



Human Subject Research Determination Worksheet

MAHEC Research Council and Mission Health Institutional Review Board

Please contact Research@mahec.net or Shelley Galvin at 771-5501 if you need assistance with determining whether your project is Human Subjects Research or QI.

PI Name: [Click here to enter text.](#)

Title of Project: [Click here to enter text.](#)

Brief Synopsis of Study: [Click here to enter text.](#)

I. Human Subject Research

Review the following questions to determine whether a project is human subject research under 45 CFR 46, and requires submission of an Electronic IRBNet application to the Mission Health IRB.

A. Does the research meet the definition of “research?”

Check either 1 or 2 below as the appropriate description of the project:

1. **Yes, a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.**

Examples may include:

- pilot studies
- comparative studies
- medical records studies
- survey studies
- medical intervention studies
- project to refine research tool in preparation for study

2. **No, NOT a systematic investigation designed to develop or contribute to generalizable knowledge**

Examples may include:

- Performance Improvement/Quality Initiative to improve the quality of patient care.
- Program evaluation which may include the collection of patient data.

If the project is **NOT** a systematic investigation designed to develop or contribute to generalizable knowledge, the project does not meet the definition of research under federal regulations.

B. Under the federal regulations “human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains:

Check either 1 or 2 below as the appropriate description of the project:

1. **Data collection through intervention or interaction with an individual**

Examples:



- Intervention includes both physical procedures by which data is gathered (for example, 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.

2. **Collection of identifiable private information about an individual**

Examples:

- 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. A code that can be linked back to the individual (such as a medical record number) is identifiable.

If you have answered “yes” to both A and B, you *must* submit your project to the Mission Health IRB.

If you have answered “no” to either A or B, the IRB office will review your project via an electronic IRBNet submission and make a determination for you. The IRB will provide you with documentation stating that your project is not human subject research.

All projects must be submitted for Determination of Human Subject Research Status.

The attached Flow Chart may assist you in this determination process.

Is an Activity Research Involving Human Subjects?

