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Disclaimer

The information provided in this presentation is consistent with the current policies and guidelines laid out within our office, the Research Ethics Board, the University and the TCPS2 and are subject to change.

This presentation is designed to provide a general orientation to the ethics submission process. Ensure to visit our website and consult with our staff for specific enquiries as needed.

Preparing for the Ethical Conduct of Research Involving Human Participants

Political Sciences and
Master of Public Administration

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Overview

- Why the need for research ethics?
- Core ethical principles
- REB exemptions
- Submitting for REB review at Western
- Helpful tips/common submission errors
- Questions

What is Research Ethics?

Research:

> “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation” (TCPS 2, 2014, pg. 13)

Ethics:

> “moral principles that govern a person's behavior or the conducting of an activity; the branch of knowledge that deals with moral principles” (google search)

Why the need for research ethics?

- Historical examples of unethical research
- Protects research participants' rights
- Protects researchers' data integrity
- Clarifies dual roles/minimizes risks
- Ensures compliance with funding agencies
- Promotes societal trust in (social) science

Consequences of not adhering to ethics procedures?

- Protocol deviation/violation report to REB (incl. how it will be prevented in the future)
- Inability to publish/inability to use data
- Suspension of research
- Investigation by Vice-President (Research)
- Employment-related consequences
- Loss of Tri-Council funding to institution

*Ethics procedures are imposed externally, REB simply monitors compliance; punitive consequences at discretion of central administration/dean of relevant faculty

Whose responsibility is research ethics and how is it achieved?

- Everyone conducting or supporting research initiatives
- Panel on Responsible Conduct of Research
- Tri-Council Policy Statement (and other resources/regulations; see below)
- Research Ethics Boards (REB)/Institutional Review Boards (IRB)
- Three overarching principles

Core Ethical Principles

1. Respect for persons –
   - Right to choose; autonomy
   - Free, informed and ongoing consent
2. Concern for welfare –
   - Obligation to do good; benefits outweigh risks
3. Justice –
   - Fairness and equity
   - Justifiable inclusion; balancing power relationship

Research Exempt from Approval

The following are examples of research that **MAY** be exempt from ethics approval:

- Research relying on publicly available information
- Secondary use of non-identifiable information
- Naturalistic observation of people in public places
- Quality Assurance/Improvement, Program Evaluation

Please visit Chapter 2 of the TCPS2 for more information on what requires ethics approval, or contact the Office of Human Research Ethics (see next slide).

Submitting to Western…

- Office of Human Research Ethics (OHRE)
- 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*

Our Staff

Director

Erika Basile

Ethics Officers

Katelyn Harris, Non-Medical REB

Kelly Patterson, Non-Medical REB

Nicola Geoghegan, Health Science REB

Karen Gopaul, Health Sciences REB

Patti Sargeant, Health Sciences REB

Administrative Support

Nicole Holme

Our Responsibility…

- To manage the review and approval process for all research involving human participants
  - Board of Record for Western and all affiliated research institutions and hospitals
- To evaluate risk to participants, researchers and the institution
- To make recommendations to ethics applications to ensure all guidelines and regulations are met prior to issuing approval

Our Goal…

- To help Western's students and faculty conduct ethical research by providing education through guidance documents, presentations and one-to-one meetings
- To facilitate timely and thorough reviews of initial and post-approval submissions

Each year we see:

- 1400 NEW submissions (480 Non-Medical)
- 1350 AMENDMENTS (250 Non-Medical)

Our Resources…

- Tri-Council Policy Statement (TCPS2) –
  - http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf
  - https://tcps2core.ca/login
- Human Ethics Website – guidance documents, templates, level of review, deadlines
  - http://www.uwo.ca/research/services/ethics/index.html
- Additional regulations depending on nature of research (e.g., Health Canada, FDA, etc.)

Our Submission Process…

- Online electronic applications through Western Research Ethics Manager (WREM)
  - applywesternrem.uwo.ca
- FAQs, training manuals/videos, updates:
  - http://www.uwo.ca/research/services/ethics/WesternREM.html
- Allow time for Board review and recommendations/resubmission
  - Prepare for at least 2-3 months from initial submission to initial approval, if possible

Helpful Tips:

1. Imagine yourself as the participant. What would you want to know? What would you be upset about if you did not know?
2. Realize the REB must see everything a participant will see and understand everything a participant will experience.
3. Remember, even public officials are participants and have rights to the same ethical principles
4. Read TCPS2
5. Review NMREB guidelines/templates

Political Sciences Scenario #1

Online surveys:

-email recruitment?

