



Submitting Exempt Research for IRB Review:

Identifying exempt studies, IRB submission requirements & conducting exempt research

[\(45 CFR 46.104\)](#)

1.0 What is Exempt Research?

An exempt study is human subject/research that is such minimal risk that it is exempt from some regulatory requirements such as signed informed consent. IRB review and approval is required for all human subject/participant research that fits one or more of the exempt review categories described in this guidance.

Exempt Research is not exempt from IRB review.

Exempt status does not lessen the ethical obligations to participants and therefore, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

2.0 Guidance for Defining Human Subject/Participant Research:

For guidance on determining if a study is human subject/participant research that falls under the scope of the human subject research regulations and IRB oversight, review the IRB Education On-Demand videos titled “Does My Study Need IRB Review” (part 1 & 2) located on the [IRB Education Website](#). Then complete the Human Participant Research Determination Tool located on [the IRB Forms and Submission Requirements website](#).

3.0 Restrictions for Exempt Research

Research may be either restricted or not eligible for exempt review if any of the following are involved:

- a. Procedures which expose participants to more than minimum risk (greater than ordinarily encountered in daily life)
- b. Prisoners (Unless incidentally included in secondary research aimed at a broader subject population)
- c. Survey or interview techniques, or observation of public behaviors, with minors (Restrictions are described in category 2)
- d. Children as research participants for any research conducted under exempt category 3
- e. Projects that are FDA-regulated, with the exception of category 6

NOTE: The WSU IRB has elected to opt out of the optional categories #7 and #8 as described in 45 CFR 46.104. These categories involve research with biospecimens in which broad consent is obtained. Any study with broad consent will not be eligible for exempt review under this policy.



4.0 Risks to Participants Associated with Exempt Research:

Exempt research involves minimal risks to participants. Risks can be physical, psychological, social, economic, or legal in nature. These risks include:

- Breach of confidentiality
 - Applicable if identifiable data will be retained
 - Note: The risk of a breach of confidentiality applies when the research involves the following:
 - coded data with a master list linking aggregate data to identifiable data,
 - identifiable surveys & interviews, and
 - audio or video recordings
- minimal discomfort with answering sensitive questions
 - applicable if research involves interview or survey questions that are of a sensitive nature.
- loss of privacy
 - applicable if the research involves in-person research activities with participants.

5.0 Informed Consent Requirements for Exempt Research:

When research involves any prospective interaction with participants (including internet surveys), consent must be obtained using an information sheet or oral consent. This allows researchers to introduce the study activities to research participants as a form of consent without a signature. This form of consent can be used for research that falls under **exempt category 1, 2, 3, 5 & 6** as described below.

Researchers who plan to obtain consent without documenting the participant's signature must request a **waiver of documentation of informed consent** in the IRB submission.

Research that falls under **Exempt Category 4** cannot feasibly obtain consent from research subjects/participants. Therefore, investigators must request a **full waiver of informed consent** in the IRB submission.

Additional details about waivers of consent can be found in section 7.2 of this guidance.

5.1 Informed Consent Requirements for Exempt Research Involving Children:

All research involving prospective interactions with children requires permission from the child's parent and the child's assent. When research involving children qualifies for exempt review under **exempt category 1,2, 5 & 6**, parental permission can be obtained without documenting a signature using the School Parent Supplemental Information Letter.



Researchers who plan to obtain parental permission without documenting the signature of the participant's parent must request a **waiver of documentation of parental permission** in the IRB submission. Additional details about waivers of consent can be found in section 7.2 of this guidance.

The child's assent can be obtained through an information sheet written at an age-appropriate reading level (for children ages 13-17), or verbally using an oral assent script (for children ages 7-12).

More information about research involving children is available in IRB Policy 8-2 Vulnerable Participants: Children which can be found in [section 8 of the IRB Policy and Procedures website](#).

6.0: The Exempt Review Categories:

The regulations define 8 distinct categories of research that qualify for exempt status. Each exempt category has specific restrictions and requirements that are intended to protect the rights and welfare of research participants.

Note: The IRB has elected to opt out of the optional exempt categories #7 & 8 as described in [45 CFR 46.104](#).

6.1: Exempt Category 1 Research: (Research conducted in educational settings)

Research conducted in established or commonly accepted educational settings that specifically involve 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 regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Consent options: Information sheet, oral consent, or parental permission with child assent if research involves children under the age of 18. Request a waiver of documentation of consent or a waiver of documentation of parental permission in IRB submission. (See details about waivers of consent in section 7.2 of this guidance).

6.2: Exempt Category 2 Research: (Research involving surveys, interviews, educational tests)

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 by the investigator in such a manner that identity of the participants cannot be readily ascertained, directly or through identifiers linked to the participants



- b. Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, reputation.
- c. The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

NOTE: This category can only be applied to research with children when the research involves educational tests or the observation of public behavior (as long as the investigator(s) do not participate in the activities being observed); and either (a) or (b) above is true.

