UNIVERSITY OF OREGON
RESEARCH COMPLIANCE SERVICES

Research Plan Guidance

Scope: The purpose of the Research Plan is to describe the proposed research in sufficient detail so that Research Compliance Services (RCS) and the Institutional Review Board (IRB) can determine if approval criteria for human subjects research is met as defined in federal regulations (e.g., 45 CFR Part 46 and 21 CFR Parts 50, 56, 312 and 812).

The Research Plan is a narrative of the study and a living document to be maintained over the life of the project. A Research Plan is required for every non-exempt project submitted for IRB review and are highly encouraged for exempt projects. The research plan and other study materials are submitted electronically through the Research Administration Portal (RAP).

The following guidelines are designed to help researchers develop a comprehensive Research Plan for review by the IRB. This guidance document covers the following:

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Study Title:

- This study title should match the title of the study that you include in the Research Administration Portal (Basic Study Information section).

Protocol Number (e.g., STUDY00000000):

- This number is created when you create a new study in the Research Administration Portal (RAP). For all new studies created in the RAP, this number will start with "STUDY" and then be followed by eight numbers. Every modification, continuing review and RNI has its own follow-on number, but they will all be linked back to the same parent study number that starts with "STUDY". The number at the top of your research plan should be the parent study number from the RAP. Projects that pre-dated the RAP and were migrated into the RAP will have a different number format.

Principal Investigator:

- This Principal Investigator (PI) should match the local principal investigator that you name in the RAP (Basic Study Information section).
- Also see our webpage on PI, faculty advisor, and research personnel eligibility requirements.

I. Instructions and General Considerations

- This guidance is comprehensive as it needs to account for different types of research from varying disciplines. Some aspects of this guidance may not be relevant to a particular research area and there could be details relative to a particular research area that are not reflected in this guidance.
- For non-exempt studies, the Research Plan must be submitted with the initial application. We also recommend but do not require this research plan be completed for exempt studies. The Research Plan will also need to be updated via a modification (if applicable) to reflect any proposed changes and IRB approval must be obtained prior to implementing the changes.
- We understand that studies conducted by a specific researcher or lab may be similar. We strongly recommend against copy/pasting research plans for use as a base document. Copy/paste artifacts in study materials cause confusion and inconsistencies that can delay the review process.
- Whenever possible, upload the Research Plan (and other documents) in the RAP as a Microsoft Word documents. Avoid using highlighting and hyperlinks. If hyperlinks are included in the text, upload screenshots of the relevant webpage.
- Do not embed additional documents in the research plan. Supporting materials like recruitment and consent forms should be uploaded as standalone materials unless otherwise requested.
- There is no minimum or maximum length requirement for your research plan.
- See the commonly used human subject research definitions for details about terminology.
- All research team members should have access to the Research Plan (once approved) and the PI is responsible for ensuring all team members understand the details of an approved Research Plan and any subsequent changes. This minimizes non-compliance and facilitates research integrity.
- The Research Plan must provide sufficient detail for IRB reviewers to be able to understand the research and evaluate the research for the ethical protection of human subjects.
- The focus of the Research Plan should be the activities taking place between the investigator(s) and the participants/subjects *for research purposes*. When applicable, please ensure the research plan clearly notes which activities/procedures would otherwise occur regardless of the research, which activities/procedures are taking place solely for research purposes and how the research impacts standard activities/procedures.
    - Example 1: if a patient is receiving a CT scan for their standard medical care and researchers want to use that scan data for their research and then ask that patient to do a follow-up scan for research purposes, the original scan should be identified in the research plan as a procedure that is taking place regardless of the research and the follow-up scan should be noted as a research only scan. If the researchers wanted the patient to do something differently in their standard scan such as use contrast for research purposes when not medically necessary, the research plan should clearly indicate that the scan would take place regardless of the research, but the contrast is being added because of the research.
    - Example 2: If students are completing a classroom assignment for a grade and researchers want to use those assignments for research purposes, the classroom assignment should be identified in the research plan as a procedure taking place regardless of the research and getting permission to use those assignments for research is the research procedure.

- The Research Plan must be written in such a way as to be understood by readers who may be unfamiliar with your field of research. Explain discipline specific terms, procedures, and concepts.
- The information in this research plan should be internally consistent (i.e., information in each section of your research plan should match what you have in other sections) and should also be consistent with what you have in your other documents (e.g., recruitment materials, consent forms, data collection tools). Once drafts are in their final stages of revision, we recommend a quick read through of all materials with a focus on consistency. Materials with inconsistencies may delay reviews.

  NOTE: See the Research Compliance Services (RCS) website and the Guidance Library for additional topical guidance, details about how to submit through the Research Administration Portal (RAP) and other resources. Be sure to incorporate relevant information from relevant guidance into the Research Plan. RCS staff are available to discuss your project and to assist you in addressing relevant information in your research plan. Contact RCS by emailing researchcompliance@uoregon.edu, by calling 541-346-2510 or by attending remote office hours.

II. Research Plan Content

- When drafting the Research Plan, follow the format and use the section headings (i.e., A – J provided below, refer to the bulleted items for section content.
- For each section, this guidance includes a description of why the information is important for the protection of human participants/subjects in research *in italics*.

