Institutional Review Board

Writing an Effective Research Plan: Overview

Campbell Unviversity

Research Plan ≠ Research Protocol

- The IRB research plan is focused on human subjects research protections, identification of risks and benefits, and methods used to reduce risks.
- It includes elements found in a research protocol.
- It requires detailed information regarding research activities, a recipe for your research project.
- Research Protocol contents are usually defined by the sponsoring agency.

Research Plan Template & Guidance

- Research Plan template found on the IRB website.
- Use the Research Plan Template Guidance document found in the Guidance Library on the IRB website.

Introduction and Background

"In reviewing the protocol, the IRB must consider the rationale for the project 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 project to previous and/or continuing work in the field.
- Discuss why novel inquiry is necessary.

Introduction and Background

- 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.
- Provide citations appropriately.
- Leave your bias at the door.
- IRB red flags: “I believe the results will show…”, “ This project will show…”, or “I feel…”

Purpose/Specific Aims/Project Objectives

"The IRB must evaluate the objective 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.
- Use lay language.
- Do not use acronyms

Research Population, Recruitment Methods & 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., 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."

Research Population

- Describe the participant population in detail
- Avoid, if possible, particularly for student research:
  - Vulnerable populations due to additional protections that are required when working with these populations,
  - Medical records/biospecimens in which you have access to but are not owned by Campbell University.
    - Information covered under HIPAA & which are identifiable at the time of access and/or recorded with identifiers.
      - If you require any of the 18 HIPAA Personal Health Identifiers (PHI) the data may not leave the covered entity or requires a data use agreement (DUA).
  - Patient populations combined with intervention or interactions at non-Campbell sites – Requires IRB review at the non-Campbell site & use of a reliance agreement.

Research Population

- List all the inclusion & exclusion criteria.
- 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 need for each group & total for the project. Ranges are acceptable (I.e., 20-25 individuals, survey distributed to 200 people with expected 65% response rate).
  - Provide rationale for targets numbers (i.g. power analysis, etc.).
  - Over recruitment = non-compliance.

Recruitment Methods

- Describe any screening procedures.
  - Screening procedures must occur prior to obtaining informed consent.
  - Justify retaining screening information and if identifiable information will be retained.
- Describe the process and/or methods by which participants will be recruited for the research, including the following:
  - If record review/biospecimen, each record = a subject.
  - Who will be conducting recruitment, etc.

Recruitment Methods

- State any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If there are not written recruitment materials.
- Provide details on who will send emails, where flyers will be posted.
- Student email addresses at Campbell are not directory information and investigators may not directly email students for research purposes.
- Include recruitment scripts, flyers, website advertisements with submission.

Compensation/Reimbursement

- Compensation: avoid if possible.
- Reimbursement: mostly likely not an issue with student research, unless funded.

Methods, Materials & Analysis

"The project 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/standard care/practice/normal education or evaluation."

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

Methods

- This is your research recipe.
- Write in the perspective of the participant.
- Clearly delineate activities, if necessary, by study group.
- Describe each step in chronological order & include a description of the research procedure & instruments.
- Include titles and descriptions of measures, questionaires, etc.
  - Titles need to be used consistently throughout the document.
- Clarify which activities are research and which are normal/standard practice.

Methods

- If the research procedures are used, provide justification & personnel qualifications.
- Estimate the amount of time to complete for each research activity.
- Describe location of research activities.
  - Be specific and provide: building and room number if appropriate.

Analysis

- 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.)

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.”

Informed Consent Process

- All human subjects research studies require an informed consent process.
- The elements required to be included in the informed consent process depends upon the amount of risk associated with research.
- The consent process is a distinct process and not simply providing the potential research participant an informed consent form to read and sign.

"The informed consent form is used only to document (obtain signature of subject) that the initial informed consent process has been completed and agreed to by the subject."

Informed Consent Process

- Most “no greater than minimal risk” research protocols do not require the use of a standard IRB consent form template.

Informed Consent Process

- Some “no more than minimal risk” and “greater than minimal risk projects” require the use of an IRB informed consent template unless the IRB approves a Waiver/Alteration of the Informed Consent Process.
  - For further information on criteria required, see IRB SOPs located on the IRB website or the IRB Investigator Manual.
  - The IRB may also grant a waiver of documentation of informed consent, when specific criteria are met.

Informed Consent Process

- Common mistakes:
  - Use of consent document for “no greater than minimal risk” research, when not required.
  - Informed consent document is not consistent with information provided in the research plan.
  - Study title doesn’t match
  - Lack of information in the research plan regarding circumstances surrounding the consent process
  - Inclusion/Exclusion criteria do not match

Protected Health Information & HIPAA

- HIPAA regulations apply to Protected Health Information (PHI).
- PHI is individually identifiable health information that is created or maintained by a covered entity (health care providers, hospitals, physician offices, health care clearing houses, health care plans), or their business associate(s).
  - There are 18 PHI identifiers, more than just participant's name.
  - If the research information/biospecimens is provided to the investigator with the 18 PHI identifiers removed, it is no longer considered PHI and covered under HIPAA & would qualify for NHSR IRB submission.

