DOES YOUR STUDY NEED IRB APPROVAL

DECISION TREE

HUMAN SUBJECTS

DOES YOUR STUDY INVOLVE DATA FROM HUMAN SUBJECTS?

NO IRB REVIEW AND APPROVAL IS REQUIRED

YES

DOES YOUR STUDY INVOLVE THE SYSTEMATIC COLLECTION OF DATA?

NO IRB REVIEW AND APPROVAL IS REQUIRED

YES

WILL THE RESULTS FROM YOUR STUDY BE GENERALIZABLE (presented/published outside of Meridian Health)?

NO IRB REVIEW AND APPROVAL IS REQUIRED

YES

MERIDIAN HEALTH IRB REVIEW AND APPROVAL IS REQUIRED

EXEMPT STATUS

1 – 2 Weeks

Most QI Studies
Most Retrospective Chart Reviews
Some Survey Studies

EXPEDITED REVIEW

3 – 4 Weeks

Some QI Studies
Some Chart Reviews
Some Survey Studies
Case Series (>3 pts)

FULL BOARD REVIEW & APPROVAL

2 – 3 Months

Some QI Studies
Intervention Studies
Studies with Vulnerable Subjects

PLEASE NOTE: The Meridian Health IRB can not provide retrospective review and approval of research or data collection.
WHAT ACTIVITIES REQUIRE IRB REVIEW AND APPROVAL

Federal law and Meridian Health Institutional Review Board (Meridian Health IRB) policy (operating under the Meridian Health Federalwide Assurance (FWA000013006) defines a project/study as requiring Meridian Health IRB review and approval if the project involves:

(1) HUMAN SUBJECTS (45 CFR 46 102.f) [a living individual about whom an investigator conducting research obtains DATA or IDENTIFIABLE PRIVATE INFORMATION]; and

(2) RESEARCH (45 CFR 46 102.d) [a SYSTEMATIC investigation (including research development, testing and evaluation) designed to develop or contribute to GENERALIZABLE knowledge].

The Meridian Health IRB Chair and/or Corporate Director of the IRB determine whether an activity meets the definition of human subject research based on Federal Regulatory definitions (45CFR46.102(d), 21CFR50, and 21CFR56).

Investigators should contact the IRB chair or office of the IRB with any questions regarding whether an activity constitutes research and/or clinical investigation involving human subjects. Investigators will be instructed to send a description of the activity by email to the IRB Office (IRB@MeridianHealth.com). For cases in which the determination is obvious based on the definitions and conditions outlined below, the IRB Office will determine whether the project is research or involves human subjects and provide an email back to the investigator identifying the determination promptly. For cases in which the determination is more complex, the IRB Chair and Corporate Director of the IRB will consult and make a determination based on the definitions below. In either instance, there may be a request for additional information to the investigator. Every effort will be made to ensure that such determinations are made in a timely manner (usually with 3-10 business days after receipt of the original inquiry). Determinations will be documented by printing out the email(s) correspondence from the investigator along with the IRB determination email(s) and maintaining them in the IRB records according to Meridian Health IRB Records retention policies and procedures.

DOES MY PROJECT REQUIRE MERIDIAN HEALTH IRB APPROVAL?

If you answer YES to the following questions—YOU NEED MERIDIAN HEALTH IRB approval prior to initiating your study.

- Does your study use data from HUMAN SUBJECTS?
  - If No, you don’t require IRB Approval.
  - If Yes, read on.
- Does your study qualify as RESEARCH?
  - If No, you don’t require IRB Approval.
  - If Yes, IRB Approval is required.
HOW DO THE FEDERAL REGULATIONS DEFINE "RESEARCH WITH HUMAN SUBJECTS"?

HUMAN SUBJECT

According to the federal regulations (45 CFR 46.102.f), a HUMAN SUBJECT means a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with individual;
- Identifiable private information.

**Intervention** includes both physical procedures by which data are 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.

**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.

Are you collecting IDENTIFIABLE PRIVATE INFORMATION about study subjects?

Ask yourself the question: "If I realize that I omitted a data point when I was reviewing a medical record (or interviewing a subject) for my research data, can I go back to that record (or that subject) to "fill-in" the omitted data point?" If the answer to that question is "Yes", then the information you collected was IDENTIFIABLE.

Some Examples of what does meet the federal definition of a human subject:

- A person who becomes a participant in research - either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient.
- Data obtained from medical records - even if the data is recorded without identifiers.
- Tissue used in research that possesses or is linked to any kind of identifiable information.
- Data obtained from surveys - even if the data is recorded without identifiers.
- Data obtained from observation - even if the data is recorded without identifiers.
- Data obtained from third parties - collecting information about family members makes them subjects.

