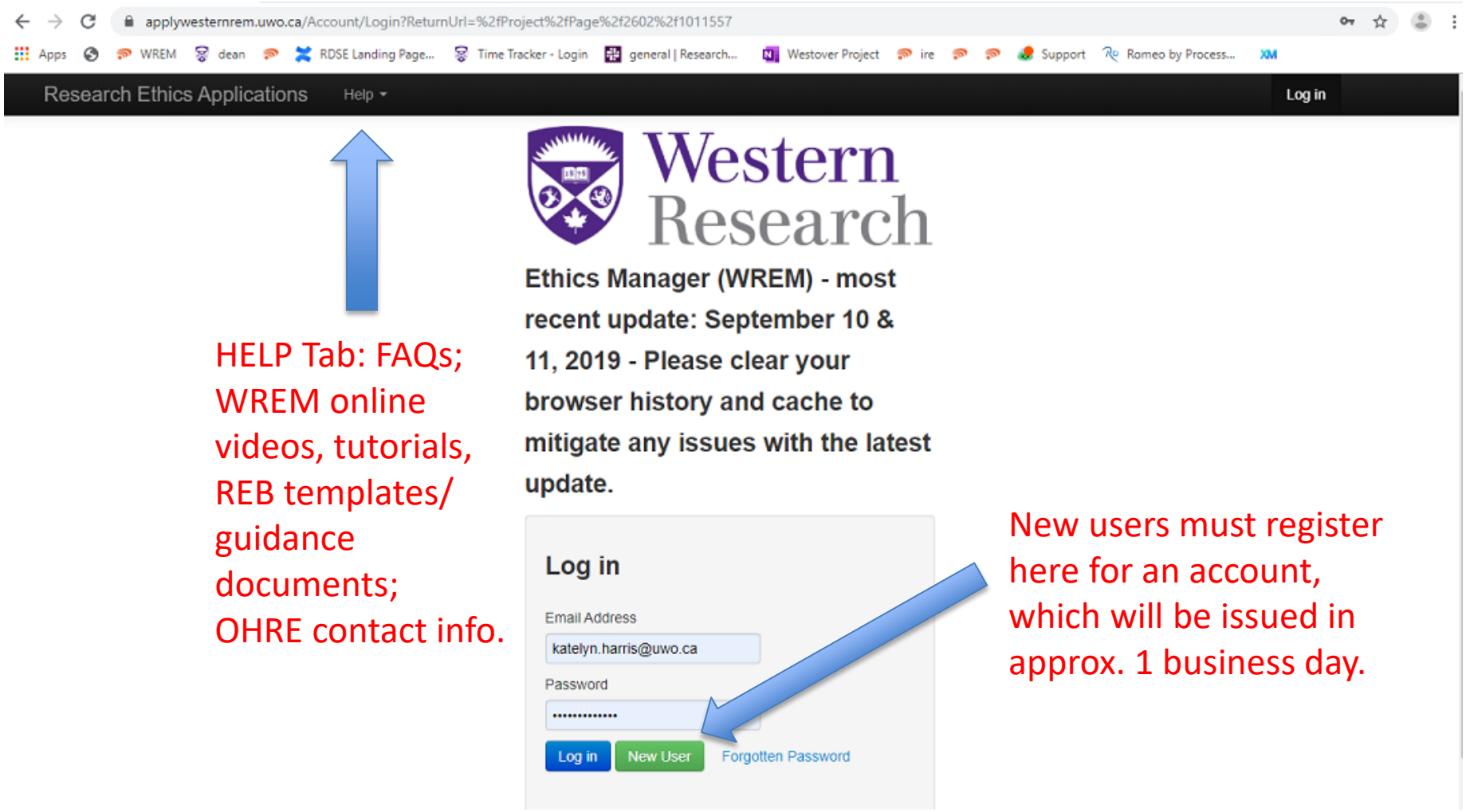
Note: Applications must be submitted by the PI.

Western's REB Review Procedures

- **Who can be PI? Only those who are eligible to hold a research account:**
  - Individuals are deemed eligible based on their job requirements.
  - Those with responsibility to conduct independent research with the support of their chair and/or dean.
  - Refer to document: Eligibility to Hold a Research Account at of Western University
  - Questions? Speak to your Chair/Dean, Call Faculty Relations and/or Research Services

http://www.uwo.ca/research/_docs/resources/Eligibility_Guidelines.pdf

Western's REB Review Procedures



HELP Tab: FAQs; WREM online videos, tutorials, REB templates/ guidance documents; OHRE contact info.

