



## **HUMAN SUBJECTS RESEARCH DETERMINATION PROCESS**

Federal regulations and Monument Health Institutional Review Board (MH IRB) policy requires **ALL** research projects involving **humans as subjects** (including involvement of humans in one or more of the categories of research exempted or waived under the federal regulations), **OR the use of identifiable protected health information** be reviewed and approved by an IRB **PRIOR** to initiation of any research related activities, including recruitment and screening activities. The MH IRB is the sole body designed to make official human subject research determinations at Monument Health.

Some categories of research are difficult to discern as to whether they qualify as human subjects research. The MH IRB has created this form to assist in this determination. Please review the entire document prior to filling out the form. It will be important to provide as much detail about the research project. The MH IRB will review the information provided to determine whether the research project will require a submission to the MH IRB as Human Subject Research. You will be notified as to the final determination. Any questions can be directed to the IRB Office at (605)755-9037 or [MHirb@Monument.health](mailto:MHirb@Monument.health).

### **INSTRUCTIONS:**

- Prior to the initiation of any human subjects research projects, principle investigators are required to submit and the MH IRB is required to review Human Subjects Research for which Monument Health is engaged.
- Read through the definitions and if you have questions ask for assistance.
- In addition, Section 4.0 below contains some examples of activities that are generally considered not to be Human Subjects Research.
- If, after reading through all information provided in this document, and you are not certain whether your project is Human Subjects Research **OR** you would like for the MH IRB to review your protocol so to provide an official determination documentation your study is not human research, submit the information explained in Section 5.0 to the MH IRB.

Note: the MH IRB can only make an official determination prior to the beginning of the research activity. The MH IRB will not make an official determination after the activity has already begun.

- If you need assistance, contact one of the offices below:

<b>Monument Health Institutional Review Board</b> Phone: 605-755-9037 E-mail: <a href="mailto:MHirb@Monument.health">MHirb@Monument.health</a>	<b>Monument Health Clinical Research Research Department</b> Phone: 605-755-4326 E-mail: <a href="mailto:research@Monument.health">research@Monument.health</a>
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## 1.0 Definitions

These definitions will provide a list of standard terms and concepts associated with human subjects research.

- 1.1 **“Clinical Investigation”** is defined as any experiment that involves a test article and one or more human subject.
- 1.2 **“Generalizable knowledge”** is knowledge based on conclusions which are drawn from particular instances that could be widely applied to populations outside the organization.
- 1.3 **“Human subject”** is defined by the Department of Health and Human Subjects as a living individual about whom an investigator obtains data through intervention or interaction or collects individually identifiable private information. It is defined the by the Food and Drug Administration as an individual who is or becomes a participant in research, either as a recipient of the test article (patient) or as a control (healthy individual). In addition, unidentified tissue specimens are defined as human subjects by FDA when the research involves in vitro diagnostic device studies.
- 1.4 **“Intervention”** is defined as physical procedures by which data is gathered or manipulations of the subject’s environment. Note: this does include collecting data from patient charts.
- 1.5 **“Interaction”** includes communication or interpersonal contact.
- 1.6 **“Individually identifiable private information”** is the individual’s private information in which the subject’s identity is or may readily be ascertained by the investigator or associated with the information. It 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. There are 18 different identifiers of Personal Health Information: names; all geographical subdivisions smaller than state; all elements of dates except year; telephone numbers; fax numbers; e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identification, serial, or license plate numbers; device identifiers and serial numbers; web Universal Resources (URLs); biometric identifiers, including finger and voice prints; full face photographic images and comparable images; and all other unique identifying number, characteristic, or code.
- 1.7 **“Protected Health Information – aka PHI”** is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or a Business Associate of a Covered Entity), and can be linked to a specific individual.
- 1.8 **“Research”** is defined as a systematic or clinical investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 1.9 **“Systematic investigation”** is a methodically driven investigation which includes development, testing and evaluation.

## **2.0 Department of Health and Human Services (DHHS) Criteria for Research Involving Human Subjects**

45 CFR 46.102(f): Human subject means a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or 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 be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

### **1. Does the activity meet the DHHS definition of research?**

- The activity employs a systematic approach involving pre-determined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.
- The activity is intended to contribute to generalizable knowledge by extending the results beyond a single individual or internal unit.

### **2. Does the activity involve human subjects according to the DHHS definition?**

- The proposed activity involves obtaining information about living individuals.
- The investigator obtains specimens or data through intervention or interaction with individuals (e.g. prospective data collection, interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication of an individual).
- The investigator is obtaining individually identifiable information about living individuals (e.g. chart reviews, lab studies on existing tissues or specimens, information from data or tissue repository).
- The data or specimens are received by or provided to the investigator with identifiable private information.
- The data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified.

### **3. The following activities are Not considered human research according to DHHS:**

- Scholarly and journalistic activities, including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. (see examples under section 4)
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by a court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense or other national security missions.

### **3.0 Food and Drug Administration (FDA) Criteria for Research involving Human Subjects (clinical investigations)**

#### **1. Is the activity subject to FDA human subject regulations?**

- The activity is a *clinical investigation* involving a product regulated by the FDA (i.e. Drug, biological, medical device, food additive, color additive, electronic product). *Clinical Investigation* is defined as any experiment that involves a test article and one or more human subjects.
- The activity involves the use of a drug, device, or biologic, excluding an “off-label” FDA agent in the course of medical practice, in one or more human subjects.
- The results of the project are required to be submitted to or held for inspection by the FDA.
- The activity involves the testing of a medical device using tissue specimens from one or more human subjects, and the results are being submitted to the FDA for approval of the device.

