I. Human Subjects Research Protocol Application: Complete parts 1-14. The information contained in these sections will help the Office for Protection of Human Subjects (OPHS) determine the level of review required for the protocol. A protocol may be determined to require a
full review by the Committee for the Protection of Human Subjects (CPHS), an expedited review by one or more CPHS members, or an exempt review by the Office for Protection of Human Subjects.

1. **Project Information:** Enter project details including title, name(s) of principal investigator(s), co-investigator(s), faculty advisor, etc.

2. **Supplemental Attachments and Documents:** Answer the series of yes/no questions. If any questions are marked "yes," follow the instructions and fill out the relevant attachment (to be included with the protocol submission).

3. **Human Subjects Research Training:** Fill in training information for all key personnel involved with the project. The UO requires that all key personnel working on research projects involving human subjects have current training in human research protection. This training is designed to help researchers understand their responsibilities to safeguard subjects and data. The [Belmont Report](http://www.uoregon.edu/~humansub/appinstructions.htm#attach_c) describes three important principles of conducting research—respect for persons, beneficence, and justice—and the training reinforces the importance of these principles.

4. **Research Overview:** Provide a brief description of the research, including hypotheses or research questions and relevance. Specific activities to be undertaken will be addressed later in the application.

5. **Roles, Academic Background and Training:** Describe experience and training for all key personnel involved in the research. This section will help determine that key personnel are qualified to perform the roles assigned to them in the research.

6. **Description of Participant Population(s):** Be as specific as possible in identifying each subject group in the study. Indicate the ages or age-ranges of each group, gender, and any specific characteristics of the target study population. If students are subjects, indicate which school(s) will be contacted (including UO classes).

   Provide the approximate *maximum* number of participants who might participate in the research. For example, if 50 subjects’ data are needed for a statistically powerful analysis, 100 subjects may need to be recruited in order to obtain the minimum amount of valid data necessary. Therefore, you should list 100 subjects. Be aware that you may not exceed that number without first obtaining IRB permission, which can be done by submitting a [Modification Form](http://www.uoregon.edu/~humansub/appinstructions.htm#attach_c).

   Under the regulations, *special populations* are more likely to be vulnerable as subjects in research and must be accorded special considerations. This is not to suggest that special populations should be excluded from research. Therefore, rationales for both including and excluding special populations must be provided. Special populations include children, people with intellectual or developmental disabilities, pregnant women, fetuses, and prisoners. Researchers using special populations should consult the [Investigator's Manual on Research with Human Subjects](http://www.uoregon.edu/~humansub/appinstructions.htm#attach_c) for information on special considerations for these groups.

   Note: Whenever any human subject in a research protocol becomes a *prisoner* at any time during the study, the investigator must report this situation to the Office for Protection of Human Subjects.

7. **Recruitment Procedures:** Indicate how you obtained potential subject contact information. Also
describe how you will notify all subjects about the study (e.g., flyers, phone calls, class announcements, subject pools, other organizations, etc.). Lastly, clearly describe the screening procedures to ensure that the people you are recruiting are eligible to be in the study. For example, if you are recruiting subjects online who must be at least 18-years-old, how will you know that those responding are actually at least 18-years-old?

Recruitment documents* (e.g., flyers, phone scripts, letters, etc.) need to be developed for all recruitment methods. Provide the complete text of what will be used to recruit subjects. Do not begin the text with mention of money or free items. Remember that recruiting is for informational purposes, not marketing, so do not “hype” the recruiting materials. The following items need to be included in all recruitment documents:

a. Name and department of investigator or research facility  
b. Clearly stated purpose  
c. Type of research  
d. An approach that is honest and straightforward  
e. Ages for eligibility  
f. Location of research and the person to contact for further information  
g. Compensation, if any (NOTE: Payment or the amount to be paid must not be shown in larger or bold print, etc.)  
h. Statement that project will be video and/or audio recorded, if applicable  
i. If the project is federally funded, the name of the funding agency.

Note: All Health and Human Services grantees must acknowledge federal funding on recruitment documents and when issuing statements or press releases.

Click here for sample templates of recruitment documents.*Submit a copy of all recruitment documents.

8. Consent Procedures: Describe how informed consent will be obtained for all subjects. How will the study be explained to subjects? How will questions be addressed? The consent process involves more than simply handing out a consent form for subjects to read and sign. Indeed, some studies should more appropriately employ a process of obtaining informed consent that does not require a signature of the participant. (Click on this link to find out more about Waiver of Documentation of Informed Consent.) At a minimum, subjects must be allowed to ask questions about the study after reading or hearing about the procedures, risks and benefits of being in the study.