New users must register here for an account, which will be issued in approx. 1 business day.

Getting started…

1. Complete TCPS2 Core Tutorial: https://tcps2core.ca/welcome
2. Imagine yourself as a participant in your study.
3. Think through all logistics of carrying out the project from conceptualization to dissemination and data destruction (e.g., 7 years post-publication per FCA).
4. Read all instructions/questions carefully and respond thoroughly and clearly.
5. Be aware that each REB application is reviewed on a case-by-case basis.

Getting started…

6. What is your research question? One REB application per research question.
7. Consider how/whether your project may evolve, and incorporate this into initial application, if possible (e.g., alerting REB of expected amendments).
8. Study instruments (e.g., interview guide, stimuli, etc.) must be a representative sample, if not complete.
9. Describe your procedures in a way that makes it easy for the REB to understand what you are doing, and what a participant experiences in your study.

Getting started…

- Review the Templates page in the WREM Help tab:
  - Guidelines for Participant Recruitment
  - Sample recruitment templates; Debriefing template
  - NMREB Letter of Information and Consent Guidance Document and Template; Assent Letter Guidance Document and Template
  - Data Security and Confidentiality – Guidance Document
  - Open Access / Open Data guidance document
  - Distinguishing between QA/QI/PE and Research
  - Multijurisdictional Guidance Document
  - Pedagogy Guidance Document

Allow adequate time for review and responses

- Current turnaround times (initial to approval):
  - HSREB: 58 days
  - NMREB: 57 days
- Determine the most appropriate board (HSREB or NMREB).
- Is Lawson approval needed?
- Full Board review? Check submission deadlines.
- Specific time restrictions? Alert REB ASAP and try to start early.

