

Certified Exempt Research	Effective Date	
	Revisions Date	12.1.2019

1.0 Purpose: The purpose of this standard operating practice (SOP) is to establish guidelines for the recognition, review and certification of human research activities that are exempt from federal regulations.

2.0 Persons Affected:

- 2.1 Individuals engaged in human research activities
- 2.2 UMCIRB Chairperson (or designees) and members
- 2.3 UMCIRB Office staff and administrators

3.0 SOP: Determination of whether human research activities can be certified as exempt is made by the UMCIRB Chairperson (or designee), acting on behalf of the UMCIRB, prior to the research being carried out. Human research determined to be Exempt shall be conducted in a manner consistent with the ethical principles set forth by the Belmont Report, the Nuremberg Code, and all state laws and institutional policies, rules, and regulations. The UMCIRB does not require any routine exchange of information related to exempt research, nor is routine continuing review performed.

4.0 Definitions:

4.1 Listed below are the criteria for protocols to be classified under an exempt status at ECU:

4.1.1 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:

- (a) Most research on regular and special education instructional strategies and
- (b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;

4.1.2 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:

- (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, e.g. coding numbers;
- (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the individual at risk of criminal or civil liability or be damaging to the person's 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.

- 4.1.3** 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.

* 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.

- 4.1.4** 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:
- (a) The identifiable private information or identifiable biospecimens are publicly available;
 - (b) 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;
 - (c) 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" or for "public health activities and purposes"; or
 - (d) 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.

4.1.5 Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine:

- (a) Public benefit or service programs (specifically, Social Security, Medicare, and Medicaid programs);
- (b) Procedures for obtaining benefits or services under those programs;
- (c) Possible changes in or alternatives to those programs or procedures; or
- (d) Possible changes in methods or levels of payment for benefits or services under those programs;

4.1.6 Taste and food quality evaluation and consumer acceptance studies if

- (a) Wholesome foods without additives are consumed, or
- (b) 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

4.1.7 The above exempt categories are applicable to Subpart D, which provides for additional protections of children involved as participants in research except for 4.1.2 and 4.1.3 above.

4.1.7.1 The exemption at 4.1.2 (a) and (b) may apply to research in children involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The exemption at 4.1.2 (c) does not apply to research involving children.

4.1.8 The above exempt categories are not applicable for human research activities involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

4.2 Additional **FDA exempt status** requirements include:

4.2.1 Any human research activity which started before July 27, 1981 and at that time was subject to requirements for IRB review under FDA regulations, provided that the investigation remains subject to review of an IRB.

4.2.2 Any human research activity that started before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

4.2.3 Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

4.2.4 Taste and food quality evaluations and consumer acceptance studies, if

4.2.4.1 wholesome foods without additives are eaten;

4.2.4.2 a food is eaten that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration; or

4.2.4.3 a food is eaten that contains an 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.

4.3 Limited IRB Review ensures there are adequate provisions for protecting privacy and maintaining confidentiality and provides privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm.

4.4 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.

5.0 Responsibilities:

5.1 Principal Investigators are responsible for:

5.1.1 Submitting an initial application for review to the UMCIRB.

5.1.2 Initiating certified exempt research after receiving written certification of concurrence from the UMCIRB.

5.1.3 Ensuring the human research involves no more than minimal risk and falls into an exempt category in order to receive certification of exemption.

5.1.3 Providing adequate provisions for protecting the privacy interests of participants.

5.1.4 Equitable selection of participants.

5.1.5 Adhering to approved consent requirements, if applicable.

5.1.6 Submitting any changes e.g., confidentiality, consent, risk profile, etc. to the UMCIRB for review and approval prior to being initiated.

5.1.6.1 The research project may be elevated from exempt to expedited or requiring full UMCIRB review after initial approval, based on new information or regulatory guidance changes.

5.1.7 Submitting any serious and unanticipated risks to participants or others to the UMCIRB.

5.2 UMCIRB Chairperson (or designee) is responsible for:

5.2.1 Reviewing applications for exempt research to confirm the exempt category.

5.2.2 Raising any pertinent ethical, administrative or procedural issues surrounding the research.

5.3 UMCIRB Office staff are responsible for:

5.3.1 Pre-reviewing and raising any issues related to the research and communicating those issues to the investigator and other appropriate individuals.

5.3.2 Forwarding an official determination letter that the study has been confirmed to meet an exempt criterion.

- 5.3.3 Retaining records on exempt protocols for a minimum of 3 years after the certification date of the research.
- 5.3.4 Reporting all exempt certifications to the UMCIRB members by reporting these in the IRB minutes.

6.0 Procedures:

- 6.1 Studies that are determined to be exempt can still raise ethical concerns, and these should be considered. Potential areas of concern include methods of recruitment, communication with subjects, consent to participate in the exempt research, and use of the data. The UMCIRB is not required to exempt studies that appear to meet exemption criteria if they raise serious ethical concerns.
- 6.2 While the federal regulations related to human research protections do not require specific consent processes and elements like those required for non-exempt studies, the UMCIRB committees endorse the Respect for Persons principle within the Belmont Report. This includes providing adequate information about a research study to the potential participant in order for them to make a voluntary decision to participate. This can still be a simple process of consent, such as providing a brief paragraph about the research before a participant completes a survey or a letter describing a study to parents of school-aged children.
 - 6.2.1 Participant agreement prior to carrying out human research activities is always preferred when prospectively interacting or intervening with participants.
 - 6.2.2 There may be some Exempt studies where an opt-out consent could be utilized, such as research using educational data from a very large number of students.
 - 6.2.3 Otherwise, the UMCIRB would review waiving consent by similar standards as for non-Exempt studies (see Waiver or Alteration of Informed Consent SOP).

Revision History

Date	Change	Reference Section(s)
12.5.2013	Updated to stand-alone document.	All
1.21.2019	Updated Exempt categories based on revised regulations	Section 4.0

References

DHHS, OHRP. [Code of Federal Regulations](#).

FDA. Code of Federal Regulations:

[Protection of Human Subjects](#)

[Institutional Review Boards](#)