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 Office of Research Integrity and Compliance (ORIC) 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 obtains:  
4.2.1 Data through intervention or interaction with the individual, or  
4.2.2 Identifiable private information.  
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 data 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.  
4.5.1 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.
5.0 Responsibilities:

5.1 ORIC 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 ORIC 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 ORIC of any changes to their activity, previously determined to not meet the definition of human research, that 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 ORIC 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.

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

6.3 If the determination is made that the activity does not meet the definition of human research, the ORIC will provide a letter indicating this to the requestor. If the activity is human research and has not been submitted in the electronic submission system, the ORIC staff will request that this be done so the human research study can be reviewed by the UMCIRB in the usual manner.

6.4 ORIC will keep record of activities determined not to be human research activities.

Revision History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<td>6.19.2015</td>
<td>1.0</td>
<td>Updated to stand-alone document.</td>
<td>All</td>
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References:

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

FDA. Code of Federal Regulations:

DHHS, OHRP. Guidance on Engagement of Institutions in Human Subjects Research
http://www.hhs.gov/ohrp/policy/engage08.html