

Tips and Tricks for

Overview

Letter of Information and Consent

Recruitment Materials

Study Instruments

Debriefing Form

Common Errors

Available Guidance Documents and Where to Find Them

Study Protocol

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

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)

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

Email Script

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

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.)

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>

