Does My Project Require IRB Review?

University of Southern Mississippi Policy and Federal Regulations require that all USM faculty, staff, and students conducting human subjects research apply for and receive approval for their research projects prior to beginning the research. Human subjects research conducted prior to or without IRB approval must be terminated immediately and all collected data must be destroyed.

Not all data involving humans qualifies as human subjects research in the federally defined sense, however. Questions about what does and does not require IRB review hinge on two key terms – what counts as research involving *human subjects* and what counts as *research*. The guidance below is intended to help clarify these two terms, and sample scenarios of projects not qualifying as human subjects research are provided. Note also the decision trees posted on USM's IRB website: Decision Tree #1 and Decision Tree #2.

Regardless, if you are unsure of whether or not your project requires IRB review, contact the Office of Research Integrity at (601) 266-5997 or irb@usm.edu. Better safe than sorry!

1. Human Subjects

Federal regulatory definition of Human Subject:

"Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; *or*

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)(1)].

The reference to living individuals means that cadavers, autopsy specimens, or specimens/ information from subjects who are now deceased are not "human subjects." (The health information of deceased individuals, however, is protected under federal and some state regulations. If you plan to analyze health information of deceased individuals for your project, you should determine whether the health information

associated with the data is “Protected Health Information” (PHI) under the HIPAA Privacy Rule.)

The definition of identifiable private information:

“Private information for which the identity of the subject is or may readily be

- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

For more information about “coded” information, see https://www.hhs.gov/oh

To apply the definition of research to an activity, you must look at the "design" or the "intent" of the investigation, the researcher's relationship with the subjects, and how the data will be used.

Activities at USM that involve human subjects typically fall into one of three categories:

Research - the purpose of the activity is to contribute to "generalizable knowledge" and the data gathered may be shared with a research community or the public at large. USM considers any project conducted for an undergraduate honors thesis, a master's thesis or a doctoral dissertation to be research.

Evaluation/Assessment/Service/Reporting - the purpose of the activity is to gather data to measure the current situation in regards to a specific phenomenon or condition. Data gathered may be shared only with the sponsor/client/requesting parties or used for internal decision making or informational purposes.

Classroom Assignments/Educational Inquiry/Practice - th