# Clinical Research at Medical University of South Carolina (MUSC)

## *Determining Review Categories**

### Does the research involve human subjects?

(HHS Title 45 Part 46.102f)

Does the research involve obtaining:

1. Information through intervention or interaction with living individuals

OR

2. Identifiable, private information of living individuals

*HINT: do you interact with a living subject OR have access to information that can identify a living subject?*

*EXAMPLE*

**NO** → STOP

Your research may not involve human subjects.

Submit a Not Human Subject Research application to IRB for final determination

**YES**

### Is the research exempt?

(HHS Title 45 Part 46.101(b))

1. Conducted in established or commonly accepted educational setting, involving normal education practices?
2. Involves the use of educational tests, survey procedures, interview procedures or observation of public behavior where subjects can't be identified, there is no adverse risk in disclosing their responses **and** does not involve interaction with children?
3. Involves collection or study of **existing** (already existing for the duration of your study) data, documents, records or pathological or diagnostic specimens **and** information is publically available or recorded in a de-identified manner?
4. Studies, evaluates or examines public benefit or service programs?
5. Involves taste and food quality evaluation or consumer acceptance studies?

*HINT (applies to most of these criteria): do you plan to store information where subjects CANNOT be identified directly or linked with a code OR is the information already publically available?*

*EXAMPLE*

**YES** → STOP

Your research may be exempt.

Submit an Exempt Research application to IRB for final determination

**NO**

### Is the research expedited?

(HHS Title 45 Part 46.110)

Is the research minimal risk AND one of the following applies:

1. Studies drugs or medical devices under (a) or (b) below:
   a. Research on drugs for which an investigational new drug application is not required?
   b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling?
2. Collects blood samples via standard routes & quantities?
3. Collects prospective, biological specimens for research via non-invasive procedures?
4. Collects data via non-invasive standard practice procedures, excluding x-rays, microwaves or unapproved medical devices for safety, effective or indication?
5. Involves materials already collected (for research or non-research) or that will be collected solely for non-research purposes?
6. Collects voices, video, digital or image recordings for research purposes?
7. Collects data on human characteristics or behavior or research using only surveys, interviews, oral history, focus group, program or human factors evaluations, or quality assurance methods?

*HINT: are you performing research that does not require FDA oversight AND does not impose more risk to subjects than is experienced in everyday living or routine care?*

*EXAMPLE*

**YES** → STOP

Your research may be expedited.

Submit an Expedited Research application to IRB for final determination

**NO**

Your research may not be expedited.

Submit a FULL BOARD Research application to IRB for final determination

***Note: research classified as genetic research involving identifiable samples/data requires FULL BOARD Review***

v. 12/2010

*These are abbreviated criteria; see IRB policies for complete review criteria