#### **2. Does the activity involve human subjects according to the FDA regulations?**

- The activity involves one or more individuals who are or become participants in research, either as a recipient of the test article (i.e. drug, biological product, medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug & Cosmetic Act), or as a control.
- The activity involves one or more individuals who participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

#### 4.0 Examples of projects generally not considered to be human subjects research

The following are examples of activities generally not considered to be human subjects research according to the definitions in Section 1.0. If your project is limited to one of the examples below, then it is likely not human subjects research and would not need the review and approval of the MH IRB.

1. **Program Evaluation/Quality Assurance Review/Quality Improvement Project:** The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.

Note: The purpose of a Quality Assurance Review (QA) or Quality Improvement (QI) study is to assure known quality. The purpose of Program Evaluation (PE) is to assess a program is doing what it is intended to do. Generally QI is designed for the purpose of improving the quality of a service, a program, a process, etc.. A QA, QI or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only.

If you can answer "yes" to all of the following questions, the project is most likely not human research:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical or Social Behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

Note an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, and may still not meet one of the definitions for human subjects research defined in Section 1.0.

2. **Evidenced-Base Practice Project:** EBP involves innovation in terms of finding and translating the best evidence into clinical practice. The purpose of EBP is to use the best evidence available to make patient-care decisions. Most of the best evidence stems from research. But EBP goes beyond research use and includes clinical expertise as well as patient preferences and values. The use of EBP takes into consideration that sometimes the best evidence is that of opinion leaders and experts, even though no definitive knowledge from research results exists.

Note all EBPs conducted at Monument Health require permissions from the department heads where the EBP project will be conducted and a review from the Nursing Council responsible to review and confirm the validity of the EBP project and the EBP project has sufficient documentation of evidenced based research prior to starting the project.

3. **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is nothing was done to the patient(s) with prior “research” intent.

Note if the case report may require a patient authorization form signed. HIPAA or other state or local laws may still apply to this case report. Please consult the entity’s Privacy Officer/Office from which you received or accessed the information contained in the report for further guidance.

4. **Course-Related Activity:** The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of human subjects research in Section 1.0.

Note for students and residents attending a college/university - some course-related activities, even those conducted by students or residents, may yield information suggesting additional investigation or analysis. If an additional activity entails human subjects research, then it must be submitted to the college/university IRB for review. If the project is being conducted at any Monument Health facility the project should be submitted to the MH IRB.

5. **Journalistic or Documentary Activity (including Oral History):** The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g, print newspaper, documentary video, online magazine.
6. **Research Using Public or Non-Identifiable Private Information about Living Individuals:** The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.

Note “de-identified data” according to HIPAA may be identifiable according to the definition of “Human Subjects” above.

7. **Research Using Health Information from Deceased Individuals:** This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Note deceased individuals are not usually considered human subjects, however the deceased’s deoxyribonucleic acid (DNA) could lead to identifying relatives. Note also HIPAA or other state or local laws may still apply to this activity. It is important to consult with the entity from which you received or accessed the information contained in the report for further guidance.

8. **Instrument/Questionnaire Development:** This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the

topic of the instrument, survey or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.

Note: If the participant is asked to provide additional information unrelated to instrument/questionnaire construction, such as demographic information, which will be analyzed as part of a research study, the project may need to be submitted to the MH IRB for review.

9. **Public Health Surveillance:** includes the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority. Also includes trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products. Includes those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (include natural or man-made disasters).





## Description of Project

If, after reviewing the information above, (1) you are unclear as to whether your project is human subjects research and would like for the MH IRB to provide an official determination for you, or (2) you believe your project is not human subjects research but would like an official MH IRB determination documentation which agrees with your assessment, then follow the directions outlined below.

**Use the outline below to provide the required information for the MH IRB to provide a thorough determination. It is suggested to copy the outline below to a separate Word Document, delete the instructions below each title, provide the information requested in the instructions, and then submit to the MH IRB Office at [MHirb@Monument.health](mailto:MHirb@Monument.health). The IRB office will follow-up after with a determination letter after review of the form.**

## Outline of the project:

**Project Title:**

**Project Lead:**

**Version Date:**

### **1. Purpose**

Describe the purpose, specific aims, or objectives of the study.

### **2. Procedures**

Describe the procedures used to obtain information from or about the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any.

### **3. Data and/or specimens**

Describe the data and/or specimens being gathered about individuals, including names of datasets you will access and links to data sources.

- **Data and/or Specimen Collection and Analysis**

Describe the data and/or specimens being collected and how they will be analyzed.

- **Data and/or Specimen Collection Method**

Describe how the data and/or specimen will be obtained. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)

- **Identifiability of Data or Specimens**

Indicate whether the data or specimens being collected for this project can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).

- **Will the Data or Specimens be sent outside of Monument Health system?** Indicate what data and/or specimens will be sent and where it is being sent.

- **Is there an intent to publish or present your results outside of the Monument Health System?**

Provide specifics as to what publications or where the results will be presented.