

<b>Determining Whether an Activity Constitutes Human Research Requiring UMCIRB Review</b>	Effective Date	
	Revisions Date	01.21.2019

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish when an activity meets the definition of human research which requires review by the University and Medical Center Institutional Review Board (UMCIRB).
- 2.0 Persons Affected:**
- 2.1 Principal investigators (PI) and research team members
  - 2.2 UMCIRB members
  - 2.3 UMCIRB office staff members
- 3.0 SOP:** When ECU or its affiliates are engaged in an activity that meets the definition of human research, UMCIRB review is required. All human research must apply protections for human participants as mandated by regulations and standards set forth in federal, state and local laws and institutional policies. All proposed human research activities must be submitted to the UMCIRB **prospectively** for review and approval. Investigators must obtain UMCIRB approval prior to beginning any human research activities.

The UMCIRB also utilizes the Office for Human Research Protections (OHRP) guidance entitled “Guidance on Engagement of Institutions in Human Subjects Research” to determine when the institution is engaged in human research activities.

- 4.0 Definitions:**
- 4.1 Research** is a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.
- 4.1.1 Systematic** means methodical in procedure or plan and characterized by thoroughness and regularity.
  - 4.1.2 Generalizable** knowledge is that which can be applied to a larger group but is based on a smaller number of people within that group; used to draw general conclusions, add to a body of existing knowledge or create a new body of knowledge.
- 4.2 Human subjects** are living individual(s) about whom an investigator conducting research:
- 4.2.1** Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - 4.2.2** Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
  - 4.2.3** The Food and Drug Administration (FDA) defines a human subject as an individual who is or becomes a participant 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.
  - 4.2.4** The above definitions exclude non-living humans. Research that uses autopsy materials or cadavers is not ‘human subject research’ and therefore does not require IRB review.
- 4.3 Intervention** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.
- 4.4 Interaction** includes communication or interpersonal contact between investigator and subject.
- 4.5 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.
- 4.6 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

**4.7 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.

**5.0 Responsibilities:**

**5.1** UMCIRB Office staff are responsible for

**5.1.1** Providing guidance to researchers about human research and whether UMCIRB approval is needed.

**5.1.2** Seeking verification that an activity is not human research, when needed.

**5.1.3** Providing a confirmation letter that an activity is not human research, when requested.

**5.2** Investigators have the responsibility to

**5.2.1** Seek clarification from the UMCIRB office when unsure about whether an activity needs UMCIRB approval.

**5.2.2** Provide truthful and accurate information when seeking clarification about or verification that an activity is not human research.

**5.2.3** Inform the UMCIRB of any changes to their activity, previously determined to not meet the definition of human research, which may require UMCIRB review and approval.

**5.3** UMCIRB/UMCIRB Chairperson (or designee) will

**5.3.1** Provide verification that an activity is not human research when requested.

**6.0 Procedures:**

**6.1** UMCIRB Office staff receives information by phone, email and within the electronic application about activities to determine whether they meet the definition of human research.

**6.1.1** Clarifications and requests for further information with the requestor may occur in order to provide accurate guidance.

**6.1.2** UMCIRB staff may ask for verification from another staff member or the IRB Chairperson if there is any question about the determination.

**6.2** If the UMCIRB office staff determine that the activity does not meet the definition of human research, documentation can be provided if needed.

**6.3** If the planned activity is human research, the UMCIRB staff will request that it be submitted to the UMCIRB for approval in the usual manner.

**Revision History:**

Date	Change	Reference Section(s)
6.19.2015	Updated to stand-alone document.	All
01.21.2019	Common Rule revisions and process clarifications	4.0-6.0

**References:**

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

DHHS, OHRP. Guidance on Engagement of Institutions in Human Subjects Research

<http://www.hhs.gov/ohrp/policy/engage08.html>

Merriam-Webster Dictionary: <http://www.merriam-webster.com>