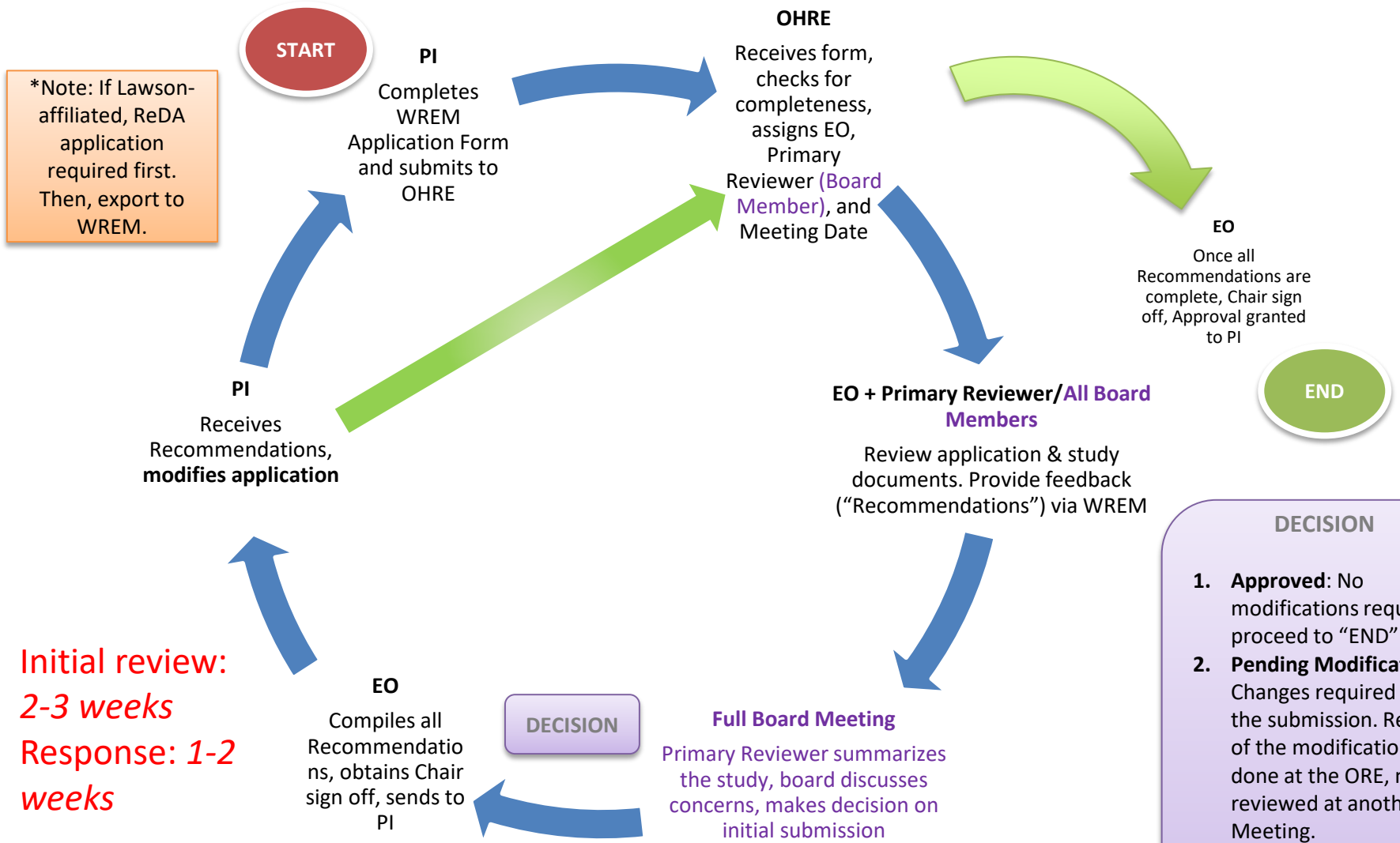
Ensure completeness and consistency

- Provide sufficient detail regarding study procedures
  - Incomplete submissions will be return without review.

- 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.

Initial REB Reviews



*Note: If Lawson-affiliated, ReDA application required first. Then, export to WREM.

Initial review: *2-3 weeks*
Response: *1-2 weeks*

DECISION

1. **Approved**: No modifications required, proceed to "END"
2. **Pending Modifications**: Changes required to the submission. Review of the modifications are done at the ORE, not reviewed at another FB Meeting.
3. **Tabled**: Significant modifications required. Board will re-review application in full following modifications

Initial REB Review

- Delegated:
  - Reviewed by Ethics Officer and REB member (faculty member with expertise)
  - First review takes approx. 2 weeks, then sent back to research team if changes needed
  - Upon resubmission, only the Ethics Officer reviews until approval

Initial REB Review

- Full Board:
  - Reviewed at monthly meeting by multiple REB members, Chair, and Ethics Officer
  - 'Approved'=approved as is
  - 'Approved Pending Modifications'=approval will be granted once the modifications requested are made and resubmitted
  - 'Deferred'=insufficient information for review, must be reviewed at another full board meeting

Submitting Responses to REB Recommendations

- Change 1.1 to “Response to REB Recommendations”.
- Include each REB question/recommendation and your specific response to each in a separate document.
- TRACKED and CLEAN copies of all documents needed and submitted in the appropriate locations.
- MUST delete the old versions.
- Version date (dd/mm/yyyy) in footers that match date entered when uploading document.

Correct

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

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

2. Q2.4 Please update study procedures to include the following details: x,y,z.

Q2.4 has been updated to include the following procedural updates: x,y,z.

