

Survey Instrument Development Guidance

When developing a research study, researchers gather preliminary information or test the research design or methods, prior to beginning their research study. This can include a literature review, consultation with experts/peers, and various methods to develop *survey instruments*. Some of these activities are not considered *human subjects research* and may be initiated prior to receiving IRB approval. The purpose of this guidance sheet is to assist researchers with determining when these preliminary activities may need IRB review and approval.

The activities covered by this guidance are:

- Literature Reviews
- Development of Survey Instrument
- Expert/Colleague Consultations
- Study Implementation
 - a. Piloting Activities
 - b. Conducting Survey

❖ *NOTE: Researchers are still required to consult with their IRB College Representative or the IRB Office to verify that no IRB approval is necessary prior to beginning activities outlined in this guidance document.*

I. IRB Definitions

Researcher(s): Someone who conducts research, i.e., an organized and systematic investigation into a topic of interest. Scientists are often described as researchers. They can be a principal investigator, co-investigator, research assistant, and/or other research personnel types.

Human Subjects Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge that involves human subjects and/or their data.

Survey Instrument: For IRB purposes this includes questionnaires, assessments, tests, surveys, or other similar instruments, outside of basic demographics, administered to research participants.

Research Procedures: An outline of the steps taken to investigate a research problem. This includes tests, procedures, and techniques used by researchers during the course of their study.

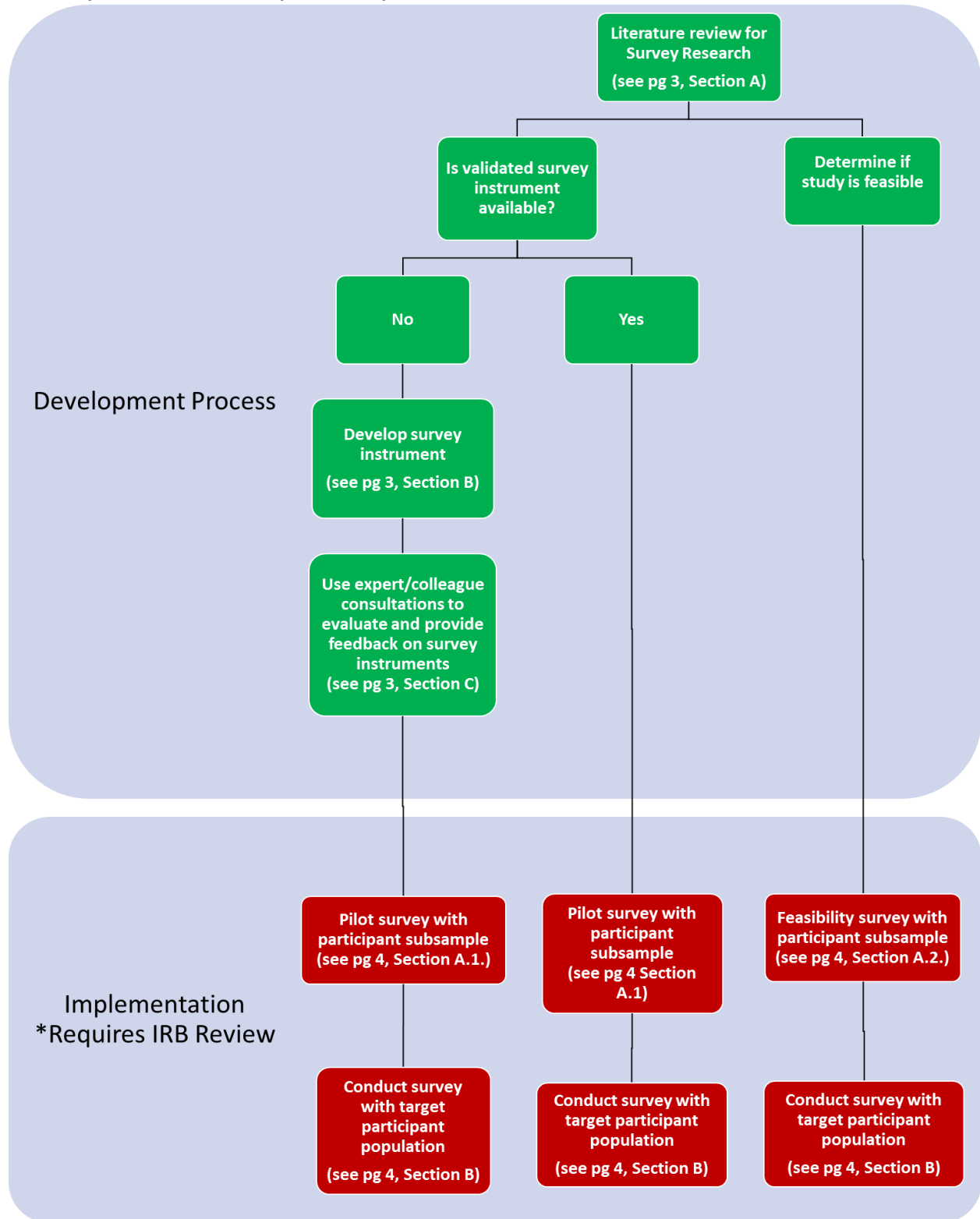
Literature Review: A comprehensive summary of previous research on a topic.

