



DEFINITIONS:

Research - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Not Research –

- a. Scholarly and journalistic activities (e.g. Oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- b. Public health surveillance activities, including the collection and testing of information or bio-specimens, conducted, supported, requested, ordered, required, or authorized by a [public health authority](#). Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- c. Collection and analysis of information, bio-specimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research; Obtains information or bio-specimens through [intervention](#) or [interaction](#) with the individual, and uses, studies, or analyzes the information or bio-specimens. **OR** Obtains, uses, studies, analyzes, or generates [identifiable private information](#) or [identifiable bio-specimens](#).

Helpful Definitions:

- a. Intervention - Includes both physical procedures by which information or bio-specimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- b. Interaction - Includes communication or interpersonal contact between investigator and subject.
- c. Private Information - Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- d. Identifiable Private Information - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- e. Identifiable Bio-specimen - A bio-specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the bio-specimen.

Public Health Authority - An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian Tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Clinical Trials - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

IRB Review Determination:

Exemption:

Note:

- The exemptions listed below may be applied to research subject to Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in research.
 - The exemptions listed below **do not apply** to research subject to Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
 - Exemptions 1, 4, 5, 6, 7, and 8 may be applied to research subject to Subpart C – Additional Protections for Children Involved as Subjects in Research. Exemption 2(a) or 2(b) only may apply to research involving children when educational tests or the observation of public behavior occurs when the investigator(s) do not participate in the activities being observed. Exemption 2(c) **may not** be applied to research involving children.
1. The research will be conducted only in established or commonly accepted educational settings (like classrooms) **AND** it 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 the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 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 is met:

- a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;
 - b. Any disclosure of the human subject's response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation;
 - 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 Section .111 (a) (7)
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response (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 be readily ascertained, directly or through identifiers linked to the subjects;
 - b. Any disclosure of the human subject's response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation;
 - 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 Section .111 (a) (7)

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. Examples being: video games or doing puzzles under various noise conditions.

If the research involves deceiving the subjects regarding the nature or purpose 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. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio-specimens if at least one of the following criteria are met:
 - a. The identifiable private information or identifiable bio-specimens are publicly available;
 - b. Information, including information about bio-specimens, 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 the 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 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 or purposes as described under 45 CFR 164.512(b);
 - d. The research is conducted by, or on behalf of, a federal department or agency using 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;
 - i. 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 a systems of records subject to the privacy act of 1974.
 - ii. 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 that 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 public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes 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 the sections 1115 and 1115A of the Social Security Act, as amended.
 - a. Each Federal department conducting or supporting the research and demonstrating projects must establish, on a publicly accessible Federal Website or in such other

manner as the department or agency head may determine, a list of the research and demonstration projects the Federal department or agency conducts or supports published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
 - a. If wholesome foods without additives are consumed;
 - b. If a food is consumed that contains a food ingredient at or below the level and for the 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 Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable bio-specimens for potential secondary research use if an IRB conducts a limited review and makes the appropriate determinations required by Section .111 (a) (8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use if the following criteria are met:
 - a. Broad consent for the storage maintenance, and secondary research use was obtained in accordance with Section .116(a)(1) through (4), (a)(6), and (d);
 - b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Section .117;
 - c. An IRB conducts a limited IRB review 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;
 - d. 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.

Expedited:

Must involve no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Clinical studies of drugs and medical devices only when certain conditions are met. See 63 FR 60364 for more information.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
 - a. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) excreta and external secretions (including sweat); (c) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (d) placenta removed at delivery; (e) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (f) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (g) sputum collected after saline mist nebulization. See 63 FR 60364 for more examples.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
 - a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt).

Full Board:

If your research does not meet the criteria to be considered for Exempt Review, Exempt with Limited Review, or Expedited Review then it must be submitted as a Full Board Review.