A. Introduction and Background

In reviewing the protocol, RCS and the IRB must consider the rationale for the study and the importance of the knowledge that may reasonably be expected to result.

- **Briefly** summarize the nature, scientific or scholarly rationale and significance of the proposed study and any relevant background information on the topic. Explain the relevance of the study to previous and/or continuing work in the field. Discuss why novel inquiry is necessary. If there is a gap in knowledge, explain how it is anticipated that this research will address the gap. If this research is intended to replicate previous research, provide rationale.

B. Specific Aims/Study Objectives

The IRB must evaluate the objectives of the research in order to determine whether the risks to participants/subjects are reasonable in relation to anticipated benefits, if any, to participants/subjects and the importance of the knowledge that may reasonably be expected to result.

- **Clearly** outline the specific research question(s). Include the study objective(s) and/or hypothesis.
- If sub-studies are included, specify how they relate to the overall aims/objectives. Make sure to distinguish sub-study information, including activities/procedures and populations all throughout the research plan.

C. Methods, Materials, and Analysis

The study design, methods, activities, and procedures must be adequately described in order for RCS and the IRB to understand what human participants/subjects will experience. RCS and the IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine purposes (e.g., standard care, standard procedures, standard activities happening regardless of the research).

NOTE: The focus of this section is on research methods and procedures. Risks must be discussed later in Section G.

- Describe the study design and research methods used to meet the study aims and objectives stated above (e.g., online survey, open ended one-on-one interview, randomized controlled trial, participant/subject observation, field-based research, lab/task based, use of extant data such as student-level school records etc.).
- If there will be multiple groups of participants/subjects completing different sets of activities/tasks, clearly delineate the activities to occur for each group.
    - If the study includes a study group/arm that is experimental or includes unproven procedures/conditions/element(s) of the research, state this.

      Note: Researchers should generally avoid using the term "treatment" in participant/subject facing materials such as the consent form when referring to the *experimental or unproven* procedures, interventions and/or elements. This helps ensure participant/subject understanding and helps minimize the potential for therapeutic misconception.
- Describe, in chronological order, all research activities/procedures involving participants/subjects or the collection of extant data about a participant/subject. Walk the reader step-by-step through the research activities and include a description of the research procedures and instruments.
    - Include the title and descriptions of any measures, questionnaires, tasks, tests, and/or procedures. Include a specific description of each. Titles need to be used consistently throughout the description(s). When collecting extant data or observations, explain the information that will be collected and/or recorded for research purposes.

- The description must specify whether activities, procedures and/or measures are standardized in the field or designed for this specific study. Identify activities/procedures that are experimental or may be new or different because of the research compared to what would take place if the research was not being conducted. If some procedures would take place exactly the same, regardless of the research, ensure that is clear.
- Depending on the complexity or number of activities/procedures, consider inserting a table or attaching an inventory list of measures as an appendix. The data collection tools, measures and all participant-facing materials should be uploaded separately into the RAP (Local Site Documents, Other attachments).
- Provide a justification for the use of the procedures/methods. This is particularly important for procedures and methods that pose more than minimal risk to participants.
    - Indicate whether you will conduct any testing/procedures that may generate clinically relevant results (e.g., results that are relatively accurate/known to be valid and may be important for the participant's health or wellbeing). If so, also describe how this is determined (and by whom) and describe how and when you will return results to participants/subjects. If you will not return results, provide rationale.
- If research will be conducted at the Lewis Center for Neuroimaging (LCNI), the investigator will need to work with the LCNI director to ensure research procedures are in line with their standard operating procedures. The Research Plan will need to reference the established LCNI SOP in the Research Plan.
- If the research involves blood or other biospecimen collection, include the following:
    - For blood draws, the volume of each draw, the method of collection (e.g., finger stick, venipuncture) and the frequency of blood draws.
    - For studies with biospecimens (blood, tissue, saliva, hair samples etc.), describe the following:
        i. The biospecimens that will be collected, how they will be obtained, how they will be used, how they will be managed, how they will be tested/analyzed, how they will be stored (if applicable) and how/when they will be destroyed (if applicable).
        ii. Whether any of the biospecimens may be used for commercial profit. If so, also indicate whether the participant/subject will or will not share in this commercial profit. If there is no chance that biospecimens will be used for commercial profit, please state that in the research plan.

      Note: if you are collecting/handling biospecimens, please also contact the Environmental Health and Safety (EHS) office regarding review requirements.

- If the study may involve genetic testing or obtaining genetic information (see Genetic Privacy Definitions), also indicate if you will conduct whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- For studies involving drugs, dietary supplements, and/or biologics, describe the following:
  - The purpose of having participants/subjects take drugs, supplements, or biologics as part of the study.
  - If you are obtaining any information about the impact of a drug, supplement or biologic on the participants/subjects, explain the information you plan to obtain, why it is necessary, and how the information will be used.
  - The route of administration for the drug (e.g., oral, topical, intravenous).
    i. The dosage to be taken, the frequency of the dosing, the rationale for the selected dose/frequency.
    ii. If the drug is already approved, please also indicate whether the dose and/or frequency proposed in the research differs from the approved label.
  - The FDA status for any drugs/biologics given to participants/subjects as part of the research (e.g., FDA approved, not FDA approved).

