

Overview of the IRB

Medical University of South Carolina



What is the IRB?

The IRB is a federally mandated body charged by federal law to protect the safety, rights, and welfare of Human Research Subjects.

What is research?

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102(I)].

Generalizable knowledge is where information can be applied to populations or situations beyond what is being studied.



What is a human subject?

A living individual about whom an investigator is conducting research:

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

Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens



Types of Applications and Levels of Review

1. Exempt
2. Expedited
3. Full Board

(Initial Studies, Amendments, Continuing Reviews, and Reportable Events)

*The MUSC IRB does not have
purview over Quality
Improvement Projects*

1. Exempt Research

- Less than minimal risk to subjects
- 6 Exempt research categories
- Does not mean exempt from initial IRB review
 - Requires determination from IRB Chair or his/her designee
 - “Exempt” from the requirements for continued IRB review
 - Reviewed on a first-come-first-serve basis

[IRB HRPP 3.2: Exempt Research Review Policy and Procedures](#)
[Guidance for Exempt Review Categories 2 & 4](#)

2. Expedited Research

- Minimal risk to subjects
- 7 Expedited research categories
- Does not mean “review light” or “fast approval”
 - Review by Chair or designee
 - Does not need to go to a Full Board Meeting
 - Reviewed on a first-come-first-serve basis

[IRB HRPP 3.3: Expedited Research Review Policy and Procedures](#)

3. Full Board

- Greater than minimal risk to subjects
- Reviewed by Full Board at a convened monthly meeting
 - Due one month prior to the next month's convened meeting

[IRB HRPP 3.4: Full Board Initial Review Policy](#)

[Meeting Dates & Deadlines](#)