

Exempt Research

Background

Federal regulations designate certain types of research involving humans as being exempt from many of the regulatory requirements governing human subjects research, and thus subject to fewer IRB review requirements. It is important to note that exempt research requires submission to the IRB office for formal certification of exemption. Some exempt research is also subject to “limited IRB review” by an IRB member to assess privacy and confidentiality protections. In all cases, human subjects research activities may not commence until a formal written certification of exemption is received by the principal investigator. This document outlines:

- [Eligibility for Exemption Certification](#) under both the 2018 Common Rule and the pre-2018 Common Rule
- [Submission Requirements for Exempt Research](#)
- [Limited IRB Review](#)
- [Key Ethical Responsibilities](#) of Investigators (e.g., informed consent, promoting voluntariness, protecting privacy and confidentiality)

Exempt Research Defined

Eligibility for Exemption Certification

To be eligible for exemption, research must meet all of the following conditions:

1. Research presents little to no risk of harm to participants; AND
2. All research procedures fit into one or more of the regulatory exemption categories (described [in the table below](#)); AND
3. Confidentiality of participants will be protected when results are disseminated (no deductive disclosure or re-identification concerns); AND
4. The research does not include prisoners. Research with prisoners reviewed under the 2018 Common Rule may be exempt if the research is intended to involve a broader population, and only incidentally includes prisoners.

Submission Requirements for Exempt Research

Principal investigators (PIs) may request exemption certification through one of the following methods in OneAegis (formerly IRBManager):

1. An IRB Application -- The typical process involves completing and submitting an IRB application through OneAegis (formerly IRBManager) for review by IRB staff. There is not a separate application for exempt studies; rather, the IRB Application is conditioned to show questions related to exempt status. In most instances, submission of data collection, recruitment, and consent materials is not required.

If the IRB reviewer determines that the project does not qualify for exemption, the application will be returned to the PI for completion of questions applicable to non-exempt research.

2. The Exempt Review Wizard – a subset of exempt research is [eligible](#) for submission and automated certification of exemption through the [Exempt Review Wizard](#). The Wizard is available in OneAegis (formerly IRBManager).

Limited IRB Review

Limited IRB review is a process required by the 2018 Common Rule for certain exemptions. It requires review by an IRB member to assure that privacy and confidentiality protections are adequate for research where the primary risks to subjects relate to harm from disclosure of their information. Investigators are routinely asked to provide information about privacy and confidentiality protections in IRB applications for exempt research. Thus, the Limited IRB Review process should not affect investigators.

Key Ethical Responsibilities

To facilitate streamlined review, IRB applications for exempt research are intended to collect only the information necessary to determine that exemption is allowable and that key ethical considerations are addressed. Researchers are not required to provide extensive detail about recruitment or informed consent processes. However, all ISU research—even that eligible for exemption—must adhere to basic ethical standards that protect and respect research subjects. Essentially, research participation must be *informed, voluntary, and the lowest-risk possible*.

Promoting Voluntariness

Participation in research **MUST ALWAYS** be voluntary. Voluntariness is compromised when prospective subjects feel pressure to participate, even when such pressure is inadvertent. This is particularly an issue when researchers hold a [position of power](#) over prospective subjects (e.g., as their teacher, supervisor, etc.). It can also occur when participants feel that participation in research is required to receive services or other benefits (e.g., medical treatment, financial support, etc.).

Researchers must design recruitment and informed consent processes that mitigate pressure to participate. Participants must be explicitly informed that participation is voluntary; when applicable, they should also be told that participation is not required to access services or treatment, receive a specific grade, etc. See IRB Guidance on [Participant Recruitment](#) and [Vulnerable Populations—Subordinates](#) for additional information on ethical considerations.

Informed Consent for Exempt Studies

Informed consent is a cornerstone principle of ethical human subjects research. Researchers must ensure prospective participants receive information about the study, sufficiently detailed to facilitate a truly informed choice. This ethical obligation exists for all research—exempt and non-exempt. Federal regulations outline formal informed consent requirements for non-exempt research. Research confirmed as meeting the criteria for exempt review (i.e., “exempt research”) is not subject to those formal requirements, allowing PIs flexibility in how informed consent is obtained.

