HRPP Guidance: Activities Not Under the Purview of the MUSC Institutional Review Board

The MUSC IRB is required by federal regulation to review projects that meet the definition of human subjects research. There are other types of activities undertaken by faculty, staff, and students that may not require IRB approval.

According to the 2018 Common Rule federal regulations [45 CFR 46.102(l)], it outlines the following as not involving human subjects research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

In addition, the following activities do not meet the definition of human subjects research requiring IRB review:

Case Reports:

A summary of clinical data, including medical history and other relevant information, that was collected initially for the purposes of analyzing and diagnosing the individual's condition and/or for instructional purposes, is considered by the IRB to be a 'case report' or 'case study'. Because this information was not collected with any intent to test hypotheses or otherwise produce 'generalizable' knowledge, the activity does not meet the criteria for 'research' (45 CFR 46.102(l)), and ordinarily does not require IRB oversight. It is the policy that the publication of case reports of three or fewer patients is NOT considered human-subject research and does NOT typically require IRB review and approval because case reporting on a small series of patients does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically for publication or presentation.

Although publishing a case report may not require submission to the IRB, authors of case reports should be aware of the use of individually identifiable health information in their publications. Under HIPAA, the disclosure of an individual's protected health information must be authorized by that individual. In other words, if a case report contains any identifiers as defined by the HIPAA regulations, authorization to disclose this information in a publication must be sought from the individual whose information is being disclosed. The subject must sign an authorization to disclose this information. When the report includes a description of a patient with a rare disorder, condition, or course of treatment, a HIPAA authorization will usually be required because those individuals may be more easily identified.

The MUSC Compliance office has posted Best Practices for Case Reports.

https://horseshoe.musc.edu/everyone/compliance/univ-compliance/research

Best Practices for Case Reports

To access the patient's medical record for case report activities, you will need the patient's approval. Patients should be asked to complete the MUSC HIPAA authorization/medical record release form and a photo consent form (if applicable). The patient must also be provided a copy of the MUSC Notice of Privacy Practices.

Authors are also directed to the CARES guidance: https://www.care-statement.org.

Program Evaluations

Program evaluations involve the systematic collection and analysis of information about the effectiveness of a program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. These evaluations may involve various methods of human interaction such as surveys, interviews, and the analysis of documents and background information. However, if the intent of these projects is to inform particular programs about that program's effectiveness and needs rather than to contribute to generalizable knowledge, they are not considered research. Nonetheless, there may still be ethical issues associated with program evaluations such as risks to participants and privacy and confidentiality concerns that should be considered by the investigator. If the evaluation aims to produce new knowledge and contribute that knowledge to a broader societal endeavor, IRB review is required.

Quality Improvement (QI) Projects

Quality improvement projects do not require IRB review and approval except when they involve "Research" as defined by the federal regulations). Precise definitions to permit the distinction between research studies and QI projects have not been established. In general, QI projects are focused primarily on improving patient care within a given patient care environment (e.g., hospital or health care organization) and, as such, the outcome of the project may not be generalizable to other patient care environments. Intent to publish a quality improvement project does not, per se, render that project "research"; however, if the outcome of a quality improvement project is published, attention should be given to avoiding "research terminology" in the publication. The MUSC QI Program Evaluation Self Certification Tool will assist in determining if your project requires IRB review.

Research *Vs.* Quality Improvement (QI)

	Research	QI
Purpose	To test a hypothesis OR to establish standards where none are already accepted	To assess or improve a process, program, or system OR improve performance as judged by established/accepted standards
Benefits	May or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit patients
Risks	May put subjects at risk	Does not increase risk to patients, except possible loss of confidentiality
Methods	Systematic data collection	Systematic data collection
Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards, or to establish internal benchmarks
Result	Answer a research question	Improves or creates a program/ process/system that results in greater safety, efficiency or satisfaction