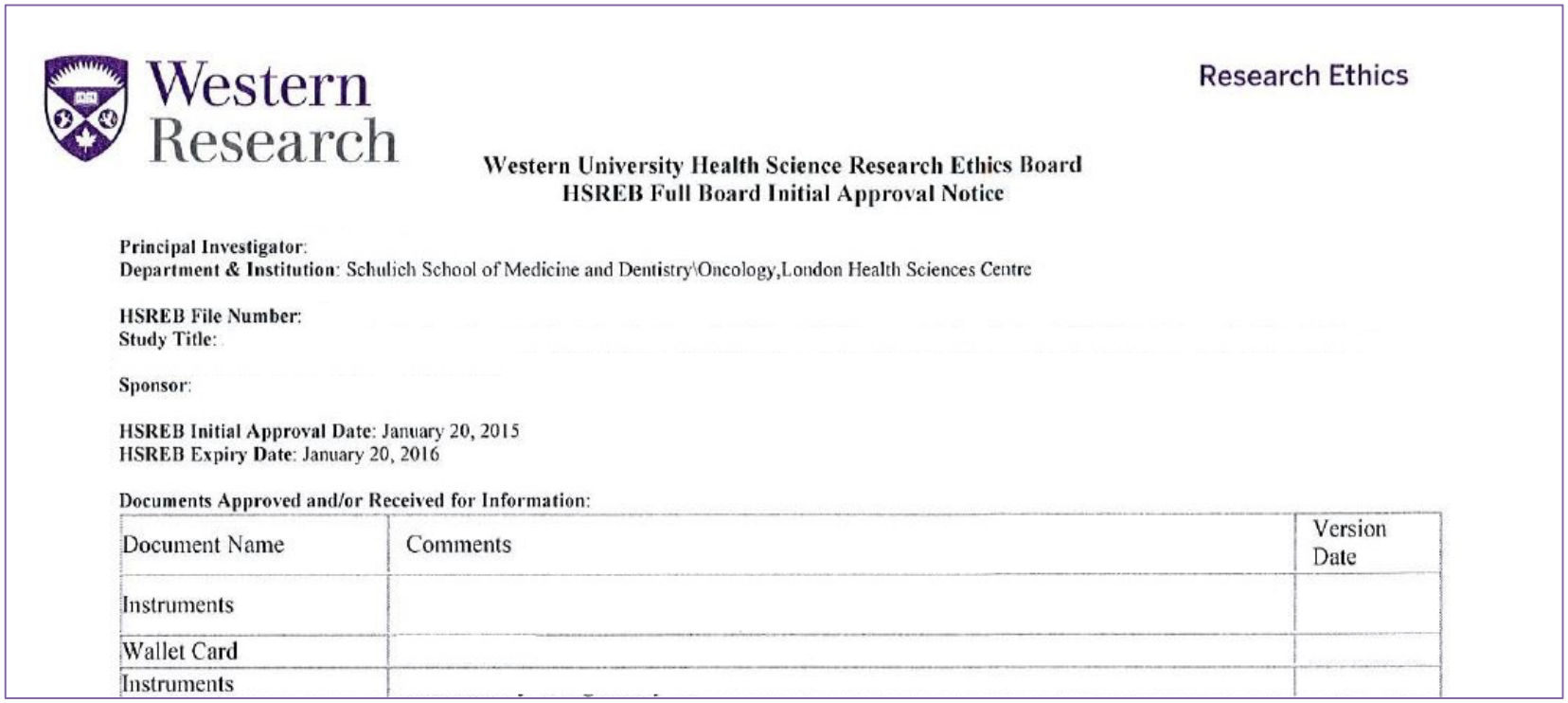
Incorrect

1. Completed.
2. Updated.
3. Done.
4. Changed.
5. Included.

Note: your response can be returned for an incomplete or missing response document.

Approval

Do **NOT** start any research activities until you have received an REB Approval Notice (sent via wremsend).



Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Full Board Initial Approval Notice

Principal Investigator:
Department & Institution: Schulich School of Medicine and Dentistry\Oncology,London Health Sciences Centre

HSREB File Number:
Study Title:

Sponsor:

HSREB Initial Approval Date: January 20, 2015
HSREB Expiry Date: January 20, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Instruments		
Wallet Card		
Instruments		

Required Post-Approval Submissions (i.e., Action: "Create Sub-Form" in WREM)

Amendment	•Modifications to the approved application and/or study documents. •Amendments must be approved prior to implementation.
Reportable Events	•**Protocol Violation/Deviation =** unapproved study activities •**Serious Adverse Event =** harmful outcome to study participant •**FYI =** minor updates to REB •**Data Safety Monitoring Board/Committee (DSMB/C) reports** •**Participant complaints/privacy breaches*contact REB prior to submitting reportable event in WREM**
Continuing Ethics Review (CER)	•Annual update required for studies extending beyond one year. •Receipt of CER approval notice required for study continuation.
Study Closure	•End of study report required when there is no further participant involvement, and all data collection, clarification and transfer is complete (including access to participants' medical record).

Special Circumstances: Conducting research with your own students

- Key Considerations:
  - Is there any pedagogical value to students?
  - Will class time be used to collect data? (If yes, pedagogical value encouraged)
  - Free, informed and ongoing consent
  - Respect for vulnerability
  - Minimizing confidentiality risks and maintaining anonymity

Special Circumstances: Conducting research with your own students

- Voluntariness:
  - Right to choose according to values/preferences/wishes
  - Should feel no pressure
    - Captive audience, peer pressure
    - Perception of impact on grades
    - Study activities during class time
    - Recruitment from someone in a position of power

Special Circumstances: Conducting research with your own students

- Minimizing risk of coercion:
  - How, when and where are potential participants approached?
  - Who is recruiting?
  - Recruitment script (verbal, email, poster, OWL)

  Person recruiting and obtaining consent should NOT be in a position of power over the student

  Examples:

  -TA, CTL staff, RA, unaffiliated instructor

Special Circumstances: Conducting research with your own students

- Explicit statements in recruitment/consent documents:
  - Participation is voluntary
  - Participation (or lack thereof) will not impact academic standing
  - Instructor will not know who participates or what data they contributed (or, if unavoidable, instructor will only know AFTER grades finalized)

Special Circumstances: Conducting research with your own students

- Confidentiality of participation and data:
  - How is data being collected?
  - How can identification concerns (re: group activities, writing styles, small class) be minimized?
  - Can all students be provided the study materials and be asked to return blank if not consenting?

