



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

The Research Plan is a narrative of the study and is a living document to be maintained over the life of the protocol. A Research Plan is required for every protocol submitted for IRB review.

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

## I. General Considerations

## II. Instructions

## III. Research Plan Content

- A. Introduction and Background
- B. Specific Aims/Study Objectives
- C. Methods, Materials, and Analysis
- D. Research Population, Recruitment Methods, and Compensation
- E. Informed Consent Process
- F. Participant Privacy, Data Disposition, and Data Confidentiality
- G. Potential Research Risks or Discomforts to Participants
- H. Potential Benefits of the Research
- I. Investigator Qualifications, Roles, and Training

## IV. Appendices to the Research Plan

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### **I. General Considerations**

- This guidance is comprehensive to include aspects of research from varying disciplines. Do not be overwhelmed by the length of this guidance document.
- Not all points will apply to all research.
- The IRB will consider what is appropriate to the proposed research.
- For each section, this guidance includes a description of why the information is important for IRB review (in italics).
- The approved Research Plan must be submitted with the initial application, each continuing review.
- The Research Plan will need to be updated via an Amendment Application to reflect any proposed changes and submitted with all other applicable protocol materials.
- There is no minimum or maximum length requirement.
- A list of commonly used [human subjects definitions](#) can be found on our website.

**NOTE: See the [Research Compliance Services \(RCS\)](#) website for additional topical guidance. Be sure to incorporate relevant information from relevant guidance into the Research Plan.**

### **II. Instructions**

- The Research Plan must provide sufficient detail for IRB reviewers to be able to understand and evaluate the research protocol.
- The focus of the Research Plan should be the activities taking place between the investigator(s) and the participants.
- The Research Plan must be written in such a way as to be understood by readers outside of the research field of expertise. Explain discipline specific terms, procedures and concepts.



- The version date must be updated each time this Research Plan is revised whether or not the revisions are being requested by RCS during the review process or being proposed by the investigator through the submission of an Amendment Application.

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### III. Research Plan Content

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- When drafting the [Research Plan](#), follow the format and use the section headings (i.e. A – I) 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 IRB review (*in italics*).
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#### A. Introduction and Background

*In reviewing the protocol, 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.
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#### B. Specific Aims/Study Objectives

*The IRB must evaluate the objectives of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.*

- **Clearly** outline the specific research question(s). Include the study objective(s) and/or hypothesis.
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#### C. Methods, Materials, and Analysis

*The study design, methods and procedures must be adequately described in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation.*

**NOTE: The focus of this section is on 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., on-line survey, open ended interview, randomized controlled trial, participant observation, field based research, lab/task based, etc.).
- If there will be multiple groups of participants completing different sets of activities/tasks, clearly delineate the activities to occur for each group.



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- Describe in chronological order all research activities/procedures involving participants. This should 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. Titles need to be used consistently throughout the description(s).
  - The description must include whether these are standardized in the field or designed for this specific study.
  - Depending on the complexity or number of procedures, consider inserting a table or attaching an inventory list of measures or questionnaires as an appendix.
  - If the research involves any procedures typically used in a biomedical/clinical setting and/or administration of medications (e.g., blood draw, ultrasound, MRI, x-rays/radiographs, etc.) include the following:
    - ◆ The justification for the use of the procedures.
    - ◆ The dosage.
    - ◆ The qualifications of study personnel to conduct the procedures.
    - ◆ 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 using deception, discuss the related activities, what that deception entails, and when and how the debriefing process will occur.
- Include an estimate of the time each participant will spend completing the activities (in minutes or hours), the number of sessions the participant 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 follow-up with participants 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., handwritten notes, survey platform, computer programs, videotapes, audiotapes, photographs, etc.).
- Describe the specific locations where the activities will be conducted (i.e., 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.
- Explain how the data will be analyzed/studied (i.e., quantitatively or qualitatively and 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, etc.).



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#### D. Research Population, Recruitment Methods, and Compensation

*In order to approve research, the IRB must determine that the selection of participants 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, including letters, flyers, emails, etc.*

##### 1. Participant Population

- Describe the participant population:
  - Provide the rationale for including the participant population. When including any vulnerable populations in the study (e.g., children, prisoners, pregnant women, fetuses, 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 exclusion criteria and rationale.
  - Address whether or not participants 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 or if a translator will be used.
    - ◆ Describe how materials will be presented in the language understandable to participants (e.g. will translated materials be used?). If there is no written language, state this and explain translation.
- Discuss the number of participants needed for the project including the following:
  - Provide the targeted 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).
  - Provide rationale for targeted numbers.

##### 2. Recruitment Methods

- Describe the process and/or method by which participants will be recruited for the research, including the following:
  - When and how will each step of recruitment occur (i.e., initial contact, introductions, follow-ups, etc.)?
  - Describe how the participant population is accessed. Discuss relevant permissions (e.g., access to listservs, online databases, etc.).



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- State 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 (e.g., PI, Research Assistant, etc.) will recruit participants and how they will be trained.
- Describe any screening tests and/or procedures that will be used to ensure that potential participants are eligible to participate.
- 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.
- For research involving treatment (e.g. behavioral intervention, drug or device studies, etc.):
  - Describe how research treatment will be distinguished from regular treatment.
  - Indicate whether the individuals who will recruit participants have provided or will provide treatment or care to the prospective participants. If treatment providers also have a role in the research, describe measures to avoid or diminish undue influence.