While the use of a formal informed consent form containing all the elements of consent is not required for exempt research, the Iowa State University IRB expects researchers to provide information about the research to prospective participants (and their parent/legal guardian, when applicable) prior to their enrollment in the study.

See [Informed Consent for Exempt Studies](#) for details about information to provide, options for consent processes, and wording examples.

Privacy and Confidentiality Protections

Protecting participant privacy and maintaining confidentiality of their information is critical. Many conditions for exemption require assessment of privacy and confidentiality protections. Best practices vary based on the nature of the research. Examples include, but are not limited to:

- Limit information collected to only that necessary to address the research questions (only collect what you need)
- Avoid collecting identifiable information (including electronic identifiers) unless it is necessary
- Ensure privacy during data collection by:
 - conducting interviews in private settings to prevent others from overhearing responses
 - providing mechanisms for private return of surveys (sealed envelopes, lock boxes, etc.)
 - encourage participants to use personal accounts (not work accounts) for study-related communications
 - instruct participants to avoid sharing identifiable information in open-ended responses when it is not necessary for the research
 - devise plans to keep participant information secure while in the field or during transmission
- Consider any special issues with online recruitment and data collection; employ practices such as
 - enabling anonymity features in online survey platforms
 - collecting emails for compensation drawings separately from responses (e.g., a separate Qualtrics survey)
 - avoiding social media use if research topics are sensitive or where persons' characteristics could be inadvertently revealed through commenting; disable tagging and commenting
 - using the blind copy email function when sending mass emails
- Separate meaningful identifiers from data in a timely manner; keep any "keys" that link identifiers to study ID codes separate from data files;
- Keep confidential the identity of research sites (schools, organizations, locations, etc.)
- Take special precautions with information that is inherently identifiable (e.g., video recordings, photographs)
- Limit access to any identifiers those with a "need to know"
- Adhere to ISU [minimum data security standards](#), as required by [ISU Policy](#)

Exemption Categories—Common Rule (applies to most ISU research)

2018 Common Rule Exemptions¹ -- 45 CFR 46.104 Effective 1/21/2019	Pre-2018 Common Rule Exemptions -- 45 CFR 46.101
2018 Exemption 1 (effective 1/21/2019) Research in educational settings involving normal educational practice	Pre-2018 Exemption 1 Research in educational settings involving normal educational practice
<p>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.</p> <p>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.</p> <p>Exemption 1 Guidance</p> <ul style="list-style-type: none"> • Research procedures must involve only normal educational practices—activities that occur in the educational setting for instructional purposes. • Requires consideration of effects of the research on student learning or the evaluation of educators. Exemption may not be granted if the research involves: <ul style="list-style-type: none"> ○ significant time and attention away from standard educational content that may have a detrimental effect on student achievement; ○ randomization to an unproven educational technique; ○ collection of information that may adversely affect educators' employment. • May be granted for research with children. 	<p>Research conducted in established or commonly accepted education settings involving normal educational practices, such as:</p> <ul style="list-style-type: none"> (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. <p>Exemption 1 Guidance</p> <ul style="list-style-type: none"> • Research procedures must involve only normal educational practices—activities that occur in the educational setting for instructional purposes. • May be granted for research with children.

¹ The 2018 Common Rule specifies two additional exemptions, 7 and 8, related to use of information under what is called “broad consent”. Exemptions 7 and 8 will not be implemented at ISU at this time and until federal guidance on expectations and practices is provided and broad consent can be assessed for feasibility.