  Note: You will need to submit a copy of the package inserts and/or investigator brochures for each drug as an attachment in the RAP system. Appendix A will also need to be provided for each drug, dietary supplement and/or biologic specified by the research.
- For studies involving devices (e.g., MRI scanners, heart rate monitors, core temperature pills, ultrasounds, activity trackers such as Fitbits or other wearables, thermometers, in vitro diagnostics, investigational devices), address the following:
  - Provide a description of the devices being used. In the description, indicate whether you are using device(s) in a novel way or with a population different from the approved indications for the device. If so, please also provide rationale. For example, if you are using a device in humans that was only intended to be used in animals, that is information the IRB will need to know. You must include information about whether there is an alternative device that is intended to be used in humans and why that device cannot be used in your research, your rationale for using this particular device only intended for animals and supporting evidence for safety. If you are using device(s) in accordance with their marketed use, explain.
  - Describe the purpose of using the device (e.g., safety monitoring, data collection tool, collecting information about the device, determining eligibility, treatment, diagnosis, prevention of disease/condition).
  - Explain whether you are collecting data about a device (e.g., how well it works, how it compares to similar devices, how the device impacts the function or structure of the body, how safe it is, the side effects of using it etc.). If so, describe the information that you plan to obtain and how it will be used. Please also describe the FDA status for the device (e.g., FDA approved, FDA cleared, Not FDA approved or cleared).

- If you are using a medical device for safety monitoring, describe the FDA status for the device.
- If you are using a medical device for safety monitoring that is not FDA approved/cleared or if you are collecting information about a device, provide rationale for selecting that device within the research plan.
- If you are using a medical device for safety monitoring that *is* FDA approved/cleared or if you are collecting information about an FDA approved/cleared device, provide a copy of the FDA approval as an attachment (e.g., 510k clearance, premarket approval order/label).

Note: If you are using a device for safety monitoring that is not FDA approved/cleared and/or if you are studying a device, you will need to submit a copy of the device manual or instructions for use as attachments in the RAP system. You may also be asked to provide these materials for other devices if RCS and/or the IRB determine that more information is needed about a device to ensure approval criteria are met. The IRB needs enough information about the devices used in the study to be able to understand the risks and discomforts associated with their use in the research. These materials need to include a description of the device and the warnings, precautions, and risks for using the device. Appendix B will also be required for all investigational devices that are being studied for safety and/or effectiveness.

- Explain if you are accessing, obtaining and/or using HIPAA protected data (Health Insurance Portability and Accountability Act).
- Explain if you are accessing, obtaining and/or using FERPA protected data (Family Educational Rights and Privacy Act).
- Explain if you are accessing, obtaining and/or PPRA protected data (Protection of Pupil Rights Amendment).
- If you are using randomization in your study, describe the different groups, the method of randomization and the probability of assignment to each group.
- If using deception, discuss the related activities, what that deception entails, and when/how the debriefing process will occur. Also include rationale for why it is necessary to use deception, mislead participants/subjects or withhold information about the true nature, purpose, or procedures of the research.
- If you will be providing participants/subjects with food and/or drinks, provide rationale, including whether this is part of the research activities.

- Include an estimate of the time each participant/subject will spend completing the activities (in minutes or hours), the number of sessions the participant/subject will engage in, and the total length of participation (in days, weeks, months, or years) from the beginning to the end of the study. If there is some flexibility in the number of visits, include information about the minimal number of visits needed to complete the study or certain phases of the study and why there is variability. Ensure consistency across study materials (e.g., recruitment, consent, etc.).
- If follow-up with participants/subjects is planned, discuss the procedures and under what circumstances follow-up will occur.

- Describe the methods of data collection and recording that will be utilized in the study (e.g., hand-written notes, survey platforms used such as Qualtrics, computer programs, videotapes, audiotapes, photographs, etc.).
- Describe the specific locations where the activities will be conducted (e.g., in what labs, clinics, field sites, or online platforms will the procedures occur?). The investigator must determine if additional local, State and/or international policies and regulations are applicable to the research and include this information in the Research Plan. For example, if you are conducting research in another country, there may be additional international regulations and requirements for your study (e.g., see OHRP International Compilation of Human Research Standards).

  Note: if your research involves an international component (e.g., international travel, international transfer of information, software and/or equipment, collaborations with international researchers and/or organizations), contact Export Controls regarding requirements.
- Explain how the data will be analyzed/studied (e.g., quantitatively or qualitatively, what statistical tests are planned), how the interpretation will address the research questions, and how the research will be disseminated.
- Describe how the data will be reported (e.g., aggregated, anonymously, pseudonyms for participants/subjects, etc.).

D. Research Population, Recruitment Methods, and Payments/Compensation

In order to approve research, the IRB must determine that the selection of participants/subjects is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations (e.g., pregnant women, fetuses, children, prisoners, cognitively impaired persons, etc.). To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants/subjects, including letters, flyers, emails, etc.

