Department: UAMS Institutional Review Board
Policy Number: 7.3
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date: May 7, 2004; February 8, 2005; June 1, 2005; January 24, 2011, January 19, 2019; October 15, 2024

SUBJECT: Exempt Categories of Research

I. Purpose

The purpose of this policy and procedure is to set out the criteria for studies classified as Exempt under the Federal Regulations

II. Policy

UAMS requires all Human Research, including studies meeting one of the Exempt categories, to be submitted for review and approval by the IRB. No Investigator or Department shall have the authority to make this decision other than the IRB.

Exemption determinations may be made by an IRB Chair; Experienced IRB Reviewer as defined in IRB Policy 7.5; or qualified IRB staff, collectively referred to as "Reviewer" in this policy.

Exemption determinations may not be made by an individual with a Conflict, as defined in IRB Policy 3.8.

All research, including that in the Exempt categories, must meet the ethical principles outlined in the Belmont Report. The Reviewer may require additional protections to meet these principles, including, but not limited to, a level of informed consent appropriate to the research or additional confidentiality or privacy measures.

Studies receiving an Exempt classification will be required to submit a Study Update annually to keep the study open. The IRB shall be notified of and approve any changes in the study scope or design prior to implementation of the changes to insure that the study continues to meet the Exempt Criteria.

These exemptions may be applied to research involving pregnant women, fetuses, and neonates subject to Common Rule Subpart B.

These exemptions do not apply to research involving prisoners subject to Common Rule Subpart C, except for research intended to involve a broader subject population that only incidentally involves prisoners.

These exemptions do not apply to FDA-regulated research.

The exemptions described at categories 1, 4, 5, 6, 7, and 8 below may be applied to research involving children subject to Common Rule Subpart D.

III. Exempt Categories

1. Research, conducted in established or commonly accepted **educational settings**, involving normal educational practices unlikely to adversely impact students' opportunity to learn required educational content or the assessment of educators providing instruction. This includes most research on regular and special education instructional strategies, or 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 observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. Information obtained is recorded such that the human subjects' identity 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 such that the identity of the human subjects can readily be ascertained, either directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

NOTE: The section of this category pertaining to educational tests may be applied to research involving children. The section pertaining to the observation of public behavior may be applied to research involving children when the investigator(s) do(es) not participate in the activities being observed. This exemption is not applicable to survey or interview research involving children or to research subject to 2c involving children.

3. Research involving benign behavioral interventions and the collection of information from adult subjects 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. Information obtained is recorded such that the human subjects' identity 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 such that the human subjects' can readily be ascertained, either directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

NOTE: Benign behavioral interventions are brief, harmless, painless, not physically invasive, unlikely to have a significant adverse lasting impact on subjects, and there is no reason to think subjects will find the interventions offensive or embarrassing. Examples include having subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a small amount of received cash between themselves and others when these criteria are met.

NOTE: This exemption does not apply to research involving deceiving the subjects about the research's nature or purposes, UNLESS the subject authorizes the deception by prospectively agreeing to participate after being informed they 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 use 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 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 reidentify subjects;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information for the purposes of "health care operations", "research", or "public health activities and purposes" as described under the HIPAA regulations; or
d. The research is conducted by, or on behalf of, a Federal department or agency using government -generated or –collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology 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.*

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 (or the approval of the heads of bureaus or other subordinate agencies delegated authority to conduct the research and demonstration projects) and designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those program, 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.

The research or demonstration project may not begin before the Federal department or agency lists project on a publicly accessible Federal Web site or such other manner as determined by department or agency.

6. Taste and food quality evaluation and consumer acceptance studies if:
a. wholesome foods without additives are consumed or
b. 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.

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7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by the approval criteria for "broad consent" studies.

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:
a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with), the applicable regulatory sections of the general requirements for informed consent;
b. Documentation of informed consent or waiver of documentation of informed consent was obtained in accordance with applicable regulatory section for documentation of informed consent;

c. An IRB conducts a limited IRB review to determine that, when appropriate, there is adequate provision to protect the privacy of subjects and to maintain data confidentiality and that that the research is within the scope of the broad consent as described above; and
d. The investigator does not include returning individual research results as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

IV. Procedure

A. The Investigator will:
   1. Submit a protocol and application through the electronic submission system, including all recruitment and consent material, surveys, questionnaires or other instruments to be used.
   2. Provide any additionally requested information.
   3. Submit any proposed or anticipated changes to the IRB, through the electronic submission system, prior to implementation.
   4. Submit an annual Exempt Study Update Form through the electronic submission system to keep study open.

B. The Exempt Reviewer will:
   1. Review requests for exemption and request additional information or modifications in order to ensure the study is conducted ethically.
   2. Document which exempt category applies to the study in the electronic system and the approval letter, or notify the investigator the study will require review using either Expedited or Full Board procedures.