

Exempt Research Categories

Category 1 - Education Research

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.

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. Research must not extend testing time or otherwise impact class time, normal education practices, or result in additional testing not currently used in the school.

- Children can be included in this category of research.

Examples:

- Evaluating a new curriculum or delivery methodology
- A study comparing two curricula that are currently being implemented.
- A study which involves interviewing teachers about their experiences or perceptions on the implementation of new classroom management, teaching strategies, or instructional techniques.

Category 2 - Surveys, Interviews, Educational Tests, and Public Observations

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; or
 - Data is either collected anonymously or data is recorded so that subjects cannot be identified.
 - Video/audio recordings and photographs are considered identifiable. Any data collection that involves these activities is not anonymous or de-identified.
 - Demographic questions can be combined to lead to subjects being identifiable, researchers should ensure they are only collecting data they need for their research and recognize if a limited subject pool could result in deductive disclosure of subject identity.
 - 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
 - Participants may be identified from data collected but the information is harmless that there would be no negative consequences to subjects in the event of disclosure.
 - 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).
 - Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects (but is still minimal risk). The IRB will conduct a limited review to determine adequate provisions or protecting privacy and confidentiality are in place.
- Children can be included when research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement) or when the investigator will observe public behavior but does not participate in that behavior or activity.
 - Children cannot be included when research will involve the use of survey procedures, interview procedures, or observation of public behavior when investigators will be involved in the activity.

Examples:

- Conducting an anonymous survey of workplace satisfaction
- Conducting a focus group about an experience or program
- Interviewing with college students regarding their plans after college
- Administering a numerical aptitude test and a working memory cognitive test to children
- Observing elementary children playground interactions, as long as the investigator has no involvement or does not manipulate the environment in any way

Category 3 - Benign Behavioral Interventions

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 is recorded without direct or indirect identifiers;
- ii. Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability); or
- iii. The information is recorded with either direct or indirect identifiers, and there are adequate protections in place for protecting privacy and maintaining confidentiality (requires limited IRB review).

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.

If the research involves deceiving subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject is informed in advance that he or she will be unaware of or misled regarding the nature or purposes of the research.

- Children cannot be included in this category of research.

Examples:

- Having subjects play an online game and then answer questions about it, game play is 30 minutes
- Video recording subjects solving puzzles under various noise conditions, study takes about 2 hours
- Subjects are asked to complete assessments of memory and attention before and after 1 hour of cognitive exercise
- Having subjects decide how to allocate a nominal amount of received cash between themselves and someone else

Category 4 - Secondary Data or Specimen Research that Does Not Require Consent

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 by the HIPAA Privacy Rule as health care operations, research or for public health activities and purposes as defined in HIPAA; 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 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 federal standards for safeguarding privacy

This category will allow secondary uses of information and biospecimens that are not pre-existing at the time that the investigator begins a particular research study.

Examples:

- Analyzing publicly accessible Facebook posts (criteria i)
- An investigator receives an anonymous dataset from a registry (criteria ii)
- Analyzing anonymous waste tissue samples (criteria ii)
- Analyzing medical records of patients when the data is not shared outside the HIPAA Covered Entity and when consent is not required (criteria iii)
- Conducting analyses of national student exam scores at the request of (or under contract to) the Department of Education (criteria iv)

Category 5 - Public Benefit or Service Program Research

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, possible changes in methods or levels of payment for benefits or services under those programs.

Note: Projects eligible for exemption under this category will be posted on the applicable federal agency's website

Examples:

- Initiating and evaluating a program supported by a Federal grant that administers financial or medical benefits under the Social Security Act.
- A state department received a federal award to administer a demonstration project with the state Medicaid services. The VCU investigator will evaluate the program as a consultant for the state department.

Category 6 - Taste and Food Quality Evaluation and Consumer Acceptance Studies

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 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.

Notes about involving children:

- Children can be included in this category of research.

At this time, UWG is NOT implementing exemption categories 7 and 8.