1. Participant/Subject Population

- Describe the participant/subject population:
  - Provide the rationale for including the participant/subject population. When including any vulnerable populations in the study (e.g., children, prisoners, pregnant women, fetuses, individuals with decisional impairment who lack capacity to consent etc.) explain why inclusion of this population is necessary to accomplish the research aims.
  - List the inclusion criteria such as age range, race or ethnicity, gender, language, and literacy, etc.
  - List the inclusion and exclusion criteria and provide rationale. For each inclusion/exclusion criteria, state the relevance to the study and whether any are related to participant/subject risks or welfare. For example, if some inclusion/exclusion criteria are necessary to minimize risks while others are for data quality reasons that do not impact participant/subject safety/welfare, please specify.

- Address whether or not participants/subjects are fluent in English and/or if any of the study activities (i.e. recruitment, consent, assessments, etc.) will be carried out in a language other than English.
  - Describe how the research team member(s) are fluent in the language of the participants/subjects or if a translator will be used.
  - Describe how materials will be presented in the language understandable to participants/subjects (e.g., will translated materials be used?). If there is no written language, state this and explain translation.
  - If you will exclude non-English speakers, provide rationale.

- Discuss the number of participants/subjects needed for the project including the following:
  - Provide the maximum number of individuals to be included in the research. If more than one group, provide numbers needed for each group and total number for the entire project. Ranges are acceptable (e.g., 20-25 individuals, survey distributed to 200 people and expected 65% response rate).
  - When identifying the number, also consider that individuals may withdraw from the study after signing consent but before completing all study activities. All participants/subjects who sign an informed consent are considered enrolled in the research study and count towards your enrollment total, even if they withdraw, do not qualify after screening, or otherwise do not complete study activities. As those individuals count towards your total enrollment, consider that when identifying your max enrollment number.
  - Provide rationale for targeted numbers.
  - When research includes obtaining, using, studying, or analyzing records or extant data, each unique record containing identifiable private information about a living individual is considered a human subject. Data about living individuals used by researchers to generate identifiable private information also constitutes a human subject.

2. Recruitment Methods

- Describe the process and/or method by which participants/subjects will be recruited for the research, including the following (also see our Recruitment guidance for more information):
  - When and how will each step of recruitment occur (e.g., initial contact, introductions, follow-ups, etc.)?
  - Describe how the participant/subject population is accessed. Discuss relevant permissions (e.g., access to listservs, online databases, etc.).
  - Describe any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If there are no written recruitment materials, explain.
  - Explain which research roles will recruit participants/subjects (e.g., PI, Research Assistant, etc.) and how they will be trained.

- If recruiting using social media and potential participants/subjects can communicate publicly with the research content, describe how you will respond to questions or comments (e.g., let them know that you will discuss specifics using private messages, email, phone or another non-public forum, create a resource of frequently asked questions and responses you can provide). We recommend that researchers turn off comments on social media when possible. However, if it is not possible to turn off comments or you would like to keep comments on, please explain. Avoid soliciting potentially sensitive information on a public facing platform (e.g., health conditions, drug use). If comments will be turned off, note this.

- Describe any screening tests and/or procedures that will be used to ensure that potential participants/subjects are eligible to participate. These screening procedures generally take place prior to consent when they are limited to asking potential participants/subjects questions online, over the phone or by accessing records. However, some screening will need to take place after consent (e.g., if research procedures like blood draws, urine tests, or prior medication wash out is needed). In the information you provide, explain when the screening is taking place in relation to consent.
- Indicate whether you will *only* be using the screening information for screening, recruiting, and/or determining eligibility or for data analysis for your research aims in this study. Also state whether you will be using this information for future research.
- If contact information or screening information will be stored and used for future research or other purposes beyond screening, also describe the following:
  - The information that will be maintained
  - The additional intended purposes of the information
  - How the information will be securely stored
  - How participants/subjects will be informed of this additional use of their information
- If screening procedures include minors, explain how the procedure will involve the parent/guardian. In most cases, the parent/guardian must also provide permission for the minor to participate in screening activities. However, if it may be harmful for the parent/guardian to be consulted about the research screening or there is another reason seeking permission may not be appropriate, explain.
- If any part of the recruitment procedures involves a language other than English, describe any differences in the recruitment procedures for non-English speaking participants/subjects.

- When researchers have an existing relationships with potential participants/subjects (e.g., supervisors recruiting their direct reports, professors/instructors recruiting their own students, physicians recruiting their own patients), describe those relationships and the steps you will take to minimize any pressure the potential participants/subjects may feel to participate in the research (i.e., undue influence or coercion).
    - For example, if the PI is an instructor and it is possible to have a research assistant or another person who is not in a position of authority over students to conduct recruitment, collect consent forms and hold on to those consent forms until after grades are due, that is one way undue influence may be minimized.

