UCLA OHRPP
Office of the Human Research Protection Program

Guidance: UCLA webIRB Guidelines for Describing Research Design and Methods (February 1, 2012)

- Purpose
- All Types of Studies
- Research Involving Individual/Group Characteristics or Behavior, Questionnaires, and/or Focus Groups
- Research Involving Clinical Interactions and Interventions

Purpose

The purpose of this document is to provide guidelines for describing the design and methodology of the research in Section 10.1/Item 4.0 of the webIRB application.

All Types of Studies

For all studies provide specific details about what procedures will be performed, when they will be performed and why they are necessary. Include the following in Section 10.1/Item 4.0 of the webIRB application:

- Provide a detailed description of each component of the study and why it is necessary. The following are some examples of components of a study protocol:
    - Preliminary studies such as a pilot or feasibility study
    - Initial screen
    - Randomization
    - Intervention
    - Procedures for control subjects
    - Follow-up
- Include the sequence and timing of all study procedures to be performed. If appropriate, attach a table to Item 1.0 in Section 10.1 to outline the study procedures.
- Indicate how information from or about participants will be accessed and describe how privacy of subjects will be protected during data collection, particularly for procedures that involve collection of sensitive information (e.g., information that could place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation).

Multi-phase research that relies on preliminary studies:

If preliminary studies will need to be completed on human subjects before the procedures for additional study phases can be defined, please either

- State that amendments will be submitted to the IRB before the new procedures will be performed, or
- Depending on the level of effort involved in the preliminary work, indicate that you will submit a new application once the preliminary studies have been performed. It may be easier to do this rather to significantly amend the initial study.

Research Involving Individual/Group Characteristics or Behavior, Questionnaires, and/or Focus Groups

The following information should be included in Section 10.1/Item 4.0 of the webIRB application for research on individual or group characteristics or behavior (e.g., cognitive or perceptual studies), or research employing survey, interview, oral history, or focus group.

- Describe the setting and mode of administering the instrument (e.g., telephone, in-person, group setting, computer-based).
- Include the approximate duration, intervals of administration and overall length of participation.
- For cognitive or perceptual studies, include the number of trials per session, the intervals between sessions, and breaks provided for subjects.
- Attach a copy of all data collection instrument(s) that will be used to item 1 in this section. Examples include:
    - Interview schedules (required for all studies),
    - Standardized instruments (required for all social-behavioral studies)
    - Un-validated surveys and questionnaires (required for all studies).
- If a study instrument is not yet designed, provide a sample of the questions or describe the subject matter to be covered. If the instrument is available in draft format, please provide a copy and indicate that it is a draft.

Research Involving Clinical Interactions and Interventions[1]

- Distinguish between those procedures that are considered standard treatment or therapy (i.e., procedures that participants would receive even if not participating in the research) versus those procedures that are considered :
    - Experimental
    - Investigational and/or
    - Procedures that are carried out solely for research purposes
- Clearly identify standard treatments, therapies and procedures performed exclusively for research purposes (e.g., blood draw, MRI).

[1]**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject's environment that are performed for research purposes.
Interaction includes communication or interpersonal contact between investigator and subject.