**Process for Activities Involving Human Participants (*including use of identifiable human data*) that do not meet the Federal Definition of Research**

Research is defined according to the federal regulations at 45 CFR 46 **a systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge.**

Therefore, all of the following must apply in order for an activity to meet the federal definition of research. The activity must:

* involve a prospective plan which incorporates data collection, either quantitative and/or qualitative, and data analysis to answer a question, **and**
* be designed to draw general conclusions (i.e., the evidence base for the process, practice, or program is not yet firmly established or accepted; **and**
* not be dependent on the unique characteristics of the target population or system in which it will be implemented (e.g., as would be the case for quality improvement activities).

*Caveat: Undergraduate theses, honors’ theses, master’s theses, dissertations and doctoral program capstone projects with human subject participants are****expected****to meet all aspects of the definition above. As such, these activities should be submitted for Institutional exemption or IRB approval through the process outlined in the HRPP SOPs.*

**If individuals know that their activity do not meet the above definition, the individual is expected to meet institutional requirements for the ethical conduct of the activity.**

**If individuals are unsure if their activity meets the above definition (for example, with quality improvement activities and Student Scholarship Week activities) the individual should**:

* complete the Determination of Human Subjects Research Checklist for Institutional Review Board form and submit it to the IRB Office (currently via the IRB inbox at irb@monmouth.edu ).
* The IRB Office Staff (IRB coordinator and ORC director) will review the submission, document the review (on behalf of the Institution) on a determination checklist, and return their determination to the researcher.
* If the response is that the activity:
	+ DOES meet the definition of research, the researchers will be instructed to complete the MU HRPP/IRB Application for Review of Human Subjects Research.
	+ DOES NOT meet the definition of research, the individual will need to meet institutional requirements for the ethical conduct of the activity.

Please note that it is important to follow this outlined process because if a researcher proceeds to conduct human subject research without obtaining the required exemption from the Institution, or approval from the IRB, it could be considered noncompliance with institutional policy and/or federal regulations (respectively).