IRB Research Summary Guidelines

In order to review research involving human participants, the University of Oregon Institutional Review Board (UO IRB) requires completion and submission of an IRB application AND a research protocol summary. The following guidelines are designed to help researchers develop a comprehensive yet succinct research protocol to facilitate timely review by the IRB. (Thesis, dissertation, grant, and funding proposals cannot be submitted as, or in lieu of, research protocol summary as they do not contain all the required information but they must be included as reference materials for the reviewer.)

General Guidance

Please use the format and topic headers stated below. IRB reviewers are accustomed to this format and using this format will facilitate the review process and assure that all basic information is included to enable meet the IRB Approval Criteria under 45 CFR 46.111 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111)

Please keep the Research Protocol Summary under three pages (references, informed consent/assent documents, and copies of questionnaires, guiding questions, survey instruments, tests, letters of support, etc. are in addition to this page limit). Write the summary in such a way as to be understood by readers outside of your field of expertise. Avoid complex terms and jargon. If complex terms must be used, please define them using plain language CDC plain language medical writing http://depts.washington.edu/respcare/public/info/Plain_Language_Thesaurus_for_Health_Communications.pdf and federal Plain Language.gov site http://www.plainlanguage.gov/howto/guidelines/bigdoc/writeShortPara.cfm

Research Summary Topic Areas and Recommended Format

A. Introduction and Background:
Summarize the background, nature, the scientific or scholarly rationale and significance of the proposed study.

B. Specific Aims/Study Objectives:
In outline form, state clearly the objectives of the research. What are you hoping to learn as a result of this research?

C. Methods, Materials and Analysis:

Methods (Procedures): Describe all the activities in which participants will take part (such as completing a survey, taking a test, answering questions in an interview, completing a specific task, undergo a procedures, completing tasks on a computer, running on a treadmill, etc.) and include an estimate of the time each participant will spend to complete the tasks (in minutes or hours) and the preparation and training for the tasks and any repeated measures. Please indicate the total length of participation (in days, weeks, months, or years). If the participant will come to participate only once, please state this clearly.

Methods: Describe the methods of data recording (videotapes, audiotapes, photographs) and explain the rationale for doing so. In some instances Participants (and their guardians, if applicable) should be given the opportunity to review their audiotapes, videotapes, or photographs before inclusion in the final data and researchers must honor requests to edit a participant from a presentation.

Clinical Research and Research with Medical Devices: Research that includes clinical procedures or medical devices, please attach a copy of the clinical procedures information worksheet. You will also be asked to provide manufacturing data on medical devices, and you will not be allowed to use any devices for experimental
purposes, that have not been produced using good manufacturing practices and good laboratory practices. Please contact the OPHS Director for specifics.

Genetic Research: Collecting or using human tissue samples (including blood or tissues collected as part of a clinical procedure for treatment purposes), is considered human subject use. The reviewer checklists have information on what to include in the consent forms for genome research and definitions of what is considered genome research. Please see these checklists and the genetics research sample informed consent document for specific information. Please provide specific scientific information on what you will do with the tissue sample, the procedures for DNA extraction, transformation of DNA into cell lines, and whether or not you will be characterizing chromosomes or proteins or metabolites associated with disease states.

Analysis:

Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively and what statistical tests you plan on using). Explain how the interpretation will address the research questions. (Attach a copy of the data collection instruments).

Explain how data will be reported (i.e. aggregated, anonymously, pseudonyms for participants, etc.). If data is collected at another institution, the investigator must include permission for data collection from the appropriate institution or IRB review.

D. Research Population & Recruitment Methods:

Participant Population & Research Setting: Describe why you chose the target participant population and the setting where the data will be collected (population selected must relate to the specific aims of the study). If you specified a particular age range race or ethnicity, gender, etc., explain how these traits are important for your research aims.

Recruitment Process:

Participant Recruitment: Include a description of how participants will be recruited or contacted. Explain who or what will be the source of participants and include criteria for participant inclusion and exclusion. Please provide a statement regarding the equity of participant selection.

Recruiting Aids: Explain the compensation provided to participants for their participation in the research study (i.e. money, goods, course credit, etc.), and how and when it will be provided. If you are conducting research in a classroom environment, state what alternative activities will be available for students not participating in the research? Describe procedures for reducing peer pressure or stigmatism for non-participants, if applicable.

Recruiters: Explain who will recruit participants, if they have or will provide treatment or care to the prospective participants, and if they will be compensated for their recruitment efforts.