Consent options: Information sheet, oral consent. Request a waiver of documentation of consent in IRB submission (See details about waivers of consent in section 7.2 of this guidance).

6.3: Exempt Category 3 Research: (Benign Behavioral Interventions)

Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant 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 participant cannot readily be ascertained, directly or through identifiers linked to the participants,
- b. Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants' can be readily ascertained, directly or through identifiers linked to the participants, and the IRB conducts a limited IRB review to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Benign behavioral interventions must be brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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.



Note: This category has additional requirements if deception is involved. This category does not apply to research involving children. Additional information about this category is available in the Benign Behavioral Interventions Guidance document located on the IRB's [Revised Common Rule website](#).

Consent options: Information sheet, oral consent. Request a waiver of documentation of consent in IRB submission (See details about waivers of consent in section 7.2 of this guidance).

6.4: Exempt Category 4 Research: (Secondary Data Collection)

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 is met:**

- a) The study involves the collection of identifiable private information or identifiable bio-specimens that are publicly available.
- b) The study involves Information, which may include information about biospecimens, that is recorded by the investigator in such a manner that the identity of the participants cannot readily be ascertained directly or through identifiers linked to the participants when:
 - The investigator does not contact the participants, and the investigator will not re-identify the participants
 - The research involves only information collection and analysis involving the investigators use of identifiable health information when that use is protected under HIPAA regulations for the purposes of healthcare operations, research, or public health activities and purposes (i.e., retrospective review of medical records).
- c) 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 the E-Government act of 2002, 44 U.S.C. 3501.

Note: This category cannot be applied to research that also involves prospective interactions or interventions with research participants (as described by exempt category 2). When research involves the collection and analysis of secondary data as described in this category and the prospective collection of data through surveys, interviews, or focus groups as described by exempt category 2, the research must be submitted for an expedited review under expedited category 5 & 7.

Consent Options: Research that falls under exempt category 4 as described above cannot feasibly obtain consent from research subjects/participants. Therefore, investigators must request a full waiver of informed consent in the IRB submission (See details about waivers of consent in section 7.2 of this guidance).



6.5: Exempt Category 5 Research: (Federally supported research involving public service programs)

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.

6.6: Exempt Category 6 Research: (Taste and food quality evaluation and consumer acceptance studies)

Research involving taste and food quality evaluation and consumer acceptance studies if (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.

7.0: IRB Submission Tips, Requirements, and Instructions:

Before Beginning:

1. Complete all required CITI Training modules.
 - CITI training modules are valid for 3 years.
 - Information about required CITI modules is available on our ["Mandatory Education" website](#).
 - On-demand training video with CITI Training guidance available on our [Education website](#).
 - eProtocol will not allow you to submit the study until the entire research team, including your faculty sponsor and the Department Chair/Dean signatory have completed all required CITI modules
 - eProtocol refreshes every 24 hours, so changes to your CITI completion records or account profile will appear in eProtocol the following day.
2. Prepare your study documents (See section 6.3 of this guidance).
3. Begin your IRB application by logging into our online submission system: [eProtocol](#) following the steps in in the [Expedited-Exempt Initial Submission Guidance Tool](#).

Tips:

- Before beginning your submission, determine which exempt review categories accurately describes your study.
- Visit our [education webpage](#) for guidance on the eProtocol submission process including eProtocol FAQ's.
- Our [Initial Submission Checklist](#) is a helpful guide!



- Make sure every Wayne State affiliated investigator listed as research personnel have completed all required CITI training modules.
 - Make sure everyone has linked their access ID to their CITI training profile. This step will allow your CITI training credentials to automatically import to your eProtocol submission.
- As you work your way through each section of the application, take the time to carefully read the instructions and each question to make sure you don't miss any important details. This will end up saving you time in the long run.
- **Contact the IRB for support:**
 - Virtual eProtocol training sessions provide investigators with live virtual one-on-one eProtocol support. The training schedule is posted on our [education webpage](#).
 - Email questions to wsuirbinfo@wayne.edu for eProtocol Submission Support.
 - Email irbquestions@wayne.edu for questions about IRB requirements, policies, document prep, and other guidance.
 - Email irbstatus@wayne.edu for the following inquiries:
 - Status updates for pending submissions under review
 - Requests for CITI Training status
- If this is your first time preparing an IRB submission, watching the following IRB Education On-Demand Videos located on the [IRB Education Website](#) is recommended:
 - Does My Study Need IRB Review- Parts 1 & 2
 - Basic CITI Guidance
 - Fundamentals of the IRB Parts 1, 2 & 3

7.1 Special Instruction on Requesting a Waivers of Informed Consent:

The regulations require specific criteria to be met to allow an IRB to approve any type of waiver or alteration of informed consent. Properly requesting a waiver or alteration of informed consent is necessary for the IRB to see that the proposed research meets all the regulatory criterion required to allow researchers to conduct research activities without consent, or without some required elements of consent.

