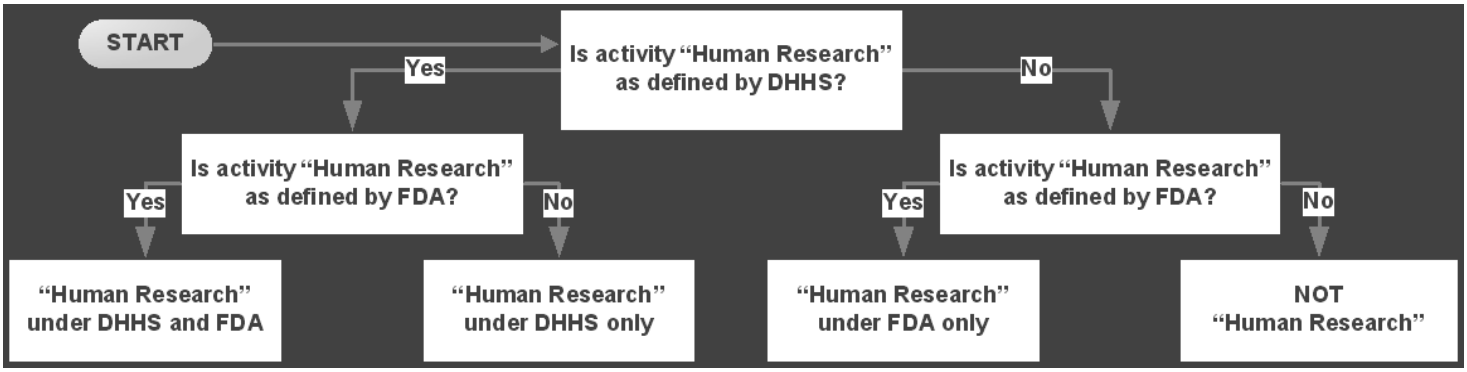
FERRIS STATE UNIVERSITY

Institutional Review Board for Human Subjects in Research

Office of Research and Sponsored Programs, 1010 Campus Drive, FLITE 410G · Big Rapids, MI 49307

# DETERMINATION OF HUMAN SUBJECT RESEARCH WORKSHEET

**Submission of this worksheet is OPTIONAL.** This worksheet is intended to serve as a guide to help the investigator determine if the activity is human subject research and regulated by the Department of Health and Human Services (DHHS) and/or Food and Drug Administration (FDA).




**Activities that meet the definition of human subject research will require an application submission to the IRB.**

1. **Research as defined by DHHS Regulations**[i].
   - Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination)
   - Is the investigation systematic? (Systematic: Having or involving a system, method, or plan)
   - Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truth, facts, information)
   - Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable)
2. **Human Subject under DHHS Regulations**
   - Is the investigator conducting the Research gathering data about *living* individuals?
   - Will the investigator gather that data through either of the following mechanisms:
     - Intervention: Physical procedures/manipulations of those individuals or their environment for research purposes
     - Interaction: Communication/interpersonal contact with the individuals
3. **Human Subject under DHHS Regulations**
   - Will the investigator gather data that is either:
     - Data about behavior that occurs in a context in which an individual can reasonably expect that no observation/recording is taking place (i.e., private information)
     - Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e., private information)

**If all items under 1 and 2 OR 1,2, and 3, are YES, the activity is Human Subject Research under DHHS Regulations.**

4. **Human Research under FDA Regulations**
   - Does the activity involve any of the following?
     - In the United States: The use of a drug[ii] in one or more persons other than use of an approved drug in the course of medical practice[iii]
     - In the United States: The use of a device[iv] in one or more persons that evaluates the safety or effectiveness of that device
     - Data regarding subjects or control subjects submitted to or held for inspection by FDA[v]
     - Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[vi]

**If YES, the activity is Human Subject Research under FDA regulations.**

[i] The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

[ii] The term ‘‘drug’’ means:
(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[iii] “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[iv] The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[v] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

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## Examples of Non-Human Subjects Research Activities and do NOT require IRB Review

A. **Quality Improvement (QI):** When an activity is specifically initiated with a goal of improving the performance of institutional practice in a relationship to an established standard, the activity qualifies as QI. If a project is originally initiated as a local QI project but the findings are of interest and the investigator chooses to expand the findings into a research study, IRB review is required at that time. The investigator should clearly indicate to the IRB that the data were originally collected as part of a QI project.
    - Any publication describing a project as "research" must have received prior IRB review and approval. Therefore, projects determined to be QI should not be published as "research"
    - A QI project that is initiated with the intent to produce research would be considered an intentional circumvention of the rules and is not permissible without IRB review
    - Projects considered to be QI must also maintain the highest integrity of confidentiality as possible
    - Characterizing a project as QI does not necessarily negate the need for informed consent

B. **Quality Assessment:** Activities that are designed to determine whether aspects of medical practice are being performed in line with established standards.

