

# Studies that do not meet the Definition of Human Research

## I. Purpose

This Procedure outlines requirements for Einstein Institutional Review Board (“IRB”) review of studies that do not meet the definition of human research.

## II. Scope

This Procedure applies to all studies at the Albert Einstein College of Medicine (“Einstein” or “College of Medicine”) and Montefiore Medical Center (“MMC”) that do not meet the definition of human research.

## III. Definitions

**Human Research:** Any activity that is either:

- “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS; or
- “Research” as defined by FDA and involves “Human Subjects” as defined by FDA

**Research as Defined by DHHS:** Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

For the purposes of this Procedure, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus 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.
  - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
  - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or 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.

**Research as Defined by FDA:** FDA has defined "clinical investigation" to be synonymous with "research". "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA, or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

**Human Subject as defined by DHHS:** Human subject means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Note: With the implementation of the revised Common Rule, the requirement of the Newborn Screening Saves Lives Reauthorization Act of 2014 that federally-funded "research on newborn dried blood spots shall be considered research carried out on human subjects" is eliminated. Whether such research involves human subjects shall now be considered using the same standards as are used for other research involving human biospecimens (e.g., whether the identity of subjects may be readily ascertained, whether the specimens are coded and who has access to the key, whether the research involves the evaluation of the safety or effectiveness of an FDA-regulated device, etc.).

**Human Subject as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

## IV. Procedure

1. Studies that do not meet the definition of human research do not need to be submitted to the IRB, unless required for other institutional purposes. If the PI requires a formal determination from the IRB, they may submit the study via the Office of Human Research Affairs's (OHRA) electronic protocol submission system.
2. Investigators may consult with the OHRA for guidance if they are unsure if their project constitutes human subjects research.
3. Quality improvement (QI) projects, defined as projects with the intent to improve a practice or process within a particular institution or ensure it conforms with expected norms, do not meet the definition of human research.
  - a. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, however, an application must be submitted to the IRB for review at that time. Please see Appendix A for further guidance on determining whether a project constitutes quality improvement or human subjects research.
4. For submissions of studies that do not meet the definition of human research, the Principal Investigator is required to submit a protocol; consent form, if applicable; and other materials, as applicable.
5. IRB staff reviews the submission and requests clarifications or revisions, as necessary.
6. IRB staff will issue a formal determination to the Principal Investigator.
7. Studies that do not meet the definition of human research are given a 3-year approval period.
8. Amendment submissions are required for substantive changes to the protocol during the course of the study. The OHRA must determine if the amended study meets the definition of human research.

## V. Effective Date

Effective as of March 23, 2020

## VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.

## Appendix A: Quality Improvement Determination Guidance

The following questions may be helpful in determining whether a proposed activity is a QI project and does not meet the definition of human research. If all of the questions below can be answered as a Yes, IRB review is not required. If the answer to any of these questions is NO, please consult with the OHRA for assistance since IRB review may be required

	<b>Project Description</b>	<b>Yes</b>	<b>No</b>
<b>Purpose</b>	Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?		
<b>Scope</b>	Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?		
<b>Evidence</b>	Is there sufficient existing evidence to support implementing this activity to create practice change?		

<b>Clinicians/Staff</b>	Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?		
<b>Methods</b>	Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?		
<b>Sample/Population</b>	Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?		
<b>Consent</b>	Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?		
<b>Benefits</b>	Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?		
<b>Risk</b>	Is the risk to patients/participants no greater than what is involved in the care they are already receiving OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?		