Pilot Activities

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1. PURPOSE

1.1. Some ***research*** studies are designed with multiple phases where the first phase is to gather preliminary information or test the research design or methods. These initial phases are sometimes referred to as "***pilot studies***". A distinction should be made whether the proposed activities are pilot activities or activities preparatory to ***research*** like when conducting a ***feasibility study***. ***Research*** means a systematic investigation, including ***research*** development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge***. Since a pilot study that meets the definition of ***research*** may create all of the same risks for subjects/participants that are created by a full-blown study, ***pilot studies*** therefore require IRB review and approval. The purpose of this ***policy*** is to provide guidance for determining when initial activities need IRB review and approval.

2. DEFINITIONS

2.1. ***Pilot Study:*** A preliminary investigation usually conducted on a small scale (e.g., 10 or fewer subjects) that may be exploratory in nature or designed to test ***procedures*** that are intended for a larger study.

2.2. ***Feasibility Study:*** An assessment of the practicality of a proposed plan or 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.

3. POLICY

3.1. Submissions meeting the definition of "***pilot study***" above and the definition of ***human subjects research*** require IRB review and approval or determination prior to beginning the project.

3.2. Even if results collected through a ***pilot study*** will not be used in ***research*** reports or publications but if the study will be conducted to develop or evaluate ***research procedures*** or test instruments, then the study represents part of the ***research*** process that leads to the development of or contribution to ***generalizable knowledge*** and meet the definition of r***esearch***.

3.3. The pilot activities should be described to study participants as such during the consent process.

3.4. Submissions meeting the definition of "***feasibility study***" above and that involve ***human subjects*** may not meet the definition of "***research***". Such submissions will be evaluated using Policy and Procedure: Determination of Human Research.

3.4.1. The IRB cannot provide retroactive approval. Information collected for a ***feasibility study*** that did not meet the definition of ***research*** may not be repurposed as a ***research*** study.

3.5. A ***pilot study*** can be modified to include main study procedures and other changes or the main study can be submitted separately and linked to the ***pilot study*** via submission documents. The investigator can make the initial assessment of the appropriate submission route for the main study.

3.6. The IRB may determine that the changes needed to transition from a ***pilot 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 (see Policy and Procedure: Review of Modifications to Previously Approved Research.)

4. PROCEDURES: Researchers

4.1. The researcher must complete the submission form through the IRB's electronic application system.

4.2. The submission or phases of the submission that are considered pilot activities must be clearly identified. The Decision Chart "Pilot Study Determination" can be used as guidance.

4.3. Potential participants must be notified during the consent process if any part or all of the activities are for a ***pilot study*** or for purpose of preparing for or contributing to the design of a larger study. The submission must include sufficient information about how the information provided may be used as part of the larger study.

5. PROCEDURES: Institutional Review Board

5.1. The IRB will review the submission to determine if part or all of the study meets the definition of a "***pilot study***".

5.2. Activities proposed as preliminary to ***research*** will be evaluated to determine if the activities meet the definition of ***research*** using Policy and Procedure: Determination of Human Research. If the activities do not meet the definition of ***research***, the ***procedures*** in that ***policy*** will be used to complete the review process.

5.3. For ***non-committee reviews***, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.

5.4. For committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required ***modifications***.

5.5. IRB Staff will document information pertaining to determinations that the requirements of this ***policy*** have been met in the review history for ***non-committee reviews*** and, for ***research*** reviewed by committee, in the meeting minutes by recording the motion to approve.

6. MATERIALS

6.1. Decision Tree: Pilot Study Determination

7. REFERENCES

7.1. Policy and Procedure: Determination of Human Research

Revision History:
03/31/2006: REV0 New Document
07/17/2015: REV1 Policy Revision