-survey questions for review

-letter of information and consent form (implied consent)

-e.g., “By proceeding with this survey, I am confirming that I have read the letter of information, agree that I am the appropriate person at the organization to respond to this survey, and that I give my voluntary consent”

Political Sciences Scenario #2

Foreseeable interview research:

-Interview questions/probes/guide

-Recruitment (publicly available contact information? snowball sampling? in-person contact?)

-Consent (written/verbal/implied?)

-Confidentiality of data (anonymous/anonymized/ coded/indirectly identifiable or directly identifiable)

-Data security (Encryption, password-protection, physically locked)

Political Sciences Scenario #3

Last minute/rare/unexpected opportunity:

A Political Sciences faculty member/researcher is at a conference/etc. for professional reasons and an opportunity arises to interview political professionals (e.g., the Prime Minister indicates they are interested and willing to talk to them). What can you do?

Political Sciences Scenario #3

1. Read TCPS2 Article 3.7A (alterations to informed consent) and Article 5.5A (secondary use of identifiable information)
2. Ask PM if interview can be used as research data, and if any restrictions on this (e.g., direct quotes? Etc.). With consent, proceed with interview. Uphold data security/confidentiality
3. Submit REB application. If minimal risk study and PM informed, researcher can demonstrate to the REB that their data was collected in compliance with TCPS2.

Political Sciences Scenario #2

1. Alternatively: Think about your general research interests. If plausible, consider having an approved protocol whereby you can conduct your research whenever/wherever this may be appropriate if the opportunity arises.
2. Submit a protocol indicating how you would conduct such interviews (e.g., audio recording? consent for direct quotes? general interview guide? general description of government officials at any level of government)
3. Submit CERs each year for ongoing approval

Stage 1

Applicant Preparation

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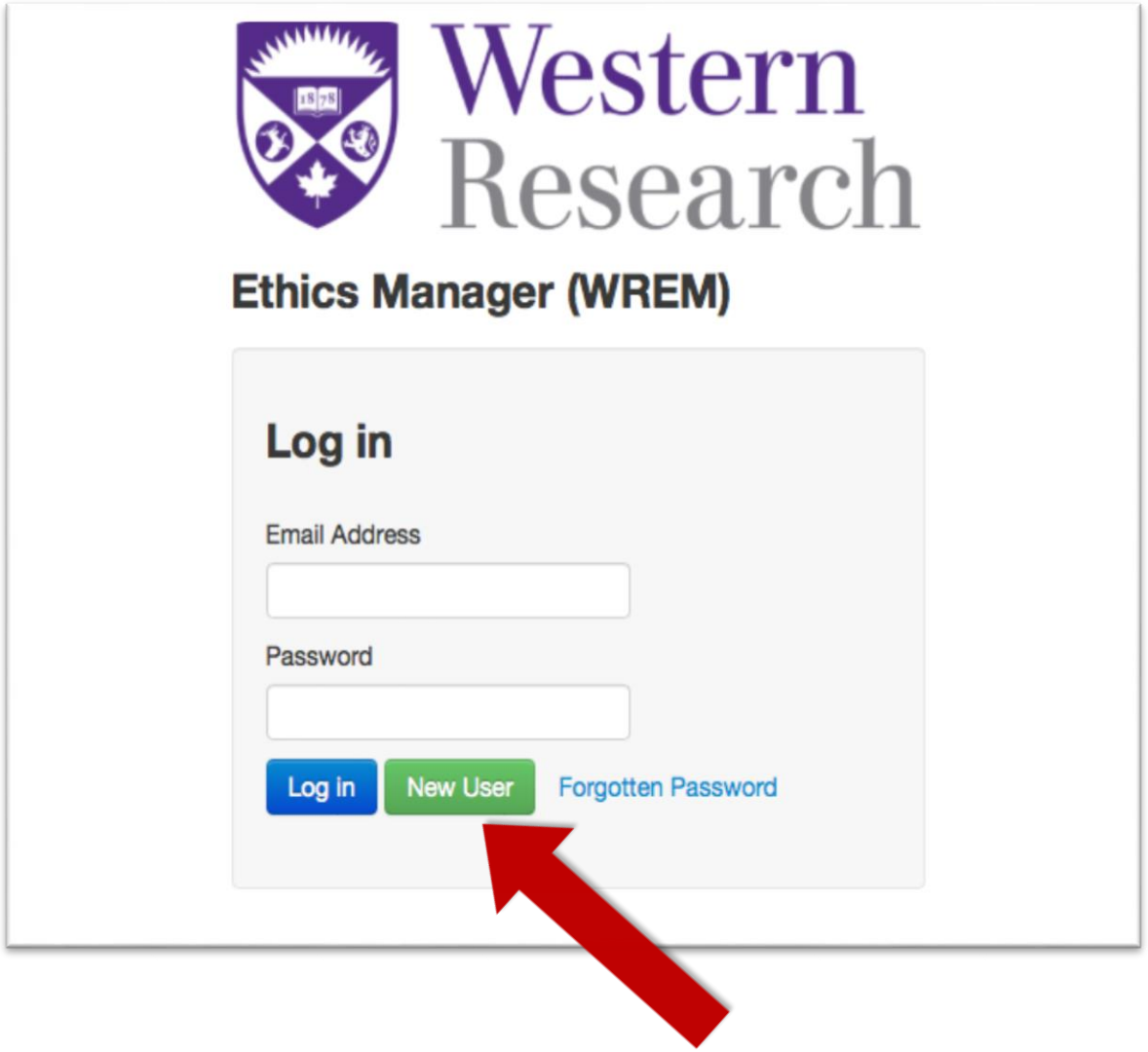
Step 1:
Who is responsible for your project?