Campbell Student's Educational Record

- FERPA regulations apply to student educational records.
- PII is personally identifiable information which is part of a student's educational record are overseen by the Registrar.
  - Only directory information may be used without authorization from the owner of the student records.
  - Use of student educational records requires approval of "legitimate educational purposes" from the owner of the student records. Generally this is the Registrar.
  - The Campbell Registrar requires signed consent by the student to access student records.
  - CUSOM & CPHS assessment offices are allowed to provide de-identified student educational records or act has an "honest broker".

Potential Research Risks

"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."

Potential Research Risks

- 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.
  - Risk of breach of confidentiality is present in almost all studies.
- A statement which says, “There are no anticipated risks with this study,” will be returned.

Potential Research Risks

- Consider the following:
  - Information risks (e.g., loss of privacy and/or breach of confidentiality). Even when data is coded or de-identified, combination of certain information may re-identify participants.
  - 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 injury, illness or disease, or death, side effects and contraindications of drugs or substances used in research).
  - Legal risks (e.g., risk of persecution, mandatory reporting).

Minimization of Risks

- For each identified risk, explain the following:
  - Mechanisms in place to reduce likelihood of the risk occurring.
  - What magnitude the effects the risk would have should they occur.
  - Mechanisms for how the risk will be minimized.
  - How the risk will be disclosed in the informed consent process.
- Remember:
  - What you consider private, a participant may not consider private.
  - Potential subjects or others close to them may have certain conditions, which you may be, researching and you may trigger a response that you have not considered.
  - Avoid suicide ideation research in college students as they are a vulnerable population when it comes to suicide.

Participant Privacy, Data Identification Level & Data Confidentiality

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

Participant Privacy

- Describe the steps that will be taken to promote the protection of participants' privacy. Consider the following:
  - Methods used to identify & contact potential participants.
  - Snowball recruiting requires participants to provide name & contact information to the investigator, may be seen as an invasion of privacy by potential participant.
- Research settings, such as conducting informed consent in a private location or research focus groups.
- Methods used to collect information from participants, such as use of internet survey platform, have all location settings been turned off or Zoom meetings having private invitations.

Participant Privacy

- The sensitivity of the requested information.
- Steps to ensure access and retention to the minimum amount of information necessary to complete the study.
- If data is collected by accessing or using identifiers, state so.

Identification Level and Protection

- Describe what data will be collected, including the level of identification, how and where it will be stored. Consider the following:
  - Most research data is identifiable. You may think your research information is unidentifiable and it is identifiable.
  - If collected in an identified manner: when, how and by who will it be de-identified.
  - If you are receiving de-identified information: who is providing the de-identified information. HIPAA & FERPA covered information has special rules.
  - Audio/video/digital records are considered identifiable.
  - Identifiable data must be stored in a Campbell Egnyte file with security measures in place such as password protected & encrypted file.

Confidentiality

- Describe steps that will be taken to secure research information. Consider the following:
  - Where & how research information will be stored & maintained.
  - The IRB can provide you a secured study file in Egynte.
  - Coded data is identifiable data, if a key code is retained and the study team has access to the key code.
  - If coded data, where will the key code be maintained & when or if it will be destroyed.
  - Identifiable data must be stored in a Campbell Egnyte file with security measures in place such as password protected & encrypted file.
  - IRB requires all research source documents, etc. to be kept for 3 years (6 years for HIPAA) and to be readily accessible to the IRB or other auditing agencies.

Benefits of the Research

“In order to approve 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.”

Benefits of the Research

- Describe any anticipated benefits that may result from the research. Consider the following:
  - There must be a benefit!
  - It is common for research participants to not receive a direct benefit from the and you may state so.
  - Include benefits to the general participant population.
  - Include general benefits of the research to society, science and humanity & the potential generalizable knowledge.
    - By what mechanism: publication or presentation.

Benefits of the Research

- If there is no benefit to conducting the research then the risk(s) are greater, the IRB will not approve the protocol. Research is hard work. If was easy everyone would be doing it, receiving funding and publishing. That's not the case.
- Remember most research fails.

Investigator Qualifications

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

Investigator Qualification

- Provide a brief description for all study team members. Consider the following:
  - Research experience!
  - Academic background.
  - Experience or expertise with the proposed participant population or subject matter.
  - Recent CV’s should be submitted with high risk level protocols.

Additional Resources

- IRB website
  - IRB Guidance Library
  - IRB Standard Operating Procedures (SOPs)
  - Resources for Investigators
- Contact the IRB office
  - Shawn Leming at irbadmin@campbell.edu or 910-893-7780