Waiver of Documentation of Consent: Allows investigators to use an information sheet or oral consent to obtain consent without a signature for minimal risk prospective studies that involve interactions with participants such as surveys or interviews,

- Applicable for studies that fall under exempt categories 1, 2, 3, 5, & 6.

Waiver of Documentation of Parental Permission: Allows investigators to use the School Parent Supplemental Information letter to obtain parental permission without a signature for minimal risk prospective studies that involve interactions with participants under the age of 18.

- Applicable for studies that fall under exempt categories 1, 2, 5, & 6.

Full Waiver of Consent: Allows investigators to collect secondary (existing) data such as medical record data without consent when there will be no interactions or interventions with participants.



- Applicable for studies that fall under exempt category 4.

Waiver of Consent for Determining Eligibility or Recruitment: This allows investigators to collect limited secondary (existing) data available to determine a participant's eligibility and make initial contact with a potential participant. The participant must provide consent before further data can be collected.

Review the information about waivers of consent and follow the instructions provided in our IRB On-Demand training video about waivers of informed consent:

[Waivers of Consent On-Demand Training Video](#)

7.2 Additional Required Documents:

- Principal Investigator's (PI) **Curriculum Vitae (CV)** or Resume
- **Consent Document:** (Not applicable for exempt category 4 studies)
 - **Information Sheet:** This is an unsigned form of consent that informs your participants of the research and allows them to indicate consent by completing the survey/questionnaire. Use [our template](#) to develop your information sheet,
 - **Oral Consent Script:** [Waivers of Consent or Alteration of Consent guidance](#) ,
 - **School Parent Supplemental Information Letter:** Parents complete the tear off section at the bottom of the information sheet if they do not wish to have their child participate. It is important to exclude any child whose parent has opted out of the research from any research related activity including any classroom observations.
- **All materials that will be presented to participants for purposes of the research** (Not applicable for exempt category 4 studies):

Examples include but are not limited to:

 - Survey/Questionnaire,
 - Interview or focus group questions,
 - Recruitment materials: Flyers, advertisements, or social medial posts, or recruitment emails,
 - Educational material: brochures, participant diaries, pamphlets, education modules, tests, or videos
- **Documentation of other required approvals:**
 - VAMC review for VA studies, PRMC review for cancer studies, WSU department of psychology review for studies conducted by Psychology faculty, staff or students, Other IRB approval memos for collaborative research involving any site that is outside of WSU and our affiliate institutions (Detroit Medical Center, Veterans Affairs Medical Center, Karmanos Cancer Institute)
- **Letters of support:**
 - Required whenever research activities will occur outside of Wayne State University or its affiliates. See our [Letter of Support guidance document](#) for more information.
- **Data/Bio-specimen sharing agreements:** Whenever research data or specimens will be transferred to WSU researchers from an institution that is outside of WSU and our affiliate institutions, or when data or specimens is sent from WSU researchers to an institution that is outside of WSU and our



affiliate institutions, agreements between the institution sending data/specimens and the institution receiving data/specimens is required. Material Transfer Agreements (MTA) are used when specimens will be shared. Data Use Agreements (DUA) are used when data is shared. Additional information is available in the [IRB Data Use Agreements & Limited Data Sets guidance tool](#).

8.0 Investigator Responsibilities and Ongoing IRB Reporting Requirements for Exempt Research:

Investigators conducting exempt studies are required to provide a status update of the research project. Amendments, unanticipated problems, and study closure requirements also apply to exempt research.

- **Status Update:** After the IRB approves an exempt study, investigators must provide a Status Update of the research project every 3 years. The status Update/Check-in date is noted on the IRB approval memo. See IRB Policy [4-7 Continuation/Renewal of a Protocol](#)
- **Amendments:** An amendment must be submitted to the IRB any time changes are being made to an IRB approved protocol submission. This includes any minor changes. IRB approval must be obtained before any proposed changes can be implemented unless the change is necessary to protect subjects from an apparent immediate risk of harm.
- See IRB Policy [4-6 Amendments to the Research Protocols and Informed Consent](#).
- **Unanticipated Problem Reports:** Required to notify the IRB of any event that could impact risks to participants. This includes a data breach for minimal risk record review studies. See IRB Policy [13-1 Unanticipated Problems and Other Reportable Events](#).
- **Closure:** A closure/final report can be submitted when research has progressed to the point where there is no longer any contact with participants, no new data is being collected, and the only data analysis remaining is analysis of de-identified data. See IRB policy [4-8 Closure of a Research Protocol](#).