#### 3. Compensation/Reimbursement

- If there is the possibility that there will be costs to the participant 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 participants are to receive compensation for their time, please describe the following or simply state no compensation will be offered:
  - The amount and nature of the compensation (e.g., cash, gift card, course credit, etc.).
  - Explain how and when compensation will be provided, including payment schedules, whether or not compensation will be reduced if the participant does not complete all activities in the study, and how any proration will occur.
  - Explain how the method and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of study visits, travel expenses, age of participant population, etc.).

#### E. Informed Consent Process

*Informed consent is a process, not just a form and obtaining informed consent is a central protection for human participants. 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 key components 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.

##### 1. Informed Consent Process

- Describe the informed consent process, including:



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- How the required [elements of informed consent](#) will be conveyed to participants (i.e., informed consent document, verbal script, online statement, letter, etc.).
  - Where and when the informed consent process will take place (i.e., 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.).
  - If multiple participant groups or consent procedures are to be included, these need to be clearly delineated.
- 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 by the IRB.

#### 2. Facilitate Understanding

- Describe how the investigator will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or encouraged to ask questions?).
- Describe any special provisions for individuals who might have trouble comprehending the consent information.
- If any participants do not speak English, describe:
  - Whether or not the researcher is fluent in the language.
  - Whether or not and how a translator will be used.
  - Whether or not translated consent materials will be used.
  - Whether or not 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.

#### 3. Documentation

- Describe how the researcher plans to document that each participant has provided informed consent and/or assent.
- 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 from the IRB.



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#### 4. Additional Considerations

If the research involves:

- Minors (those under the age of majority) or individuals of diminished capacity:
  - Describe the capacity of the participant and their ability to assent.
  - Describe how assent to participate will be obtained and documented.
    - ◆ If a [waiver of assent or waiver of assent documentation](#) 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.
- Deception:
  - Explain how participants will be deceived and why it is necessary for the study.
  - Deception is 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.
- Protected Health Information:
  - If the research involves the use of [protected health information](#) from a covered entity (including those listed on the [UO Hybrid Entity Status and Documentation of HIPAA Covered Components declaration](#)), describe how authorization from participants to access and use their information will be obtained (i.e., signed HIPAA form).
    - ◆ 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.
- Clinical Trials:
  - For a study that meets the definition of a clinical trial, one IRB approved informed consent form used to enroll subjects must be posted on a publicly available Federal Web site that has a repository for such informed consent forms. More information about the posting requirement and definitions can be found on our website [here](#).
  - Describe in this section of the Research Plan where the consent form will be posted and acknowledge the required timeframe for posting (e.g., [clinicaltrials.gov](#) or the [regulations.gov document portal](#)). NOTE: the investigator will be responsible for demonstrating at the time of continuing review, progress reporting, and/or closure of the study that this requirement has been satisfied.



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#### F. Participant Privacy, Data Disposition, and Data Confidentiality

*In order to approve research, the IRB must determine that there are adequate provisions in place to protect the privacy of 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 methods used to identify and contact potential participants.
  - The settings in which an individual will be interacting with an investigator.
  - The appropriateness of all 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 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 provides information about a family member for a survey).
- Describe what personal or identifiable information will be obtained to facilitate the research and as part of data collection. If participant data will be collected without identifiers, please state this.

##### 2. 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 (i.e., contact information for recruitment).
  - Any existing data and its disposition (i.e. obtaining data from another source coded, or identifiable etc.).





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#### 3. Confidentiality

- Describe the steps that will be taken to secure data and/or specimens for the research.
- Describe 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 number) will be stored?
  - Who will have access to the code key?
  - If, how, and why the code key will be retained.
- If participant identities will 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 be allowed to review prior to dissemination).
  - How permissions from participant 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 (e.g., training of staff, authorization of access).
  - How long the records will be kept after the study is completed.
  - The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.).
- Describe any intent for future use of data beyond this research including:
  - If other researchers will be permitted access/use the data.
  - How data will be maintained and stored.
  - How participant permissions for the future use will be obtained and tracked.
- If seeking a Certificate of Confidentiality through NIH, this needs to be stated.



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#### 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 the 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).
  - 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 or harms (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, or 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.
  - 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.
- If the protocol involves treatment or intervention, describe the “standard of care” and describe how the risks of the research treatments or interventions compare.
- When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants.
  - 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.



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#### H. Potential Benefits of the Research

*In order to approve this research, the IRB must determine that the anticipated benefits to research participants 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 population.
  - General benefits of the research for society, science and humanity; potential generalizable knowledge.

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

#### I. 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 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 and administer surveys.
- Note: Do not list individual names. Limit roles to Principal Investigator, Co-Investigator, Faculty Advisor, Research Assistant, and Project Coordinator.



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#### 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/documentated?

#### 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.).

### IV. Appendices to the Research Plan

Complete applicable [appendices](#) and attach to the Research Plan. If the following appendices do not apply to the research, do not include. Applicable appendices become part of the Research Plan and are required with each subsequent submission.

- Appendix A - Drugs: for research involving the use of any drug, substances, or biologics.
- Appendix B - Medical Devices: for research involving the use of a medical device.
- 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 coded or identifiable DNA samples/genetic information.