<p>2018 Exemption 2 – (effective 1/21/2019) Surveys, interviews, educational tests, observation</p>	<p>Pre-2018 Exemption 2 Surveys, interviews, educational tests, observation</p>
<p>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 <u>at least one</u> of the following criteria is met:</p> <ul style="list-style-type: none"> • 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; • 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 • 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 [determine there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data]. <p>Exemption 2 Guidance</p> <ul style="list-style-type: none"> • Exemption 2 applies to surveys or interviews <u>with adults</u> when information is: <ul style="list-style-type: none"> ○ Gathered anonymously; OR ○ Not sensitive or risky to subjects if disclosed; OR ○ Identifiable, but adequate privacy and confidentiality provisions are in place (determined through <i>limited IRB review</i>). • “Survey” refers to information collected through questionnaires or similar procedures, including asking subjects to provide verbal or written responses to scenarios, vignettes, or other similarly presented 	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:</p> <ul style="list-style-type: none"> • information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and • any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. <p>Exemption 2 Guidance</p> <ul style="list-style-type: none"> • Applies to surveys or interviews <u>with adults</u> where information is: <ul style="list-style-type: none"> ○ Gathered anonymously; OR ○ Not sensitive or risky to subjects if disclosed. • Audio and video recording of the interactions is allowable under Exemption 2, with adequate privacy and confidentiality protections. • Does not apply to research involving ANY intervention (e.g., physical data collection procedures or manipulations of the subjects’ environment, such as manipulating room temperature or interviewer gender, measuring height or weight, etc.). • Does not apply when significant risk or discomfort to subjects is inherent in the data collection procedure (e.g., asking detailed questions about traumatic experiences). • Surveys and interviews with children <u>are not eligible for Exemption 2</u>.

information. It does not include any collection of biospecimens or physiological measures.

- Audio and video recording of the surveys, interviews, or public behavior is allowable, with adequate privacy and confidentiality protections.
- Exemption 2 may not be granted when:
 - Research involves ANY intervention (e.g., physical data collection procedures or manipulations of the subjects' environment such as manipulating room temperature or interviewer gender, measuring height or weight, asking subjects to manipulate objects or play a game, etc.).
 - Significant risk or discomfort to subjects is inherent in the data collection procedure (e.g., asking detailed questions about traumatic experiences).
- Limitations for research with children:
 - Surveys and interviews with children are not eligible for Exemption 2.
 - Observation of public behavior of children may be granted exemption only if the investigator(s) do not participate in the activities being observed.
 - Research involving educational testing with children may not be granted exemption if information is sensitive and identifiers are collected with responses.

2018 Exemption 3 (effective 1/21/2019) Benign Behavioral Interventions	Pre-2018 Exemption 3 Surveys, interviews, observation of public officials
<p>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:</p> <ul style="list-style-type: none"> • 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; • 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 • 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 [determine that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data]. <p><i>Benign behavioral interventions</i> are</p> <ul style="list-style-type: none"> • brief in duration, • harmless and 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. <p>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</p>	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption 2, if:</p> <ol style="list-style-type: none"> (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. <p><i>Exemption 3 Guidance</i></p> <p>This exemption has rarely applied to research at ISU. Additional guidance is not provided because the exemption category has been eliminated in the 2018 Common Rule.</p>

2018 Exemption 3 (effective 1/21/2019) Benign Behavioral Interventions	Pre-2018 Exemption 3 Surveys, interviews, observation of public officials
<p>to allocate a nominal amount of received cash between themselves and someone else.</p> <p>If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable <u>unless</u> 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.</p> <p>Exemption 3 Guidance</p> <ul style="list-style-type: none"> • Exemption 3 applies only to <u>behavioral interventions</u>—not biomedical interventions such as ultrasound, MRI, height/weight/body composition measurement, etc. • Subjects’ responses must be collected via verbal or written responses (including data entry) or audiovisual recording; responses must be <ul style="list-style-type: none"> ○ Gathered anonymously; OR ○ Not sensitive or risky to subjects if disclosed; OR ○ Identifiable, but adequate privacy and confidentiality provisions are in place (determined through <i>limited IRB review</i>). • Subjects must voluntarily agree to participate <u>prior to</u> their inclusion in the study (i.e., some type of informed consent process is required). • Deception research -- Exemption 3 may be granted for studies involving minor deception (e.g., withholding of the purpose or nature of the study), IF <ul style="list-style-type: none"> ○ Deception is authorized by subjects -- they are prospectively informed that they may be unaware of or misled regarding the nature of purpose of the study; ○ The information withheld from subjects is unlikely to meaningfully effect their willingness to participate; 	

2018 Exemption 3 (effective 1/21/2019) Benign Behavioral Interventions	Pre-2018 Exemption 3 Surveys, interviews, observation of public officials
<ul style="list-style-type: none"> ○ The deception does not preclude disclosure of risks or discomforts or the voluntary nature of participation; ○ The deception does not involve misleading subjects about anything that may be substantially upsetting or cause distress (e.g., misleading subjects to believe their questionnaire responses indicate a mental illness, misinforming subjects about possible adverse consequences, etc.). ● Exemption 3 does not apply to research with children. 	

