Title: Pilot Studies and Feasibility Work
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Standard Operating Practice: 2

2.1. Executive Summary

This document provides information regarding pilot and feasibility studies completed at NC State University. This document contains information regarding NC State University's IRB policy, standard operating procedures, and terms and definitions (see Appendix A). This document outlines the processes that researchers should follow in seeking IRB approval for their research, and any considerations that the IRB will consider regarding the review of pilot and feasibility studies.

2.2. Standard Operating Practice

All pilot studies and some feasibility studies must undergo IRB review and receive approval before they are conducted.

2.3. Operational Procedures

Both pilot studies and feasibility studies (as defined in Appendix A) help to determine that the larger study may achieve the intended research goals. Although federal regulations make no distinction between pilot studies, feasibility studies, and other research projects, the NC State University IRB has determined that all pilot studies must undergo IRB review and receive approval before they are conducted, and that some feasibility studies may need to undergo IRB review and approval before they are implemented.

2.3.a. Pilot Studies and the IRB

While data collected through pilot studies may not ultimately be used in research reports and publications, pilot studies represent part of the research process that leads to the development of, or contribution to, generalizable knowledge.

1. Even if results collected through a pilot study will not be used in research reports or publications and even if the study is only done to develop or evaluate research procedures and/or test instruments, the study represents part of the regulated research process and will require IRB review and approval.
    a. Information obtained from the pilot study leads to the development of or contribution to generalizable knowledge. Thus, pilot studies meet the definition of research and will need to undergo IRB review and approval before implementation.
    b. Pilot studies involving human subjects require the same scrutiny regarding risks and benefits and participant protections. Even if pilot study data will not be published, the pilot study's methods may still pose risks to human subjects that must be identified, mitigated, and communicated to the participants in the pilot study.
2. Pilot studies are used as strategies to check the soundness of a data collection method, procedure, or instrument. For example, a pilot study addresses a question like "Does the data collection tool gather the information it was designed to gather?"

2.3.b. Feasibility Studies and the IRB

Submissions meeting the definition of "feasibility study" below (refer also to Appendix A) and that involve human subjects may not meet the definition of "research" and may not need IRB review and approval.

1. A feasibility study will not need IRB approval when experts, colleagues, peers, or lab members (junior members included) provide feedback on the methods, procedures, or

instruments and do not provide information about themselves in any way (thoughts, feelings, opinions, physiological responses, etc.).
    a. Information collected for a feasibility study that did not meet the definition of research may not be repurposed as a research study, nor can that information be used as data for the main research study.
2. A feasibility study will need IRB approval when experts and colleagues provide feedback on the methods/procedures/instruments and also provide information about themselves in any way (thoughts, feelings, opinions, physiological responses, etc.).

2.3.c. IRB Application Preparation for Pilot and Some Feasibility Studies

A researcher planning to conduct a pilot study or feasibility study requiring IRB approval must submit an IRB application and provide sufficient details to address how a smaller scale investigation is worth pursuing with a goal of obtaining results that may add to the generalizable knowledge while minimizing any anticipated risks to the subjects.

1. The researcher must complete the submission form through the IRB's electronic application system.
2. Submissions that are considered pilot/feasibility activities must be clearly identified. Explicitly identifying the study as a pilot/feasibility study in an IRB submission helps the committee to contextualize the research, particularly when it comes to justification for the sample size or research design.
3. The submission must include sufficient information about how the information provided may be used as part of the larger study.
4. The researcher must justify the need for the number of subjects required and why the subjects are to be selected if different from the target population.
    a. For sample size in a pilot or feasibility study, the IRB may be satisfied with a rationale as to why the proposed number of subjects was chosen (e.g., "15 is the number of available subjects and is expected to provide enough data to determine whether the questionnaires are understandable").
    b. Sometimes it is appropriate to use the research team as the pilot participants. This approach can serve as a participant protection for both pilot or feasibility study participants and future participants due to the expertise of the pilot or feasibility study participants. If research team members are used in this way, they are considered participants and not just researchers. Please see our guidance regarding researchers who serve as participants in their own work.
5. Potential participants must be notified during the consent process if any part or all of the activities are for a pilot or feasibility study or for purpose of preparing for or contributing to the design of a larger study and that they are participating in a pilot/feasibility study.
6. Once approved, a pilot or feasibility study can be modified to include main study procedures and other changes or the main study can be submitted. The investigator can make the initial assessment of the appropriate submission route for the main study and they can discuss options with the IRB office staff. The IRB may determine that the changes needed to transition from a pilot/feasibility study to a main study so significantly impact the design and/or risk assessment that a modification is not appropriate and that a new initial submission will be required.

2.3.d. IRB Review and Approval for Pilot and Feasibility Studies

The IRB will review the submission to determine if part or all of the study meets the definition of a pilot study or a feasibility study requiring IRB review and approval. Activities proposed as preliminary to research will be evaluated to determine if the activities meet the definition of human subject research.

Appendix A

Definition of Terms

Research

"The federal regulations that govern human subjects research (45 CFR 46) define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Human Subject

Federal law 45 CFR 46 defines a human subject as a "living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

- Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- Identifiable private information is private information for which the identity of the subject is or may be readily ascertained by the investigator or triangulated with other information to identify a participant.
    - Whether or not identifiers are considered readily ascertainable is determined in conjunction with the IRB.
- An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Pilot Study

A pilot study is a preliminary investigation usually conducted on a small scale that may be exploratory in nature, designed to test or develop procedures, to test study design (including survey or instrument development), or to test methods that are intended for a larger study. A pilot study is usually (but not always) completed with a participant group related to the intended target population. Pilot studies are considered research with human subjects and will require IRB review and approval before implementation. Reasons to complete a pilot study include exploring a new topic, testing instruments, testing study design and procedures, and preparation for a grant application.

Feasibility Study

A feasibility study is an assessment of the practicality of a proposed plan, method, or use of an instrument for data collection, often involving colleagues or experts who can evaluate if the proposed method/design/instrument will result in sufficient information to answer the research questions. A feasibility study is not always considered research with human subjects and more likely than not will not require IRB review and approval before implementation. Reasons to complete a feasibility study include: assessing the practicality of a research plan is practicable, assessing whether the research is needed, and garnering feedback regarding methods/instruments used in data collection.