C. **Quality Assurance:** The process of reviewing, analyzing, or evaluating patient and/or provider specific data that may indicate the need for changes in systems or procedures that would improve the quality of care. The analysis is protected from legal discoverability, and the review is often triggered by predetermined thresholds/criteria. This analysis must be conducted with a specific committee structure. The knowledge generally is for local and immediate application.

D. **Medical Practice and Innovative Therapy:** A commonly cited definition of medical practice describes an activity that is designed solely to enhance the well-being of an individual patient. A type of medical practice that is often confused with research is a class of activities that have been called "innovative therapy." Innovative therapy describes an activity that is designed solely to benefit individual patient(s) but in which the ability of the activity to result in the desired outcome is to some degree unproven.

E. **Medical Practice for the Benefit of Others:** In some situations, the goal of medical practice is to benefit people other than those directly affected by the health care intervention. Examples of medical practice for the benefit of others include blood donation and some vaccination programs. In terms of determining research/non-research, the critical features of this form of medical practice is that the goal of the activity is to benefit a well-defined group of people in a predictable way.

F. **Public Health Practice:** Public health practice is similar to medical practice for the benefit of others in that the activity involves people who do not directly benefit from the intervention. The most common situation in which there is confusion about the distinction between a public health practice and research is with public health practices that require the review of private, identifiable information about health status. Examples of public health practices that often do not involve research include surveillance (i.e., monitoring of diseases) and program evaluation (i.e., immunization coverage or use of clinical preventive services such as mammography).

G. **Outcome Analysis:** Outcome analysis is a nonspecific term that may be used to describe a variety of projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition. Because medical research usually involves a formal analysis of outcome, use of the term *outcome analysis* to describe a non-research activity is confusing. Nevertheless, it is common practice for health care providers to perform descriptive analysis of medical outcomes that are appropriately describes as something other than research but do not clearly fall into a better defined category. Recognizing that there is no accepted definition of outcome analysis in the context of health care evaluation, the main difference between a non-research outcome analysis and a quality assessment project is the comparison of results to an established standard is not a defining feature of outcome analysis.

**H. Resource Utilization Review:** Medical record review is often conducted to evaluate the use of resources in a specific health care activity. Terms such as *cost control* are used to describe this class of activity, but the terms *utilization review* or *resource utilization review* are more general and often more accurately reflect the fundamental goal of projects in this category. Although a research project may involve review of resource utilization, the term *resource utilization review* usually refers to a non-research activity.

**I. Education:** The transferring of information from one group of people to another is a common activity in all aspects of society. The regulatory definition of research focuses on the desire to develop or contribute to "generalizable knowledge". The reason to mention education in the context of a discussion about the definition of research is that it is important to recognize that the goal of most educational activities is to spread or "generalize" knowledge. The fact that an activity is undertaken for the specific purpose of teaching somebody something does not mean that the activity involves research.

## Examples of activities involving Human Subjects and IRB review is required:

**A.** Investigator obtains specimens or data through intervention or interaction with a living individual (i.e., interviews, surveys, physical procedures, manipulations of the subject's environment, or any other direct communication with a subject).

**B.** The Investigator is obtaining identifiable private information about living individuals (i.e., chart review, lab studies on tissues or specimens, information from data or tissue repository).

**C.** Data or specimens are received by or provided to the investigator with identifiable private information.

**D.** Data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified.

## Per FDA and DHHS, activities involving Human Subjects and one of the following require IRB review

A. The activity employs a systematic approach involving predetermined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory AND the activity is intended to contribute to generalizable knowledge by extending the results beyond a single individual or an internal unit (i.e., publications or presentations)

B. The activity involves the use of a drug, excluding an FDA approved drug in the course of medical practice, in one or more human subjects

C. The activity involves the use of a medical device, excluding an FDA approved device in the course of medical practice, in one or more human subjects

D. The results of the project are required to be submitted to or held for inspection by the FDA

E. 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

F. 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

G. 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 uses or as a control