If methodologically appropriate, anonymous online surveys may afford the greatest privacy/confidentiality

Special Circumstances: Conducting research with your own students

- Best practices for protecting confidentiality IF identifiable information must be collected:
  - CTL staff/unaffiliated RA collect and retain identifiable info (incl. signed consent forms/master lists).
  - Only de-identified data be provided to researcher.
  - Data released to researcher after final grades have been approved.

Special Circumstances: Conducting research with your own students

- Compensation – Course credit
  - Bonus? Built into syllabus?
  - Must be approved by institution (e.g., dean/chair)
  - Alternate assignment of comparable exertion
  - Right to skip any question and withdraw at any time without loss of credit
  - Process for allocating credit while protecting confidentiality:
    - What identifiers needed?
    - Who will track?

Special Circumstances: Conducting research with your own students

- Compensation – Financial
  - Value commensurate with risks without enticement
  - Draw for gift card
    - How notified? What identifiers needed? (e.g., email address – collected/stored separate from data)
    - Odds of winning should be disclosed in consent process (e.g., number of draws, number of participants)

Special Circumstances: Conducting research with your own students

- Longitudinal studies (e.g., pre-post test)
  - Assignment of unique IDs to link data across time-points
    - Self-generated by participants (alphanumeric code based on static but unidentifiable personal details recallable by participant)
    - Pre-assignment on master list (collect written consent/contact info, assign unique ID, provide ID to participants)

    *Depends on methodological requirements/ feasibility (lowest level identifiability possible)

Special Circumstances: Conducting research with your own students

- Requesting grades, GPA, etc. from Registrar and/or collection of student number
  - How will you collect?
  - What type of consent?
  - How will you protect?
  - How will you link to other data?
  - Who will be responsible for de-identifying?
  - Who will be responsible for storing identifiers?

Special Circumstances: Conducting research with your own students

- Dual purpose (e.g., QA/QI? Coursework?)
  - What activities are mandatory? Optional?
  - Voluntary and explicit consent needed for research purposes.
  - Recruitment and LOI/C must be clear on difference between original purpose and research purpose.
  - Identification requirements? How managed? By whom? De-identification process? Retention of data?

Special Circumstances: Conducting research with your own students

- Timing of research activities
  - Previously discussed required pedagogical benefit for in-class studies.
  - Research activities should not take place during exams:
    - Not ethical to consent participant during exam
    - May be perceived as mandatory to pass
    - Undue stress on student participant

Special Circumstances: Conducting research with your own students

- Educational interventions (e.g., evaluating new technology/method of teaching)
  - Control groups –
    - Same section? Across sections?
    - Flip intervention for equal treatment OR provide to all students if hypothesized to be beneficial
    - Logistical challenges when measuring with actual marks ("damage" may already be done OR course has ended)
    - Care needed to address ethical principles; researchers to justify and demonstrate sensitivity to potential issues

  Difficult to advise due to range of potential methodologies; best to be reviewed/discussed on a case-by-case basis

Special Circumstances: Conducting research with your own students

- Secondary data (e.g., feedback surveys, assignments, etc.)
  - Subject to TCPS2 Article 5.5A and 5.5B
  - If identifiable, consent may be required (see conditions in Article 5.5A).
  - If non-identifiable (anonymized/coded), REB review needed but no consent.
  - Additional institutional approval may be required (e.g., dept. head/Registrar)

Special Circumstances: Student course-based pedagogical research assignments:

- Instructor/designee responsible for ensuring ethical acceptability (i.e., parameters, recruitment, consent process, confidentiality/data security).
- Administrative review by OHRE via WREM.

Special Circumstances: Student experiential/community-engaged learning opportunities:

- Will students be conducting 'research-like' activities?
- If yes, what is the intended data output?
  - To advance academic knowledge? (Research)
  - To advance an organization/community partner? (QA/QI)

If students are conducting research (or collecting data that is foreseeable for research use), REB review is needed for their particular projects.