3. Compensation/Payments

- See our payments/compensation guidance for more information.
- If no compensation/payments will be offered, state this.
- If there is the possibility that the research will result in costs to the participants/subjects or to a third party (e.g., an insurer), identify the specific expenses (e.g., drug tests, procedures, hospitalization, travel, etc.) and provide a justification for those costs.
- If recruiting from a university human subjects pool (e.g., the psychology/linguistics pool, etc.), please note additional requirements/restrictions regarding compensation as stipulated by the pool. Also see our website on Participant pools for more details.
- If participants/subjects will receive compensation for their time/expenses or payments intended as incentives, describe the following:
    - The amount and nature of the payments (e.g., cash, gift card, course credit, Clincard etc.). If you may use more than one type of payment method, explain.
    - Explain how and when compensation/payments will be provided, including payment schedules, whether payments will be reduced/prorated if the participant/subject does not complete all activities in the study, and how any proration will occur.
    - If compensation/payments will be provided via email, specify when/how the participant email is collected. State if you are collecting identifiable information that will be linked with research responses.
    - Explain how the method and amount of compensation/payment is appropriate for the participant/subject population and study activities (e.g., based on time commitment, number of study visits, travel expenses, age of participant/subject population, etc.) and will not pose an indue influence to participate.

E. Informed Consent

Informed consent is a process, not just a form, and obtaining informed consent is a central protection for human participants/subjects. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation.

Below are the required elements of the informed consent process. In some cases it may be appropriate to seek a waiver or alteration of informed consent or a waiver of documentation of informed consent from the IRB. Also see our informed consent guidance.

1. Informed Consent Process

- Describe the informed consent process, including:
    - How the required elements of informed consent will be conveyed to participants/subjects (e.g., informed consent document, verbal script, online statement, letter, etc.).
    - Where and when the informed consent process will take place (e.g., in-person in private room, phone, etc.).
    - Any cultural considerations (e.g., tribal or group permission requirements, age of majority, technological limitations, etc.).
    - Steps that will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence.
    - Which research roles (e.g., PI, Research Assistant, etc.) will conduct the consent process and how that person will be trained (e.g., previous experience or related training, one-on-one training with PI, etc.). Specific individuals do not need to be identified by name.
    - If multiple participant/subject groups or consent procedures will be included, the consent process for each group should be clearly delineated.
    - Steps you will take to minimize potential for coercion or undue influence.
    - No informed consent may include any exculpatory language through which the participant/subject is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Please explain any steps you will take to ensure the consent process and documents will not include exculpatory language.

- In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent. See the RCS Waiver or Alteration of Informed Consent Guidance for the criteria that must be met and information that must be included in this section to request consideration of a waiver or alteration of informed consent.
    - If you are requesting a waiver or alteration of consent or assent, provide rationale for each criterion.
    - If you are requesting a waiver or alteration for some participants/subjects but not all, clearly describe which populations will need the waiver/alteration and why.

2. Facilitate Understanding

- Describe how the investigator will ensure that the participants/subjects understand all aspects of their involvement in the research (e.g., will participants/subjects be asked questions about the procedures, and/or encouraged to ask questions?).
- Describe any special provisions for individuals who might have trouble comprehending the consent information.
- If any participants/subjects do not speak English, describe:
    - Whether the researcher is fluent in the language.
    - Whether and how a translator/interpreter will be used.
    - Whether translated consent materials will be used.
    - Whether there are any differences in the consent process for different populations based on the language they speak.
- Describe the process by which the investigator will ensure ongoing consent (e.g., how will you re-consent or notify participants/subjects of new information that may impact their safety or their willingness to continue participation).

3. Documentation

- Describe how the researcher plans to document that each participant/subject has provided informed consent and/or assent. Unless a waiver is granted or a study qualifies for exempt review, *signed* informed consent is required. Signed consent can be obtained using wet ink signatures (e.g., obtained in person, asking participants/subjects to mail back signed consent forms, asking participants/subjects to scan and email or fax signed consent forms) or electronically (e.g., using finger, stylus or mouse to sign electronically using a signature block on programs such as Qualtrics or REDCap, eSignatures using programs like DocuSign). Typed names are generally not considered to be an authenticated signature and often require a waiver of documentation of informed consent.

- Additional considerations for electronic informed consent:
  - For all studies, signatures must be legally valid within the jurisdiction where the research will be conducted and there needs to be a mechanism where the signatures can be shown to be legitimate (e.g., use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature"). Asking participants/subjects to type their names into a field without having any other method to authenticate a specific individual as the source of that signature are generally not permitted for non-exempt studies without a waiver of documentation of consent.
  - If hyperlinks are used to provide additional information/resources, the IRB should be provided with the linked content for review and approval.
  - Additional considerations for FDA regulated studies involving electronic consent:
    - The identity of an individuals must be verified (see 21 CFR 11.100(b)). FDA regulations do not specify any particular method for verifying the identity of an individual and will accept many different methods. For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity can also be considered.
    - The date of the electronic signature must be captured. This is required for FDA regulated studies but should be obtained for all non-exempt studies where signatures will be obtained.
- If signed informed consent will be obtained, describe how a written copy of the consent will be provided to the person signing the consent form to keep for their records.
- In certain circumstances, the IRB may waive the requirement to obtain a signed consent form based on specific criteria. See the RCS Waiver or Alteration of Informed Consent Guidance for the criteria that must be met and information that must be included in this section to request consideration of a waiver of documentation of informed consent from the IRB.
  - If you are requesting a waiver of documentation, provide rationale for each criterion.
  - If you are requesting a waiver of documentation for some participants/subjects but not all, clearly describe which populations will need the waiver and why.