Expert/Colleague Consultations: Meeting with an expert or colleague in your field of study in order to seek advice regarding the development of study design or a *survey instrument*.

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.

Feasibility Study: An assessment of the practicality of a proposed plan or method or use of an instrument for data collection and to evaluate if the proposed method/design/instrument will result in sufficient information to answer the research questions.

II. Survey Instrument Development Graphic



III. Development Process

A. Literature Review for Survey Research

Before designing a research study, researchers conduct a literature review to compile a comprehensive summary of previous research on their proposed research topic. The literature review pulls information from scholarly articles, books, and other sources relevant to a particular area of research to assist with developing study design and survey instruments that will be administered during the study.

This activity typically does not require review by the IRB. There are two important exceptions;

1. Use of data from an article itself is not within the purview of the IRB, but contacting the author to obtain data **not** in the article does require IRB review and approval.
 2. Use of data from unpublished articles because the data has not yet been made public.
- ❖ Unless one of the two above exceptions apply, these activities do not require IRB review and approval prior to implementation.

B. Development of Survey Instrument

Researchers frequently administer already validated survey instruments in their studies, but often there is not a validated survey instrument that will answer their research question. In these instances, researchers must develop their own survey instrument. In addition to a literature review, researchers may use several methods to develop and refine their survey instrument. This includes expert/colleague consultations, pilot/feasibility studies, etc. These methods will be outlined in subsequent sections.

- ❖ Some of these activities may require IRB review and approval prior to implementation.

C. Expert/Colleague Consultations

Before implementing a study it is sometimes necessary to assess the practicality of the proposed research design, method, or survey instrument. This frequently will involve consulting with experts or colleagues who can evaluate and provide feedback on study design, research procedures, survey instruments, assessments of current literature, etc. Experts or colleagues can evaluate if the proposed method/design/instrument will result in sufficient information to answer the intended research questions.

- ❖ These types of consultations typically do not require IRB review and approval prior to implementation; some exceptions may apply, contact the IRB Office for additional information.

IV. Study Implementation

A. Piloting Activities

Piloting activities are a strategy used by researchers to test a survey instrument using a smaller sample of the participant population compared to the planned sample size. These activities include *pilot surveys* and *feasibility studies*, as defined in Section I. Both these activities require IRB approval because they meet the definition of research and may create all of the same risks for subjects/participants that are created by a larger study.

All activities that are conducted to develop or evaluate research procedures or survey instruments (i.e. piloting activities) require IRB review. These activities represent part of the research process that leads to the development of or contribution to generalizable knowledge and meet the definition of human subjects research. This applies even if the results collected will not be used in subsequent research reports or publications. These piloting activities should be clearly described to study participants during the consent process.

1. Pilot Survey

Questionnaires, assessments, tests, surveys, or other similar instruments in a question & answer format require that the questions read clearly, allow respondents to answer the question, and elicit meaningful responses. Researchers who have created new surveys, or who have modified existing surveys, often need to verify that their survey meets these criteria and will conduct a pilot survey. A pilot survey is administered to a smaller sample of the participant population compared to the planned sample size. The researcher then uses the information collected to modify their *survey instrument*.

- ❖ Submissions meeting both definitions in Section I for “*pilot study*” and “*human subjects research*” require IRB review and approval prior to implementing the study.

2. Feasibility Study

Often researchers need to determine feasibility of their research prior to initiating a larger study. A feasible study is capable of being done and answering the questions outlined in the research design. This involves a feasibility study, which is a strategy to assess the practicality of a proposed plan, research procedure, or use of a survey instrument for data collection.

- ❖ Submissions meeting both definitions in Section I for “*feasibility study*” and “*human subjects research*” require IRB review and approval prior to implementing the study.

B. Conduct Study with Target Population

Once researchers have finalized and/or validated their survey instrument via any of the above methods and is ready to fully implement their study, IRB review and approval is required. Depending on the methods used, the researcher may or may not have already obtained this IRB approval.