For more information about what constitutes identifiable information, please refer to the table of Protected Health Information as defined by HIPAA at the end of this guidance.

Some Examples of what does not meet the federal definition of a human subject:

- Tissue obtained from another source (not directly from the patient) that is either:
  - totally anonymous and unlinkable to the person who it was obtained from, or
  - is coded such that the researcher obtaining the sample does not know who it belongs to, AND a confidentiality agreement assures the researcher cannot learn the identity of the person who the sample was obtained from.
- Data obtained from another source (not directly from the patient or their records) that is either:
  - totally anonymous and unlinkable to the person who it was obtained from, or
is coded such that the researcher obtaining the data does not know who it belongs to, AND a confidentiality agreement assures the researcher cannot learn the identity of the person who the data was obtained from.

- **Data or tissue collected about/from individuals after they are deceased**
  - federal regulations governing research define a human as a "living individual"
  - Using deceased tissue subsequently in humans for research purposes (e.g. transplanting organs/tissue from a deceased individual into a living individual as part of a research protocol) does equal human subjects research (because of the person who is receiving the tissue).
  - NOTE: HIPAA requires you to obtain a Certificate for Research with Decedents Info

**RESEARCH**

According to the federal regulations (45 CFR 46.102.d) RESEARCH means a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.

There are two significant points to consider:

1. **What is a systematic investigation?**
   The dictionary defines systematic as having a method or plan, possibly concerned with classification. Definitions of investigation include a detailed or careful examination, exploration, or to learn the facts about something complex or hidden. Attempting to answer a question or prove/disprove a hypothesis are clear indications that an activity is a systematic investigation. (Note: the absence of a hypothesis does not automatically mean an activity is not a systematic investigation.)

2. **What is developing or contributing to generalizable knowledge?**
   You are developing/contributing to generalizable knowledge if you intend on sharing the information you produce with others, be it at a poster presentation, at a conference, or in a publication.

Some examples of what is not considered to be research include:

- **Quality Improvement** – Quality Improvement is defined by The Centers for Medicare & Medicaid Services as “an assessment, conducted by or for a QI organization, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up”. They go on to further define QI as “a set of related activities designed to achieve measurable improvement in processes and outcomes of care achieved through interventions that target health care providers, practitioners, plans, and/or beneficiaries”. [Source: AJCC, 2007;16:424-426]. The Institute of Medicine defines Quality Improvement as “a systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product”.
  - Quality Improvement projects are not considered research in that although it is a systematic investigation, there is no intent to share the information with others (contribute to generalizable knowledge). For example, the pharmacy can conduct quality assurance and compare the use of a medication PO vs IV administration and not require Meridian Health IRB approval provided they do not publish the results. When the intent is to publish results and therefore contribute to generalizable information, the QI project must obtain Meridian Health IRB approval prior to data collection, analysis and publication.
- If the information you are gathering for the Quality Improvement project is only for internal use and distribution (i.e. within the Meridian Health system), it is not considered generalizable and therefore not considered “research”, and does not have to be submitted to the IRB.
- If there is any possibility that you will use these data to document the effectiveness of a particular program, curriculum or strategy for improvement in a paper or presentation to a broader professional audience, then it meets the definition of “research” and you must obtain approval to conduct the research from the Meridian Health IRB prior to collecting the data. You must also complete an Meridian Health IRB training course. (The course is available online and takes two to three hours to complete.) If you do not obtain Meridian Health IRB approval and complete the course, you cannot use the data for publication.

**Case reports (Clinical Vignette (one patient) or Case Series (3 or fewer patients)**- are not considered research in that although they contribute to generalizable knowledge, they are not systematic investigations. The clinician is simply sharing information about interesting cases for educational purposes.

  - If you attempt to answer a question, or prove/disprove a hypothesis, you are no longer dealing with a case report and instead are now dealing with research. In addition, case reports are usually limited to no more than a few patients. Once you start to exceed three subjects it appears that you are doing something systematic (attempting to prove a point or answer a question) and Meridian Health IRB approval is required.

