



I. Policy

A. Introduction

MUSC has designated the MUSC IRB as the reviewer for the determination of “exemption” from the requirements for continued IRB review and monitoring. The determinations of exemption may be made by IRB administrative staff knowledgeable about this area of federal regulation, the IRB Chair or Vice Chair, or an IRB member. The IRB may not create new categories of exempt research.

B. Responsibilities of IRB Reviewer in Reviewing Exempt Research

1. Reviewers of exempt research are subject to the HRPP Program Guide Section 1.6 “IRB Governance and Operations Policy and Procedures” Subsection 4.11 *IRB Member Conflict of Interest Policy*.
2. No exempt research may proceed without written IRB approval.
3. While the Principal Investigator may request a particular category of exemption, the final determination will be made by the IRB administrative staff, the IRB Chair or Vice Chair, or an IRB member.

C. Regulatory Criteria for Exempt Research

1. The regulations found at 45 CFR 46.101(b) and 21 CFR 50.104 provide the criteria for studies that may be exempt from IRB review and approval.
2. Regardless of the exempt status, the MUSC IRB requires that any research involving human subjects be conducted in an ethical manner with scientific rigor and respect for subjects.
3. The conduct of exempt research is subject to all applicable MUSC policies, IRB policies, and appropriate federal and state laws and applicable Health Insurance Portability and Accountability Act (HIPAA) regulations.
4. When reviewing exempt research applications, IRB reviewers will give special consideration to research that may raise ethical consideration and evaluate whether the research upholds MUSC’s

ethical standards. When conducting such reviews, issues such as the level of risk, the equitable selection of subjects and provisions to maintain the privacy interests of participants and confidentiality of the data must also be adequately addressed. If there are interactions with participants, the IRB should determine whether there should be a consent process that will disclose such information as the activity involves research, a description of the procedures, the participation is voluntary and the name and contact information for the researcher.

5. The Principal Investigator is responsible for assuring that the research is carried out in an ethical manner that includes appropriate subject protections.
6. A new application must be submitted before a Principal Investigator can proceed with any modifications to an exempt research study. Certain changes may disqualify the research from exempt status; therefore, Principal Investigators should consult with the IRB whenever questions arise about whether planned changes to an exempt study may change the required level of IRB review.
7. Exempt studies are expired by the IRB five years after the initial date of approval. The Principal Investigator must submit a new application to extend the study.

D. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

II. DETERMINATION OF EXEMPTION AND REVIEW PROCEDURES

A. HHS Exempt Research Categories (45 CFR 46.101(b))

Unless otherwise required by department or agency heads, HHS Regulatory Provisions allow exemption from federal policy for the protection of human subjects when the only involvement of human subjects falls within one or more of the categories below:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior; unless: (i) information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. (The Department of Veterans Affairs (VA) also includes loss of insurability in this category.)

The only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the Principal Investigators do not participate in the activity being observed.

To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

3. Research not exempt under 2 above may be exempt if: (i) the human subjects are elected or appointed public official or candidates for public office; or (ii) federal statute(s) require(s) with exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter (e.g., Department of Justice or National Center for Educational Statistics).
4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Principal Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. To qualify for this exemption, the data, documents, records or specimens must be in existence before the project begins.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency head and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

DHHS Guidance for this category of exempt research stipulates:

- a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
 - b) The research or demonstration project must be conducted pursuant to specific federal statutory authority.
 - c) There must be no statutory requirements that the project be reviewed by an IRB
 - d) The project must not involve significant physical invasions or intrusions upon the privacy of participants.
 - e) The exemption should have authorization or concurrence by the funding agency.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: None of the exemption categories in the HHS regulations for research involving human subjects apply to research involving prisoners.

B. FDA Exempt Research (21 CFR 56.104)

The FDA provides only three types of exemption:

1. Research started before July 27, 1981, and either did not require FDA approval before that date, or, was subject to requirements for IRB review prior to that date, and remains subject to review by and IRB which meets FDA requirements.
2. Emergency use of a test article, provide any such use is reported to the IRB within five (5) working days and any future use of the test article at the institution is subject to IRB review.
3. The taste and food quality evaluation provided in category six of the HHS regulations.

NOTE: For VA- Regulated Research: Human subjects research cannot be qualified as exempt under this policy if any disclosure of the participant's responses outside of the research could reasonably place the participants at risk of loss of insurability.

III. PROCEDURES

- A.** The Principal Investigator identifies the exemption category and submits supporting data as appropriate.
- B.** The IRB administrative staff, IRB Chair, Vice Chair or IRB member will conduct a review of the project to determine if it qualifies for exempt status according to IRB policy and human subjects research regulations. Request for revisions and/or clarifications will be entered electronically along with the study team responses.
- C.** If there are no questions/concerns, or if responses are satisfactory, and the research as described on the application fits the exempt criteria, the Reviewer will electronically approve the application and the approval letter will be generated.
- D.** If the reviewer makes the decision that the research does not fit the exempt criteria, then the IRB staff will notify the study staff that exempt status has not been approved. The study staff will be provided with the rationale for this decision and of the need to submit the research study for expedited or full board review.
- E.** The applications submitted for exempt consideration are evaluated based upon the DHHS and FDA criteria for exempt research determinations in subsection 3.
- F.** At each meeting, minutes of the previous meeting are available to all IRB members. Exemption determinations are included in the "Report of Expedited, Exempt, Acknowledged Items" of the minutes.

IV. REFERENCES

- A.** [HHS Exempt Research Categories \(46.106\(b\)\)](#)
- B.** [FDA Exempt Research \(21 CFR Part 56.104\)](#)