Only Research Eligible Faculty can act as the Principal Investigator (PI) on a research project being submitted to our office.

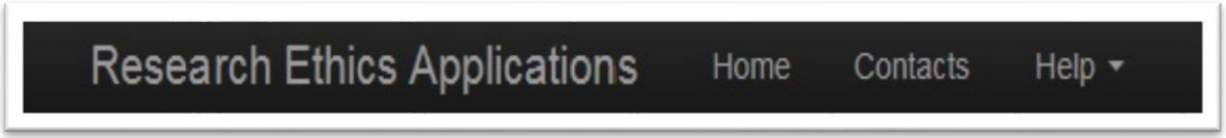
The PI is fully responsible for the conduct of the study, everything that is written in the protocol and for the student conducting the research.

Step 2: Get Set-Up



Step 3: Complete your application

- See Help tab in black navigation bar for tutorial on using the system (HELP, FAQs) and for templates/guidance documents to assist you in preparing your application (TEMPLATES)



Step 3: Complete your application

- Ensure you **respond fully and appropriately** to each question in the form.
- To minimize delays, ask for clarification as needed and communicate clearly and consistently across documents.
- Note all Info icons – help text
- WREM application form has been revamped to avoid many historical errors

Stage 2

Initial Review Process

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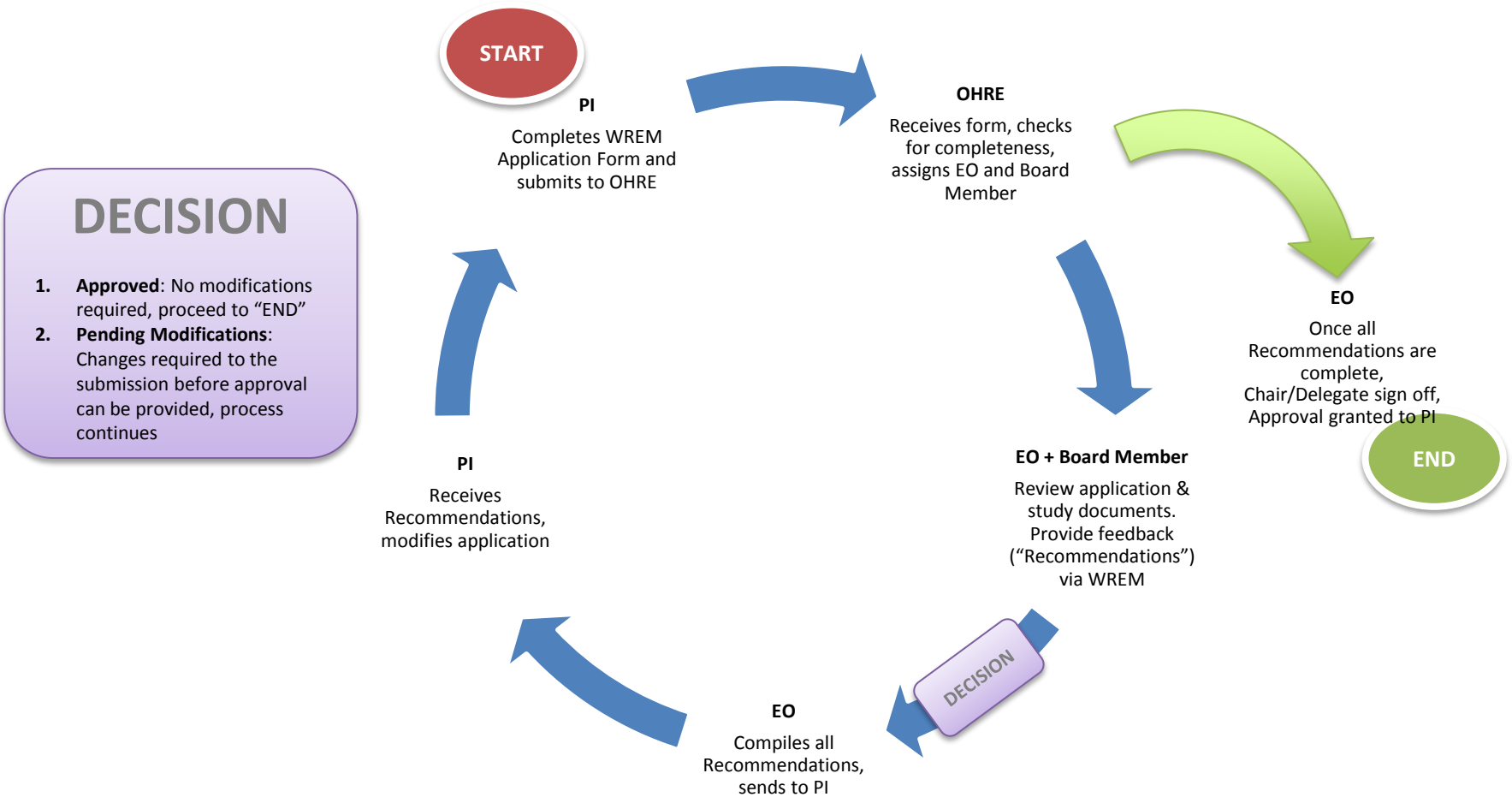
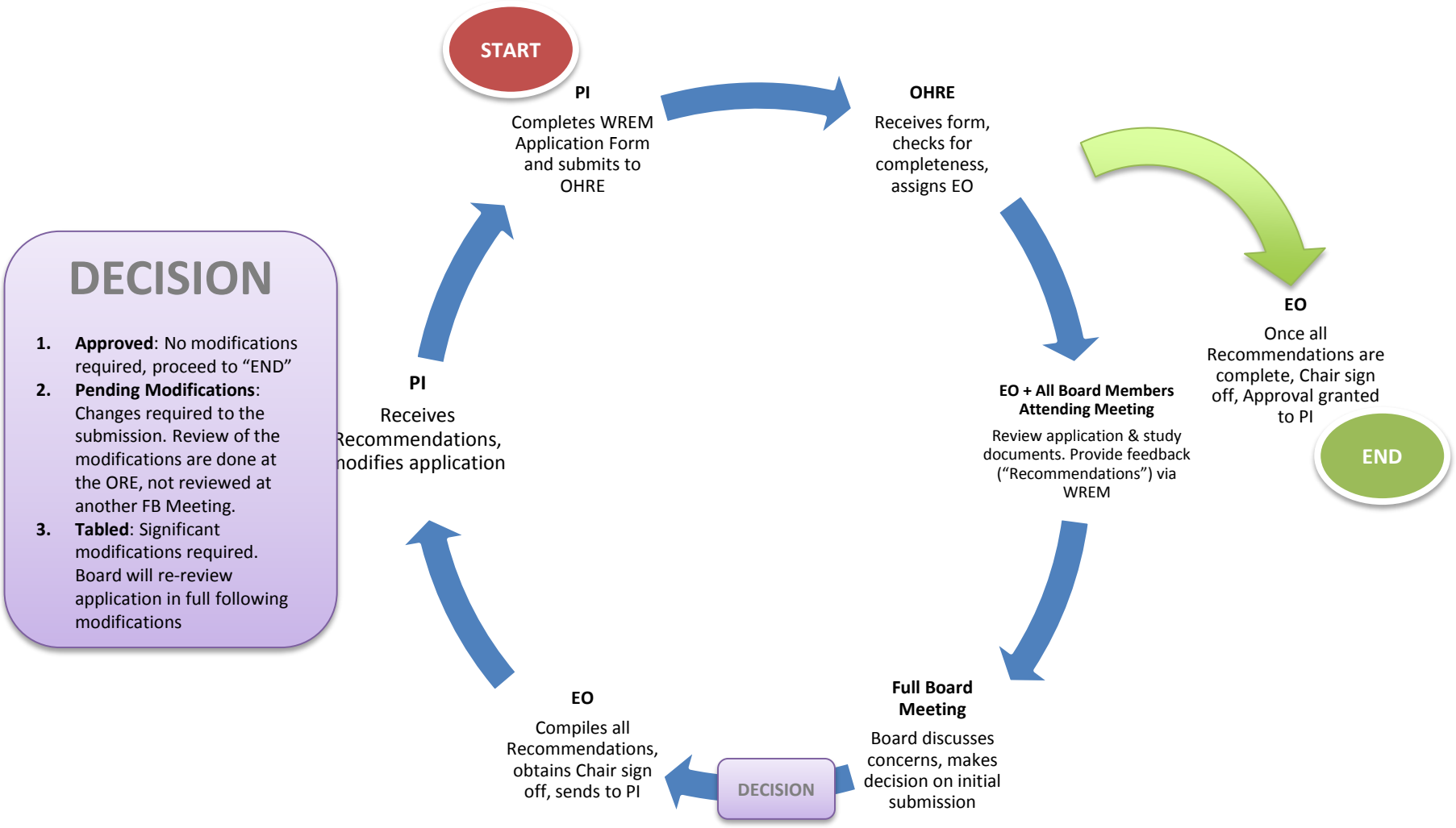
Initial Reviews: The Delegated Process