Consent documents must be written in non-technical, jargon-free language at an 8th grade level. Assent documents must also be written in age-appropriate language. A detailed description of the basic elements of consent is in the Investigator’s Manual. Investigators with projects involving more than minimal risk and/or those working with special populations must consult the Investigator’s Manual for additional informed consent elements.

The following items need to be included in all consent documents*:

a. Purpose of research
b. Procedures, including duration, frequency and locale  
c. Potential risks and how they will be managed  
d. Potential benefits to subjects and society  
e. How confidentiality will be handled  
f. Indication that participation is voluntary and subjects may withdraw without penalty or loss of benefits to which they are otherwise entitled  
g. Terms of compensation, as applicable  
h. Investigator and faculty advisor phone numbers for questions regarding the research  
i. Office for Protection of Human Subjects phone number for questions about rights as a research subject or in the event of research-related injury  
j. Indication that subject will be offered a copy of the form to keep.

Note: Federal regulations require that all signed consent forms must be kept by the researcher for a minimum of three years after the project has been completed.

Note: Be aware that if a drug or device is to be used in the research, no claim may be made as to its superiority, safety or effectiveness in the recruitment or consent process or documents.

Click here for sample templates of consent/assent documents.

*Submit a copy of all consent/assent documents. It may be necessary to translate your consent/assent documents in a language other than English. If that is the case, include a copy of the translated version, along with the English version.

9. Research Methods: Each activity of each group must be completely described, including the expected time involvement of participants and location for each activity. Each method* used for collecting data must also be listed. Be sure to describe all activities subjects are asked to engage in sequentially, i.e., from the point at which they have agreed to participate to the end of their involvement in the study.

* Submit a copy of all surveys, questionnaires, instruments, interview questions, etc.

10. Data Collection and Disposition: Provide complete information concerning the type of data to be collected. Also include plans for recording data, maintaining its confidentiality and storing it. Describe how data will be disposed after the study, or, alternatively, provide a rationale for maintaining the data. Be sure to provide this information for all data collected. For example, if you are collecting survey data and taking notes on observed participant behavior, be sure to account for the survey data and the observation notes.

A Data and Safety Monitoring Plan may be required for some research. Also, if Protected Health Information is being accessed, a HIPAA Authorization Form must be included.

11. Compensation: Indicate whether or not subjects will be compensated for participating. Describe the form of compensation (e.g., cash, gift certificate, class credit, etc.) and when and how subjects will receive compensation. It may be appropriate to prorate compensation in the case that a subject does not complete all research activities; however, subjects may not be punished for not completing activities. Remember, they are free to discontinue participation at any time without penalty.
Note: Financial payment to subjects may be appropriate, but the amount and payment schedule should be determined carefully so as to avoid problems of coercion or undue influence.

12. Benefits: Describe the potential benefits to individual subjects. For example, if subjects receive the results of a cholesterol test for having their blood drawn, that is a direct benefit to subjects. Nevertheless, do not overstate benefits. Also, keep in mind that compensation for participating is not considered a benefit. Benefits to the general subject population also need to be described. While current subjects may not benefit directly from the study, future members of the same class of subjects may indeed benefit, as in the development of new teaching strategies that result from the study. Benefits to science and humanity include what you hope to contribute to the discipline of study and to society at large.

Note: Avoid using definitive language when describing benefits, either in the application or in the consent document.

13. Risks and Methods to Minimize Risks: Carefully consider the examples of risks to subjects. Categorize the level of each risk to subjects, describe the risk(s), and explain what will be done to minimize the risk(s). If there is no risk, describe how you came to that conclusion.

Risks are assessed according to the probability of occurrence, in addition to the possible severity of its occurrence. Focus groups or group interviews pose special problems for participants, in that confidentiality cannot be guaranteed in a group setting because there is no way to ensure that group members will not repeat what is said in the group to people outside the group. The risks described in this section should be those that are "reasonably foreseeable," rather than a list of all possible risks no matter how remote.

The risk/benefit ratio is crucial to the review and approval of research with human subjects. Some research cannot be approved unless benefits to participants or humanity outweigh the risks to subjects. Projects of more than minimal risk to subjects require special considerations and additional elements in informed consent (refer to Manual Section VI, "Risks to Subjects," and VII, "Informed Consent").

14. Investigator Agreement: This page must be filled out by hand. Read, sign and date the agreement form. If you are a student, your faculty advisor must also sign and date the agreement form. This form describes your responsibilities as a researcher and those of any faculty advisor on the project.

II. Attachments: The answers to certain questions in the application will determine if the researcher needs to complete any attachments. Carefully follow the instructions in the application.