4. Additional Considerations

If the research involves one or more of the following additional considerations, address as follows:

- Minors (those under the age of majority):
  - Describe the capacity of the participant/subject and their ability to assent. If you believe the participant is too young or is otherwise incapable of providing meaningful assent due to maturity or psychological state, please explain and provide rationale.
  - Describe how assent to participate will be obtained and whether it will be documented.

- If children will not sign an assent form, describe how you will obtain assent verbally or through another means and keep track of who assented and who did not.
- If a waiver of assent is being requested, provide justification.

- Explain how the permission of the parent(s), guardian(s), or legally authorized representatives will be obtained and documented.
- If a waiver of permission or waiver of permission documentation is being requested, provide justification. Please be specific about how each criterion is met. Passive/opt out permission requires a waiver (also see our website on passive consent).

- Individuals who lack capacity to consent (e.g., due to dementia, head injury, unconsciousness, or other reasons)
  - Describe any methods you will use to identify who may lack capacity to consent due to cognitive or decisional impairment. This may include assessment of capacity at various points in the recruitment and consent process, depending on the circumstances and the participant/subject population. Consider whether participants/subjects are likely to have complete, progressive, fluctuating, or temporary decisional impairment, and how this will affect your ongoing assessment of their capacity to consent.
  - Include information about how consent will be obtained from a legally authorized representative (LAR) who is acting on the participant's behalf.
  - Unless the participant/subject has severe decisional impairment (e.g., unconscious, unresponsive) investigators will also need to obtain assent from the participant/subject. Describe how assent will be obtained and documented (e.g., if participant/subject is able to sign an assent form, noted in the study record after verbal assent).
  - Describe how you will monitor the participant/subject for signs of dissent or distress (e.g., saying "no," "stop," turning or pushing away, putting their hands up, shaking their head, producing audible sounds of distress) and stop. If you will re-attempt to obtain assent at a later date, describe how many times you will attempt and how it will be done.
  - Confirm you will obtain consent from the participant/subject if they regain capacity to consent and will withdraw them from the study if consent cannot be obtained at that point.
- Deception:
  - Deception will generally require an alteration of informed consent. Provide justification for how the use of deception meets the criteria for alteration of informed consent. See the RCS Waiver or Alteration of Informed Consent Guidance for the criteria that must be met and information that must be included in this section to request consideration of a waiver or alteration of informed consent by the IRB.
  - Describe the debriefing process and provide a script or a debriefing document. If you do not believe it is appropriate to debrief participants/subjects, after data collection is complete, provide rationale.

- Protected Health Information (HIPAA):

  The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that protects the privacy and security of health information that is maintained by covered entities such as health care providers, insurance companies and hospitals. Some institutions, such as the University of Oregon are called hybrid covered entities which means that only some departments and units of the university are required to comply with HIPAA. For questions about UO's hybrid entity status and covered components, contact Safety and Risk Services. For more information about HIPAA, you can also see our HIPAA website.

  - If your research involves the use of protected health information from a covered entity or UO covered component, describe how authorization from participants/subjects will be obtained before accessing and/or using their information (i.e., signed HIPAA Authorization).
    - If requesting a waiver of authorization, see the HIPAA waiver guidance for the criteria that must be met. Justification for how the criteria are satisfied must be included in this section.

  Note: If HIPAA will apply to your study, please also complete Appendix D and attach it to your submission in the RAP.

- Education Records (FERPA):

  The Family Educational Rights and Privacy Action (FERPA) is a federal law that was enacted to protect the privacy of parents and students and provides guidelines for maintaining the confidentiality of education records for students. It gives parents/caregivers and adult students control over the students' education records and prevents schools from sharing information without written consent unless certain exceptions are met. FERPA applies to educational agencies/institutions such as elementary schools, middle schools, high schools, and universities that receive federal funds.

  - If your research involves access to and/or release/transfer of FERPA protected education records, *signed and dated written consent* must be obtained before an educational agency or institution discloses personally identifiable information from the student's education records. Opt-out or "passive consent" will not fulfill this requirement. It also requires additional details to be included in the consent materials (e.g., specify the records that may be disclosed, purpose of disclosure, parties or class of parties who will have access to the records). FERPA permits some exceptions to the consent requirements (see 34 CFR 99.31).

- If you would like to *waive* parent/guardian permission or consent for a study involving FERPA protected education records, describe how you will obtain a FERPA exception. An exception will also be required if you would like to waive the FERPA signature/date requirement.

  Note: For UO education records, you will need to reach out to the UO Registrar (registrar@uoregon.edu). For educational institutions/agencies external to the UO, you will need to work with them directly. For more information, see our website on permissions and Approvals, including the Permission Chart.

- If you *will obtain* parent/guardian permission or consent for a study involving FERPA protected education records, describe how you will meet FERPA requirements for obtaining signed and dated written consent.

F. Participant/subject Privacy, Confidentiality, and Data Disposition

In order to approve research, the IRB must determine that there are adequate provisions in place to protect the privacy of participants/subjects and maintain the confidentiality of research records and data collected.

