



# Western Research

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## **Tips and Tricks for Writing Your Ethics Application Documents**

# Overview

- What is a 'Study Protocol'?
- Letter of Information and Consent
- Recruitment Materials
- Study Instruments
- Debriefing Form
- Common Errors
- Available Guidance Documents and Where to Find Them

# Study Protocol

- The ‘Who, What, When, Where and How’ of your research project
- Should include sufficient detail for reproducibility, and allow for changes to the document via future amendments to be reflected clearly
- A single document which should describe:
  - Study background
  - Rationale
  - Objectives
  - Design
  - Methodology
  - Statistical/Analysis Considerations
  - Organization of the research project

# Letter of Information

- Templates provide both suggested and required language, as well as formatting and important sections
- Required: Institutional logo, project title (as is in WREM), document title, PI details and contact information
- Should begin with an invitation to participate and the purpose of the study
- Key variable sections include Procedures, Risks, Confidentiality
  - Procedures – Should clearly describe all study activities that the participant will participate in, study duration, number of sessions, audio-recording, location
  - Risks – Outline all foreseeable risks, harms, inconveniences and any efforts to minimize them
  - Confidentiality – How, where, how long will data be stored? List all protection measures (e.g., encryption), include who will have access to each type of data, identifiability of data

# Consent Documents

- Note: The consent form should be in the same document as the LOI, but on a separate (final) page.
- Written Consent form includes:
  - Project title, document title, PI details and contact information, Additional Research Staff
  - Statement that participant has read the Letter of Information, has had all questions answered, and agrees to participate
  - Space for name, signature, and date of both participant and person obtaining consent
  - Checkboxes for all additional, non-mandatory components of participation (i.e., audio-recording, contact for future studies, use of quotations etc.)\* optional sub-studies require their own LOIs
  - Additional considerations/requirements when collecting consent from Sub-decision maker, using a translator or witness

# Consent Documents Cont'd

- Verbal Consent form includes:
  - Project title, document title, PI details and contact information, Additional Research Staff
  - The script being read to participants to obtain their consent
  - Explicit questions that the participant has read (or had read to them) the Letter of Information, whether they have any questions or had their questions answered, whether they agree to participate, and any optional consent items (as mentioned in Written Consent)

# Consent Documents Cont'd

- Implied Consent includes:
  - A 'consent statement' such as 'Submitting the survey is indication of your consent to participate' or 'You indicate your voluntary agreement to participate by responding to the survey'
  - Does not need to be a separate page from LOI

# Consent Documents Cont'd

- Parental Consent/Participant Assent
  - Parents should have a Letter of Information (LOI) written to them about their child and include all components of a typical LOI
  - In addition to the requirements of a written consent form, the parental consent form should also include the name of the child, the name of the parent/guardian, and the signature of the parent/guardian
  - Assent letter should be formatted like the LOI but describe the study in a language that is appropriate for the age group
  - Assent form should collect the name of the participant, date, age of participant, name and signature of person obtaining assent



# Recruitment Materials

- Recruitment materials should reflect exactly what participants see/hear when being recruited.
- Recruitment materials should include:
  - Study title
  - Institutional logo/letterhead or clear description of institutions involved
  - Brief overview of study procedures
  - Study duration and number of study sessions
  - Principal Investigator details and institutional contact information
  - Study location
  - Inclusion/Exclusion Criteria
  - Statement that participation is voluntary and information will be kept confidential
  - NMREB only: Compensation

# Recruitment Materials Cont'd

- Email Script
  - Include subject line, greeting, email content
  - Mass email recruitment subject line: Mass Email Recruitment
  - Include email sent to organizations asking them to distribute recruitment materials
  - Communication from primary care personnel introducing study
- In-Person Recruitment Script
- Telephone Script

# Recruitment Materials Cont'd

- Social Media ads (e.g., Facebook, Twitter)
  - Include exact wording, images, active hyperlinks/QR codes
  - Include statement not to comment or reply via platform (contact researcher directly)
- SONA ad
- Poster/Flyer
- Survey Panel (e.g., MTurk)

# Study Instruments

- Data Collection Forms
  - Used primarily in secondary data analysis or chart reviews
  - Should outline the datapoints that the research team is collecting/analyzing
  - Gives REB overview of data that is being used in research
- Interview Guides
  - Include the questions being asked in interview, or a representative sample of questions to be asked (i.e., when using semi-structured interviews)
  - Include any instruction provided to participants before the interview begins

# Study Instruments Cont'd

- Surveys/Questionnaires
  - Do not include identifiers on the survey instruments. If they are required, they should be collected on a separate page/link. This must also be uploaded for review.
  - When using an online platform, the URL is not required before approval but a document should be uploaded that includes all survey questions.
- Focus Group Guides
  - Include the questions being asked in the focus group, or a representative sample of questions to be asked
  - Include any instruction provided to participants before the interview begins (i.e., using pseudonym/unique ID to identify themselves before speaking)

# Study Instruments Cont'd

- Observation Guide
  - Guides research team in observation practices and provides REB overview of what is being observed.
  - Should include key points of observation (i.e., participant number, behavior being observed, time of day, etc.)
- Visual/auditory stimuli
  - Include a representative sample of the stimuli being presented to participants (i.e., word lists, pictures, audio recordings, etc.)

# Debriefing Form

- A page used to provide participants with further information about the hypotheses, procedures and purpose of the study.
- Mandatory when using deception and should include in-depth reasoning why it was necessary to deceive the participant.
- Can include a re-consenting process if deception was used and is feasible.
- Must include project title, institutional logo, PI details and contact information, version date
- Should include a thank-you statement to participants.
- Should include a list of resources available to participants for research that may cause distress
- Could include a list of references for participants to read more on the research topic

# Common Errors

- Inconsistencies between study documents WREM application and/or other study documents
- Missing required/important information
- Uploading documents incorrectly in WREM
- Version date and page numbers missing
- Naming documents incorrectly (i.e., for approval notices, clean and tracked)



# Available Guidance Documents

- There are guidance documents and templates available for nearly all components of a research project (and more to come)
- WREM>Help>Templates
  - <https://applywesternrem.uwo.ca/Personalisation/DisplayPage/50>



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