2018 Exemption 4 (effective 1/21/2019) Secondary use of information or biospecimens	Pre-2018 Exemption 4 Secondary use of information or biospecimens
<p>Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met:</p> <ul style="list-style-type: none"> (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 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 and purposes" as described under 45 CFR 164.512(b); or (iii) 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. <p>Exemption 4 Guidance</p> <ul style="list-style-type: none"> • Exemption 4 is limited to <u>secondary use</u> of information or biospecimens that have been or will be collected or generated for non-research 	<p>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:</p> <ul style="list-style-type: none"> • these sources are publicly available <u>or</u> • if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. <p>Exemption 4 Guidance</p> <ul style="list-style-type: none"> • Exemption 4 applies largely to accessing identifiable information that is routinely gathered for non-research purposes. Common examples include information from student records, medical records, biospecimens collected for clinical care, etc. • Information gathered must be existing at the time the research is proposed; Exemption 4 does not apply to information yet-to-be gathered (even for non-research purposes). • Information must be immediately recorded by the investigator in a manner that subjects cannot be identified. • Secondary use of information about children may be granted exemption when all applicable conditions for exemption are met. • Exemption 4 does not apply to research using existing information or biospecimens that include any identifiers, such as: <ul style="list-style-type: none"> ○ Names, addresses, email addresses, phone numbers, social security numbers, IP addresses; ○ Identifying numbers, such as social security numbers, license numbers, account numbers, etc. ○ ID codes, if any member of the research team can connect the ID codes with subjects' identities;

2018 Exemption 4 (effective 1/21/2019) Secondary use of information or biospecimens	Pre-2018 Exemption 4 Secondary use of information or biospecimens
<p>purposes or from research studies other than the proposed study when the information is:</p> <ol style="list-style-type: none"> 1. Publicly available <ul style="list-style-type: none"> ▪ From public library archives, ▪ From government /institutional records or commercial entity where public access is provided upon request or the only requirement is paying a user fee or registering as a visitor 2. De-identified <ul style="list-style-type: none"> ▪ Information is recorded by the investigator such that the identity of subjects cannot be readily ascertained ▪ Research does not involve any contact between the investigator(s) and subjects other than to obtain their informed consent to use the data. Thus, this exemption does not apply if the research also involves components where subjects will be contacted (e.g., surveys, interviews, etc.). ▪ Subjects will not be re-identified 3. Subject to HIPAA Privacy Rule protections, including <ul style="list-style-type: none"> ▪ Authorization from individuals for research use of their protected health information; or ▪ Waiver of authorization from a Privacy Board or IRB; ▪ Sufficient data security measures 4. Conducted by a government agency using government data obtained for non-research purposes and adheres to federal privacy standards. <ul style="list-style-type: none"> • Secondary use of information about children may be granted exemption when all applicable conditions for exemption are met. 	<ul style="list-style-type: none"> ○ Inherent identifiers (e.g., video recordings or photographs of people); ○ Demographic information when it can be used in combination to re-identify individuals.

2018 Exemption 4 (effective 1/21/2019) Secondary use of information or biospecimens	Pre-2018 Exemption 4 Secondary use of information or biospecimens
<ul style="list-style-type: none"> • When information was collected from a different study, the investigator’s use must align with what subjects were told during the informed consent process for the original study. • Exemption 4 does not apply to secondary research using information or biospecimens that include any identifiers, such as: <ul style="list-style-type: none"> ○ Names, addresses, email addresses, phone numbers, social security numbers, IP addresses; ○ Identifying numbers, such as social security numbers, license numbers, account numbers, etc. ○ ID codes, if any member of the research team can connect the ID codes with subjects’ identities; ○ Inherent identifiers (e.g., video recordings or photographs of people); ○ Demographic information when it can be used in combination to re-identify individuals. 	

