

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 the IRB Chair or Vice Chair, or an IRB member.

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 the IRB Chair or Vice Chair, or an IRB member.

C. Regulatory Criteria for Exempt Research

1. The regulations found at 45 CFR 46.104 and 21 CFR 56.104 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. Limitations on Exemptions

Children: Exemptions #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children

Prisoners: Exemptions do not apply EXCEPT for research aimed at involving broader subject populations that only incidentally includes prisoners (45 CFR 46.104(b)(2))

E. 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 46.104(d))

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, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (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.); or
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7). *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”*

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.

3.

i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7). *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”*

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the

subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - i. The identifiable private information or identifiable biospecimens are publicly available;
 - ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels

of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
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.

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 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 \(45 CFR 46.104\)](#)
- B. [FDA Exempt Research \(21 CFR Part 56.104\)](#)