For Research including Treatment: If recruiters will also provide treatments (either chemical or behavioral), how will you distinguish research treatment from regular treatment? What measure will you take to diminish undue influence that a treatment provider may have on prospective participant?
Note: Generally speaking, to avoid undue influence a regular treatment provider should not be the same person who recruits participants, using colleagues or research staff not directly involved in treatment to recruit participants avoids the appearance and likelihood of undue influence to participate. In clinical situations, it is appropriate for the clinician to initially inform the prospective participant of the research, but the consent process and enrollment should be performed by another person who does not participate in regular care.

E. Informed Consent Procedure

Attach a copy of the consent form and describe the procedures for obtaining consent. Explain how the assent or consent will be secured. Describe special provisions for individuals who might have trouble comprehending the consent information (ask questions about the procedures, the length of participation, voluntary participation, etc.). Standard headers and language should be used whenever possible. Sample informed consent documents with standard headers and language can be found on the IRB webpage. If participants do not speak English, a complete consent for translated in their language and in English must be submitted.

All of the following basic elements must be included in the informed consent

- A statement that the study involves research
- The purpose of the research in lay terms (in language understandable to the participant)
- The expected duration of the participant’s participation (specify days, weeks, months)
- The time commitment of participation for the procedures (“The interview will take 2 hours”)
- A brief but complete description of all procedures to be followed (if research includes treatment describe which procedures are experimental)
- The reasonably foreseeable Risks or Discomforts associated with participation, and that there may be unforeseeable risks
- The benefits to the participant or others which may reasonably be expected from the research
- A statement of confidentiality that provides the participant a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher)
- A statement that participation is entirely voluntary and may be discontinued at any time
- A statement that withdrawal from participation will not result in denial of entitled benefits
- Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure
- The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness (unless a waiver of consent documentation is requested)
- A statement and check box that indicates the participants have a copy of the informed consent document (unless the consent process is waived).

The above information may not apply to some types of research (telephone surveys, oral history, anonymous interviews). In these cases an IRB waiver of certain elements of informed consent may be
requested and is encouraged. Do not list risks that are not present in the consent form, simply state the real risks that are present in the research. If you are using an assent process for children, it should be specific to the age of the population being studied (please see sample assent guidelines for children).

Readability Statistics:

To check the reading level of your consent form using Microsoft word spell check, open the spell check, and click on options. Check “readability statistics” and then click OK. Then run a spell check. When the spell check is complete, readability statistics will appear, including the Flesch-Kincaid grade level. Most consent forms for the general public or state sponsored projects must have a reading level of 8th grade or lower. Federal grants generally require a reading level of 6th or lower. To assist you in lowering the reading level of your consent forms, there are a number of web sites that provide good examples of plain language:

1) Plain Language.gov: http://www.plainlanguage.gov/
2) Harvard Medical Glossaries for asthma, lupus and arthritis: http://www.hsph.harvard.edu/healthliteracy/resources/glossaries/index.html has three plain language glossaries. These sources provide good samples of complex medical ideas in simple plain language

F. Provisions for Participant and Data Confidentiality:
Describe how the privacy of participants' responses will be protected (i.e. responses will be anonymous, assigning pseudonyms, assigning codes, etc.). If you plan to identify participants, contact the OPHS for guidance. Describe where the data will be stored and who will have access to it. Describe the security of the area where data will be stored (locked office, computer stored data is password protected, firewalls, virus detection, etc.). Describe what will happen to video and/or audiotapes after transcription. Will they be destroyed or used later for research purposes? (Please note that the participant should have the opportunity to opt out of videotaping or it must be a condition of participation, in research with sensitive information video and audio tapes may not be appropriate and may increase the risk of participation unnecessarily).

G. Potential research risks or discomforts to participants: Research risk is the probability of harm occurring as a result of participation in research and the degree of harm (participant may become bored, uncomfortable, or upset). For any project involving more than minimal risk, please contact the Office for Human Research Participant Protection for guidance. Describe any risks to participants that are reasonably foreseeable, even if unlikely, and the safeguards in place against these risks.

Risks may include psychological, social, economic, physical and legal risks. While you may not expect any risk of participation, no protocol is with out risk, be it a risk of a loss of confidentiality or the unlikely triggering of past emotional experiences. In many protocols the greatest risk is breech of confidentiality, however, this risk can be easily minimized with good privacy & security protections.
H. **Potential research benefits to participants**: A benefit is a valued or desired outcome or advantage. Describe any direct benefits participants could potentially accrue or benefits the participant class/population may accrue or if the data is being collected to add to generalizable knowledge on a specific question or problem. If there are no benefits directly to participants, state this. Explicitly address how risks compare to benefits. Please note that payment for participation is not a benefit, it is a recruitment aid. Investigators should not call it payment.

I. **Investigator experience**: Briefly describe your experience with the proposed participant population and procedures and enclose a current copy of your C.V. or resume.