1. Privacy

- Describe the steps that will be taken to promote the protection of participants' privacy. Consider the following:
  - The setting of the research, including the settings in which an individual will be interacting with a research team member.
  - A participant/subject's expectation of privacy
  - The methods used to identify and contact potential participants, such as during recruitment.
  - The appropriateness of the personnel present for research activities.
  - The methods used to obtain information about participants.
  - The sensitivity of the requested information:
    - In relation to the potential privacy risks of the information.
    - In relation to options for participants/subjects to disclose identity.
  - Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
  - Steps to ensure access to the minimum amount of information necessary to complete the study.

- Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human participant" (e.g., a participant/subject provides information about a family member for a survey that is both identifiable and private).

- Describe what personal or identifiable information will be obtained to facilitate the research and as part of data collection. If participant/subject data will be collected without identifiers, please explain how this will be done.

2. Confidentiality

- Describe the steps that will be taken to secure data and/or specimens for the research.
- If participants' private information will be coded (i.e., identifying information has been replaced with a number, pseudonym, etc.), include:
  - How the key to decipher the code (i.e., list linking participants' names with pseudonyms or participant/subject number) will be stored
  - Who will have access to the code key
  - If, how, and why the code key will be retained (if applicable).
- If participant/subject identities may be disclosed as a result of this research (e.g., attributing a direct quote, etc.), provide:
  - Justification for appropriateness of direct identification.
  - Parameters for disclosure (e.g., will participants/subjects be allowed to review the information to be released prior to dissemination? Limitations on disclosure).
  - How permissions from participant/subject will be solicited including any restrictions.
- Describe storage and transfer including:
  - How the data will be collected and stored, including format (e.g., audio/video recordings or photographs, hard or electronic copy, identifiable or de-identified).
  - Security during transmission and sharing between researchers and participants.
  - Who will have access to data and how are they trained and vetted before they are given access to identifiable data/specimens.
  - How long research information will be kept while the research is being conducted (e.g., audio will be deleted after transcription, etc.) and how long the records will be kept after the study is completed. Note: a study cannot be closed if researchers plan to maintain *identifiable* information/specimens that could be used, studied, analyzed in the future.
  - If you will retain identifiable information for safety purposes, please explain the information that will be retained and the specific safety purpose for retaining it.
  - The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.). See Data Handling Quick Reference and Data Security Tools Guide for more information.

- Describe any intent for future use of data beyond this research including:
    - Whether other researchers will be permitted access/use the data/specimens.
        - If data/specimens will be shared, please also explain whether you will provide them with *identifiable* information/specimens.
        - If data/specimens will be de-identified before sharing, describe that process.
    - How data will be maintained and stored.
    - How participant/subject permissions for the future use will be obtained and tracked.
    - If conducting a longitudinal study or if there is a possibility of future research with the same population, explain the potential for re-contacting participants/subjects and the information that will be retained for this purpose. Ensure the consent form also describes this potential.

3. Data Disposition

- Describe what data will be collected, including identifiable information and audio/video/digital recordings or photos. In addition, consider the following:
    - Any other information collected to facilitate the research (e.g., contact information for recruitment).
    - Any existing data and its disposition (e.g., obtaining data from another source coded, or identifiable etc.).

G. Potential Research Risks or Discomforts to Participants

In order to approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated benefits to participants as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of all reasonably foreseeable risks or discomforts.

- Describe any reasonably foreseeable risks of harm or discomforts for individuals and/or groups that may result from participation in the research. While risks associated with participation may not be expected, most protocols carry some risk. Consider the following:
    - Information risks (e.g., loss of privacy and/or breach of confidentiality).
    - If there is a strong likelihood that researchers will need to break confidentiality to make a mandated or other report to authorities (e.g., child/elder abuse, plans to harm self or others), consider confidentiality risks and other risks that may result. This is particularly relevant to studies that explicitly ask questions about behaviors that require reporting.
    - Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).

- Social risks (e.g., social stigma, chance of being ostracized or shunned).
- Economic risks (e.g., change in employment or insurability).
- Physical risks, harms, and/or discomforts (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, death, side effects and contraindications of drugs or substances used in the research).
- Legal risks (e.g., risk of prosecution, mandatory reporting).
- Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.).

- For each identified risk, explain all of the following:
  - Likelihood of the risk occurring. When possible, provide frequency of each risk in terms of percentages or fractions along with the source of those details (e.g., in 100 participants, 1 participant experienced nausea or 1% of participants experience nausea).
  - Magnitude of the effects the risk would have should they occur.
  - How the risk will be minimized.
  - How the risk will be disclosed in the informed consent process.
- Provide support for the risk details (e.g., citations for frequency/severity of risk, attach package insert/investigator brochure for drugs, instructions for use for device). If you provide citations as a form of support, also include a summary in the research plan of the key findings from those citations that support your risk assessment.
- If the protocol involves standard treatment or intervention, describe the "standard of care" and describe how the risks of the research interventions or research activities compare.
- When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants. For some studies, a separate data and safety monitoring plan (DSMP) may be required by the study sponsor and/or regulatory entity. See our website on Safety Monitoring, Participant Privacy and Confidentiality of Data for more information.
  - If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach.
  - If there is an established Data and Safety Monitoring Board/Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP or in a separate DSMB/C charter attached with your submission.

