The 2018 Revised Common Rule:

Exempt Guidance

Criteria for Exemption

The Designated Reviewer determines if the proposed research is exempt from federal policies governing human subject protections. This determination is made in accordance with:

- The OHRP Decision Chart #2- "Is the Research Involving Human Subjects Eligible for Exemption under 45 CFR 46.104(d)?"
- The criteria for exemption as specified under 45 CFR 46.104 (d)(1), (d)(2), (d)(3), and (d)(4) and 21 CFR 56.104(c) and (d). If an investigator wishes to request an exemption under 45 CFR 46.104(d)(5) or (d)(6), they are instructed to contact the HRP for guidance. The criteria for exemption under 45 CFR 46.104(d)(7) and (d)(8) will not be utilized as the concept of broad consent is not implemented at MUSC at this time.
- If subjects are under the age of 18 years, the exemption criteria described in 45 CFR 46.104(d)(2)(i) and (ii), may only apply when the research is limited to (a) the use of educational tests or (b) to observations of public behavior when the investigator does not participate in the activities being observed.
- The exemption criteria in 45 CFR 46.104(d) do not apply to studies involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- The exemption criteria [with the exception of 45 CFR 46.104(d)(6) / 21 CFR 56.104(d)] do not apply to FDA-regulated research studies.

Limited IRB Review

For exemptions under Criteria 2 (iii) and Criteria 3(i)(C), the Designated Reviewer will conduct a limited IRB review to determine that the study is no more than minimal risk and to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data as required by 45 CFR 46.111 (a)(7). A Designated Reviewer conducting a limited review may not disapprove research.

Breaking down the exempt categories 1-8 (45 CFR 46.104)

Exempt Research Category 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."

Applicability to vulnerable populations:
-Pregnant women may be included in this type of research.
-Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
-Research involving children is eligible for this exemption.

Exempt Research Category 2
(Educational tests, surveys, interviews, observation of public behavior)

The 2018 changes to the Common Rule provide additional flexibility with regard to the kind of information that can be collected in survey/questionnaire research under exempt review.

NOTE: 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.

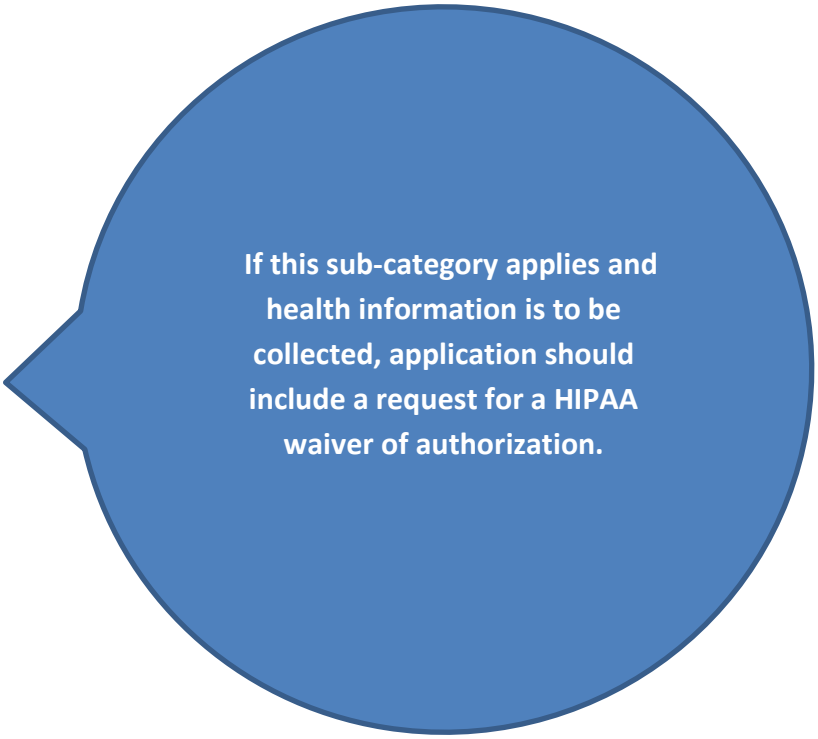
The regulation:

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation 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 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

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 §46.111(a)(7).



Exempt Research Category 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 46.111(a)(7).

(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.

Applicability to vulnerable populations:
-Pregnant women who are adults *may* be included in this type of research
-Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
-Research that could include children is *not* eligible for this exemption.
-Research involving decisionally-impaired persons is *not* eligible for this exemption.

Exempt Research Category 4
(Secondary research)

Perhaps the most impactful procedural change as a result of the Revised Rule relates to secondary research, i.e. retrospective chart review studies. Many of these were previously reviewed as expedited and may now be eligible for exempt review under Category 4.

Two things now allowable under exempt review which were not included previously:

- Recording of HIPAA identifiers or links to identifiers for information collection studies
- Use of not yet existing or not currently "on the shelf" data

Note that secondary use of identifiable biospecimens in which the researcher would like to document/retain a link between the identifiers and the specimen is still not allowed under Category 4 –those must still be reviewed via expedited review.

The regulation:

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;

Secondary research under this sub-category must be recorded in a non-identifiable manner.

This sub-category allows secondary research use of identifiable health information. IRB application should include a HIPAA waiver of authorization request when this sub-category applies. Note that category 4 iii specifies "only information collection". Research involving storage of identifiable biospecimens must still be submitted for expedited review.

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, 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, 5 U.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.

Exempt Research Category 5

Research that qualifies under this category must be on federal programs and subject to the approval of federal department or agency heads. Local or state programs do not qualify under this exemption (though it may fall under another exemption category). If your research is eligible for this exemption, the federal agency will generally provide a letter indicating such or post the information on a public website.

Exempt Research Category 6

Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use 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.

Exempt Research Category 7 and 8

These exemptions are not available at MUSC.