IRB Exempt Research

Exemption Categories

Revised 12/12/2022

All research activities at Morgan State University involving human subjects are subject to approval and overview by the Internal Review Board (IRB).

There are currently eight (8) categories of Exemption from IRB overview. The categories of Exempt research are defined by federal regulations. They are a subset of minimal risk research involving human subjects that does not require approval by an IRB. However, they do ***require*** a review and a final determination by the IRB.

The MSU IRB is responsible for reviewing and granting all determinations of Exempt human subjects research.

Exemption #1: EDUCATIONAL EXEMPTION [45 CFR 46.104(d)(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.

Exemption #2: SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR [45 CFR 46.104(d)(2)]

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).

Exemption #3: BENIGN BEHAVIORAL INTERVENTION [45 CFR 46.104(d)(3)(i)]

A "benign intervention" is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact.

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:

(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).

Exemption #4: SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION / BIOSPECIMENS) [45 CFR 46.104(d)(4)]

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 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).

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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.

Exemption #5: PUBLIC BENEFIT / SERVICE PROGRAM RESEARCH [45 CFR 46.104(d)(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.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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.

Exemption #6: TASTE/FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE [45 CFR 46.104(d)(6)] – remains unchanged

(i) If wholesome food without additives are consumed; OR

(ii) 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 Good Safety and Inspection Service of the U.S. Department of Agriculture.

Exemption #7: STORAGE/MAINTENANCE OF IDENTIFIABLE BIOSPECIMENS WITH BROAD CONSENT [45 CFR 46.104(d)(7)]

This category covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for non-research purposes or for research other than the current research proposal. The Exemption can only be used when there is broad consent from the participants for the storage, maintenance, and secondary research use of their identifiable materials if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8)

Exemption #8: USE OF IDENTIFIABLE DATA / BIOSPECIMENS OBTAINED WITH BROAD CONSENT [45 CFR 46.104(d)(8)]

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.