Special Considerations: Dissemination

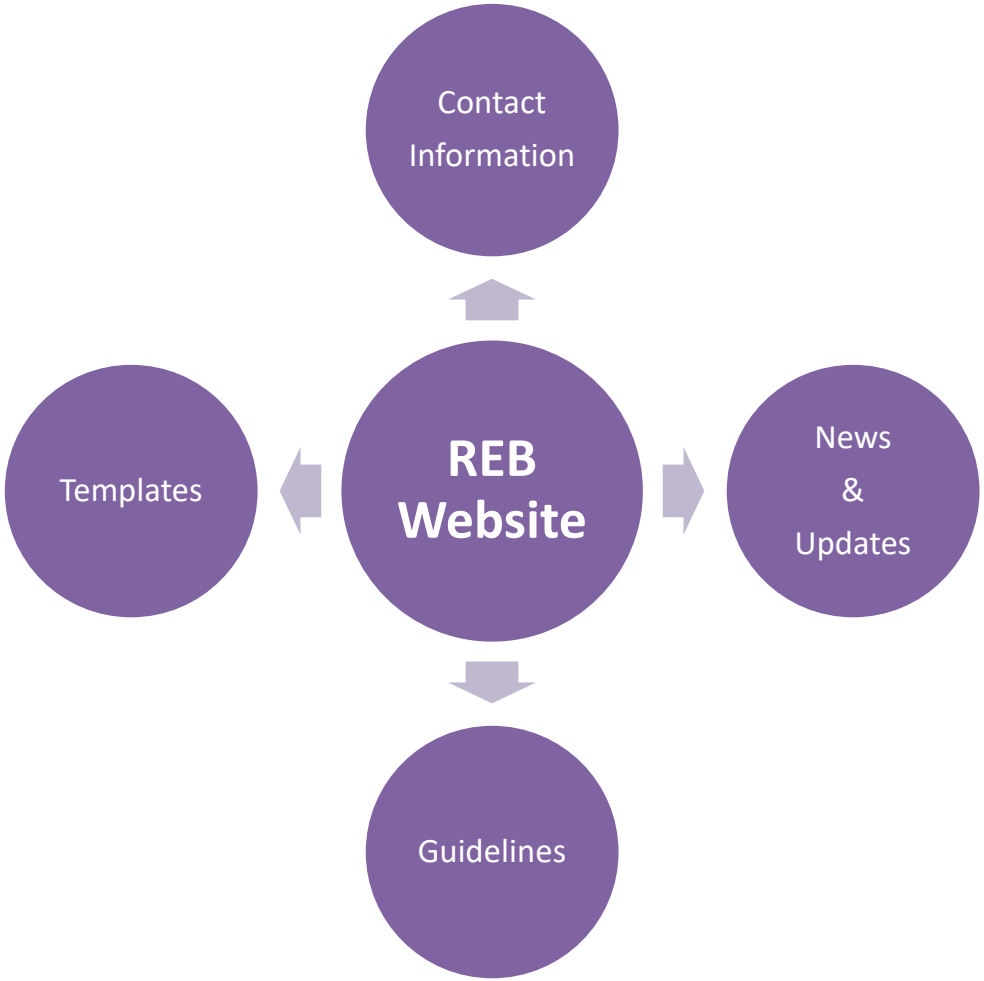
- Registries, Publications, and Open Access:
  - If you wish to share any data outside the research team (e.g., in a registry, open access repository, for publication purposes, for other researchers to verify the findings or re-analyze, or for public archiving), this needs to be indicated in the REB application & LOI/C.
  - Stating “no one outside the research team will have access to the study data” will prevent sharing in the future.

Special Considerations: Future use of data

- Secondary Use of Research Data:
  - *REB requirements depend on the character of the data that will be analyzed:*
    - **Anonymous** at time of collection – exempt from REB review (see TCPS2 Article 2.4)
    - **Non-identifiable** at the time of secondary use – REB review, no consent (see TCPS2 Article 5.5B)
    - **Identifiable** (even if not identifiable upon dissemination of secondary findings, or if access to the code is needed to re-identify participants) – REB review, consent needed UNLESS certain conditions are met (see TCPS2 Article 5.5A).

In sum…

- There is a lot to consider when preparing for research involving humans – especially when those participants are your students, but there are a lot of resources to support you!
- Get started early and think through the logistics of your project.
- Become familiarized with the WREM system and REB guidance and templates.
- Reach out! We're here to help.


Contact Information
Templates
REB Website
News & Updates
Guidelines

Thank you!

QUESTIONS?

OPEN DISCUSSION?

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