2018 Exemption 5 (effective 1/21/2019) Federal research and demonstration projects	Pre-2018 Exemption 5 Federal research and demonstration projects
<p>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.</p> <p>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.</p> <p>Exemption 5 Guidance</p> <ul style="list-style-type: none"> • Exemption 5 covers a limited scope of federally funded or supported research designed to study, evaluate, improve, or otherwise examine public benefit or service programs. • The exemption has been expanded in the 2018 Common Rule to allow exemption when this research is <i>funded by</i> a federal agency (not just <i>conducted by</i> a federal agency). 	<p>Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:</p> <ul style="list-style-type: none"> (i) Public benefit or service programs; (ii) Procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or <p>Possible changes in methods or levels of payment for benefits or services under those programs.</p> <p>Exemption 5 Guidance</p> <ul style="list-style-type: none"> • Exemption 5 covers a limited scope of research designed to study, evaluate, or otherwise examine public benefit or service programs. • Such research must be conducted by the federal agency, and thus this exemption does not apply to ISU research.

2018 Exemption 5 (effective 1/21/2019) Federal research and demonstration projects	Pre-2018 Exemption 5 Federal research and demonstration projects
<ul style="list-style-type: none"> • The scope has been expanded to include research with focus on <i>improving</i> these programs—not just evaluating or examining programs. • Each federal agency that conducts or supports this research must identify/list the research and demonstration projects conducted under Exemption 5 on a publicly accessible website. Each project must be published on this list before human subjects research activities begin. 	

2018 Exemption 6 (effective 1/21/2019) Taste tests & food quality evaluation	Pre-2018 Exemption 6 Taste tests & food quality evaluation
<p>Taste and food quality evaluation and consumer acceptance studies,</p> <ul style="list-style-type: none"> (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 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. <p>Exemption 6 Guidance</p> <ul style="list-style-type: none"> • Generally, applies to taste tests of typical foods that persons may routinely consume in daily life; • May be applied to research with children when appropriate; parent consent is required; • Exemption 6 does not apply to research involving <ul style="list-style-type: none"> ○ Investigational products, or research intended to support applications to the FDA for marketing of a food additive; ○ Alcohol consumption; ○ Vitamins, dietary supplements; ○ Food with risks of serious physical harm (serious allergic reaction, vitamin or nutrient deficiency, etc.). 	<p>Taste and food quality evaluation and consumer acceptance studies,</p> <ul style="list-style-type: none"> (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 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. <p>Exemption 6 Guidance</p> <ul style="list-style-type: none"> • Generally applies to taste tests of typical foods that persons may routinely consume in daily life; • May be applied to research with children when appropriate; parent consent is required; • Exemption 6 does not apply to research involving <ul style="list-style-type: none"> ○ Investigational products, or research intended to support applications to the FDA for marketing of a food additive; ○ Alcohol consumption; ○ Vitamins, dietary supplements; ○ Food with risks of serious physical harm (serious allergic reaction, vitamin or nutrient deficiency, etc.).

Exempt Categories—FDA Regulations

Research subject to FDA oversight is exempt only under very specific conditions as follows:

1. Any investigation which commenced before July 27, 1981, and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
2. Any investigation commenced before July 27, 1981, and was not otherwise subject to requirements for IRB review under FDA regulations before that date.
3. Emergency use of a test article, provided that such emergency use is reported to the IRB within five working days. Any subsequent use of the test article at the institution is subject to IRB review.
4. Taste and food quality evaluations and consumer acceptance studies if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level found to be safe by the FDA or approved by the EPA or the FSIS/USDA.

For FDA-regulated studies, research involving children may not be deemed exempt.

When both Common Rule and FDA regulations apply to research involving human subjects, the IRB applies the most restrictive regulations from each to the research being conducted to ensure the protection of the rights and welfare of the human participants and compliance with federal requirements.

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