H. Potential Benefits of the Research

In order to approve this research, the IRB must determine that the anticipated benefits to research participants/subjects and the knowledge researchers expect to gain are reasonable in relation to the potential risks.

- Describe any anticipated benefits that may result from the research. Consider the following:
  - Direct benefits that may result from participation (e.g., psychological or emotional benefits, learning benefits, physical benefits, diagnostic or therapeutic benefits, etc.). If there are no direct benefits to participants, clearly state this.
  - Benefits to the general participant/subject population.
  - General benefits of the research for society, science and humanity; potential generalizable knowledge.
- Potential benefits should be explained in terms of any direct impact on the prospective subject, in addition to the anticipated societal benefit of the research. The description of potential benefits to the subject from the use of the test article (and control, if appropriate) should include appropriate details, and should be clear, balanced, and based on reliable information to the extent such information is available.
- Avoid overly optimistic representations of benefits. If the benefit to participants/subjects is unclear or if there is no anticipated benefit to participants, please explain. For example, if you are testing an intervention to see how effective it is, do not promise benefits of the intervention since they are not known.

NOTE: Compensation/payments for participation is not a benefit and should not be included in this section.

I. Clinical Research and/or Clinical trials

There are at least three different types of clinical trials (HHS, NIH, and FDA). Studies that meet one or more of the clinical trial definitions have additional requirements. The requirements will vary depending on which clinical trial definition the study meets. Studies that are not federally funded and are not FDA regulated, are generally not required to comply with the additional clinical trial requirements. However, researchers can choose to voluntarily comply with the additional clinical trial requirements and some journals have policies that mandate additional requirements. See our Clinical trials website for more information about what may be considered a clinical trial and the applicable requirements for each.

- For federally funded and/or FDA regulated research, state if you believe the study meets any of the clinical trial definitions (see on Clinical trials website). RCS and/or the IRB may also request rationale in some cases for why your study does not meet the clinical trial definitions.

- For a study that meets the definition of an HHS clinical trial and is federally funded/supported, one IRB approved informed consent form used to enroll participants/subjects must be posted on a publicly available Federal Web site that has a repository for such informed consent forms (e.g., clinicaltrials.gov or the regulations.gov document portal). The consent form will need to be posted no later than 60 days after the last study visit by any subject. If applicable, describe in this section of the Research Plan where the consent form will be posted and acknowledge the required timeframe for posting. NOTE: the investigator will be responsible for demonstrating at the time of continuing review and/or closure of the study that this requirement has been satisfied.
- For a study that meets the definition of an NIH or FDA regulated clinical trial, describe how the trial will be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Provide the NCT number if known.

J. Investigator Qualifications, Roles, and Training

In order to approve this research, the IRB needs to determine that research personnel are adequately trained and knowledgeable regarding the study procedures and the protection of human research participants.

1. Investigator Qualification

- Provide a brief description for all key research personnel (i.e., Principal Investigator, Faculty Advisor, Co-Investigators or any other research personnel with responsibility for study oversight and research design). Include all of the following:
  - Academic background.
  - Research experience.
  - Experience with the proposed participant/subject population.
  - Experience with the proposed procedures and methodology.
  - For students, include any applicable coursework (e.g., research methodology courses).

2. Roles and Research Duties

- Describe the roles and the associated research activities/duties. For example, Research Assistants will consent participants/subjects and administer surveys.

Note: Do not list individual names unless requested by RCS/IRB**.** Limit roles to Principal Investigator, Co-Investigator, Faculty Advisor, Research Assistant, and Project Coordinator. When specific names are included, the research plan must be updated for consistency if/when the individual is removed from the study and can be easily overlooked.

- If you are collaborating with other institutions or external researchers, briefly describe the role of the external personnel in this study (if applicable). Additional materials may be needed for the reliance (see our collaborations page for more information).

3. Training and Oversight

- Describe how the study personnel will be adequately trained to conduct research activities in accordance with the approved protocol and in compliance with federal regulations and university policy.
- Describe any specific training or expertise required for procedures proposed in this research. Explain all of the following:
    - Training standards or requirements that must be met.
    - Who will be providing the training?
    - How will the training be tracked/documented?

4. Translator

- If a translator will be used for any aspects of the research, provide the translator's name and qualifications for translation (e.g., native speaker, student of the language, etc.). See our Translations and Translated Materials website for considerations about who is a qualified translator.

III. Appendices to the Research Plan

Complete applicable appendices and attach to the RAP (see Attachments guidance for RAP for where to upload). If the following appendices do not apply to the research, do not include.

- Appendix A - Drugs: for research involving the use of any drug, substances, or biologics.
- Appendix B - Medical Devices: for research where a medical device is being investigated as part of this research
- Appendix C - Ionizing Radiation: for research involving the use of ionizing radiation (X-ray, DEXA scan, etc.).
- Appendix D - HIPAA: for research involving the use of Protected Health Information.
- Appendix E - Genetic Materials: for research involving DNA samples/genetic information.