Attachment A—Funding Information: Only complete this attachment if the research is or will be funded. Also, submit a copy of the grant proposal. This is needed to ensure that the funded research is consistent with the human subjects protocol.

Attachment B—Human Subjects Research Conducted Online: Only complete this attachment if any research activities will be conducted online. Online activities include the use of email, online surveys, website postings, chat rooms, data storage servers, etc., for research purposes. Be sure to review the Minimum Guidelines before completing the form. This attachment is needed to
address the unique issues of data security presented with the use of online data collection.

**Attachment C—Use of Existing Data in Research:** Only complete this attachment if research includes the use of previously collected data. Permission to use the data may need to be obtained prior to accessing the data. Permission letters need to be written on official letterhead and signed by an authorized agent of the organization involved. The letter needs to identify what data are being provided and indicate that the agent understands the purpose of the research for which the data will be used. If the existing data are publicly available, permission to use it is not required. The purpose of this attachment is to determine if the use of existing data places subjects at greater risk than those associated with other research activities.

**Attachment D—Use of Audio/Video Recording or Photography in Research:** Only complete this attachment if any research activities will be audio/video recorded or photographed. This attachment is necessary because such recordings could potentially present greater risks, particularly to loss of confidentiality.

**III. Additional Forms (if needed)**

**Research Involving Drugs, Biologics, Substances or Devices:** If the research involves the use of any drug, biologic, substance or device, this form will need to be completed. The Food and Drug Administration (FDA) oversees the use of drugs, biologics, substances and devices in research. The purpose of this form is to determine that the use of the item in the proposed research has been approved by the FDA.

**Research Involving Ionizing Radiation:** If the research involves the use of ionizing radiation, this form will need to be completed. The use of ionizing radiation potentially poses greater than minimal risks to subjects. All research involving the use of ionizing radiation must be approved by the Radiation Safety Committee before the protocol can be approved by the IRB. The purpose of this attachment is to describe the use of ionizing radiation and the precautions in place that will protect subjects against undue risks.

**IV. Additional Support Documents:** Some research projects will require additional documentation to support the protocol application. For example, if research is being conducted at another university, it may be necessary to provide documentation of IRB approval from the other university. Below are described other documentation that may be necessary to complete your research protocol application.

Please note that, at a minimum, all letters must be written on official letterhead, be signed by an appropriate authorizing agent, mention the research project and the principal investigator by name, and indicate for how long the authorization will last.

**Permission to Conduct Research at Non-UO Sites:** If your research will be conducted at a non-UO establishment that will not be engaged in research (e.g., you want to approach people in person to recruit them for your study, or you want to hold a focus group at a school, etc.), a letter of permission from the establishment must be on file with OPHS before research activities may begin there. In addition to the above-mentioned requirements of all letters, this letter must specifically state the activity(ies) for which permission is being granted.
Permission to Release Existing Data Set: If your research will involve the use of non-publicly-available data, a letter of permission from the individual or agency releasing the data must be submitted. The letter must establish permission for the researcher to use the data and may establish ways that the data will be used and protected.

Letters of Abiding and Complying: If your research will be conducted at a non-UO establishment that does not have its own IRB and all or some of its members will be engaged in research, a letter of abiding and complying must be on file with OPHS before research activities may begin there. In addition to the above-mentioned requirements of all letters, this letter must specifically state that the establishment agrees to abide and comply with the requirements of the UO IRB.

Independent Investigator Agreement: If persons outside of the research team will be engaged in research, it may be necessary for an Independent Investigator Agreement to be obtained before that individual may conduct any part of the research. Independent Investigators do not need to be listed as members of the research team in the protocol, nor do they need to provide proof of human subjects research training. However, it is the responsibility of the Principal Investigator to ensure that any Independent Investigators are properly trained to perform the research tasks to which they are assigned. For example, if they are obtaining informed consent, they must understand that potential participants may not be pressured to participate, and they must have enough knowledge about the study to be able to answer questions about it.

Data and Safety Monitoring Plan (DSMP): Many federal funding agencies require that a Data and Safety Monitoring Plan be created. DSMPs are meant to ensure that all clinical research has a level of monitoring appropriate to the scope and risk and that the monitoring is an integral part of the research plan. The purpose of the DSMP is to describe how subject safety and data integrity will be monitored.

Data Use Agreement: If your research involves accessing data from an individual or agency subject to the Health Insurance Portability and Accountability Act (HIPAA), a Data Use Agreement must be obtained before data may be accessed by the researcher.

Other Establishment IRB Approval: If your research will be conducted at a non-UO establishment (university, hospital, etc.) that has its own IRB, documentation of that establishment’s IRB approval of the research must be on file with OPHS before research activities may begin there.