[NOTE: IRB approval is required not only during the period when patients are being entered into the study, but for the entire time that PRIVATE INFORMATION about study subjects is being collected/analyzed for an investigational purposes.]
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<tr>
<th><strong>TYPE OF PROJECT AND IRB APPROVAL REQUIREMENT</strong></th>
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<td><strong>NON-RESEARCH</strong></td>
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<td><strong>Clinical Vignette</strong></td>
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<td><strong>Case Series</strong></td>
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<td><strong>Retrospective Chart Review</strong></td>
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<td>• Minimal Risks</td>
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<td>• Research involving the collection or study of existing data…</td>
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<td>• Data cannot be linked to participants (no PHI)</td>
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<td>• The reviewed materials already exist at the time the research is proposed and are not prospectively collected</td>
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SOME COMMON EXAMPLES

Pilot Studies
Generally, a pilot study is defined as a preliminary investigation to determine the feasibility of a study. It is usually done on a small scale (usually fewer than 10 subjects) and exploratory in nature. Its purpose is to refine data collection procedures, instruments, or research design. Pilot studies answer questions such as "in what order should the survey instruments be distributed". These questions do not qualify as questions that will contribute to generalizable knowledge and thus pilot studies do not qualify as research and do not need IRB review and approval. Nonetheless, it is assumed that the proper steps will be taken to protect human subjects (e.g., use of informed consent, confidentiality, etc.). NOTE: If sensitive data, vulnerable populations, or methods with more than minimal risk are to be used, a consultation with the IRB Chair must occur before data is collected unless IRB review and approval is sought.

However, if it is possible that the data collected in your pilot study will be used solely or in combination with other data for publication purposes, IRB review and approval is required BEFORE data collection begins.

Secondary Data Analysis
Secondary data analysis involves using previously collected data to answer new questions. If the source of the data is public (e.g., newspaper accounts, census data held in public libraries, published school test scores) and the new analysis would not permit the identification of or pose significant risk to the participants from which the data was obtained, than IRB review and approval is not needed. If the source of the data is not public (e.g. Meridian Health databases or government databases which require special permission to access) or an investigator's previously collected data that has not received IRB approval, then IRB review and approval is needed. (In many cases, these projects may meet the criteria for an Exempt Review).

- Example: The investigator wishes to examine public census data and 911 call statistics to determine if there is a relationship between low income neighborhoods and 911 calls and there is no collection of PHI. NO IRB REVIEW/APPROVAL NEEDED.
- Example: The investigator wishes to examine the characteristics that predict repeated child admissions for abuse by examining medical record data. IRB REVIEW/APPROVAL IS NEEDED.
- Example: The investigator brings previously collected (and IRB approved) data from another institution and wishes to continue the analysis and publication of this data. IRB REVIEW/APPROVAL IS NEEDED.

Program Evaluation or Quality assurance studies
Research that is part of a program evaluation or quality assurance measure may or may not fall under the oversight of the IRB. If the project is conducted with the goal of contributing to generalizable knowledge, the IRB must review it. (In many cases, these projects may meet the criteria for an Exempt Review.)

Observation of children or college students
Research that involves the observation of either children or college students, in a classroom or another setting, requires IRB review and approval. In some cases this research qualifies for Exempt status. In most cases, however, you are conducting research on subjects who are part of a special population. Children (under 18 years of age) are always considered a special population within the Meridian Health system.

Observations of adults
Research that involves the observation of adults, in either a public or private setting, requires IRB review and approval. In some cases this research qualifies for Exempt status. In other cases, however, you are conducting research that might put the subjects at risk (e.g., confidentiality issues, legal issues), which requires full IRB review and approval.
SPECIAL CONSIDERATIONS

If You May Publish
If your research uses human subjects and there is any possibility that you might publish your data (theses, dissertations, and conference presentations are considered publications), you must obtain IRB review and approval.

If You Decide Pilot Data is Publishable
If you begin a project using human subjects and later realize that the data you have gathered could contribute to generalizable knowledge (or be published), you must submit the project for IRB review as soon as possible. This will insure that all future data collection has IRB approval. The IRB does not give retrospective approval of projects (i.e. IRB cannot approve data already collected prior to the IRB review and this data is not to be used in publications).

Use of Amendments
If you are working on a current project that is similar to the new proposed project, you might be able to make an amendment to the current IRB projects' protocol instead of writing a new protocol. The amendment would have to outline clearly all of the changes that you are proposing (e.g., new investigators, extra subjects, another questionnaire).

Always Follow Ethical Guidelines
Even in cases in which your project does not require IRB review, you are still bound by the ethical treatment of human subjects guidelines. These guidelines can be found on the Meridian Health IRB Intranet site or through contacting the Meridian Health Office of the IRB at 732-776-4850.
PROTECTED HEALTH INFORMATION

The Privacy Rule allows a covered entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members; these elements are enumerated in the Privacy Rule. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.