Full Board Reviews: The Full Board Process



Timing is Important

If requiring Full Board review (i.e., high risk procedures/vulnerable populations), check Full Board Deadlines: http://www.uwo.ca/research/services/ethics/deadlines.html

Please allow ample time for approval; you may NOT start your research until you have received your approval notice

Common Errors:

- Not following instructions
- Not providing adequate information
- Providing inconsistent/illogical information
- Not updating changes to all relevant places
- Inappropriate snowball sampling
- Proposing to send data via email (not secure)
- Rejection of submissions is very rare; instead, recommendations for revision will be made to meet ethical standards

Opportunities to speed up process:

- Pre-drafted templates (e.g., sample recruitment emails/letters of information/consent forms or scripts)
- WREM application form templates (e.g., sample text for specific questions in form)
- DUPLICATE function in WREM for duplicating similar projects and updating only the relevant information
- Following instructions; asking for clarification

Stage 3

Ongoing Review Process

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WREM Sub-Forms

Reportable Events

- Any deviation from the approved study information must be reported promptly.
- Any adverse event that occurs during the study must be reported promptly.

Amendments

- Any change to the approved application and associated study-related documents must be submitted for REB review prior to implementation.

WREM Sub-Forms

Continuing Ethics Review (CER)

- All studies are approved for 1 year. To extend approval beyond one year, a CER must be submitted (or your study will be suspended and risk file closure).
- Courtesy reminders are automatically sent via WREM.

Study Closure

- This form is completed at the end of the study.
- You can complete this as long as there will be no further contact with the participants and no further data collection (but is advisable to keep active until data analysis is complete).

Thank you!

QUESTIONS?

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