Research may be eligible for exemption from federal regulations if it is no more than minimal risk for human subjects and all the activities associated with the research fall into one or more of eight specific exemption categories as defined by the revised Common Rule. *Exempt categories 7 and 8 are not applicable at this time as AWC*. While most exempt research does not require IRB review, the IRB **must independently determine** that relevant safeguards and ethical education training are in place. Therefore, studies that may qualify for “Exempt,” must be submitted to the IRB for initial review. The IRB Chair or designated IRB member conduct initial exemption reviews. Exemptions do not require a convened IRB meeting. *Research that contains elements of exempt and non-exempt activities is NOT eligible for IRB exemption.*

Once an exemption determination is made by the IRB:

* The exempt protocol is not subject to continuing review; and
* The PI does not need to amend the exempt protocol; *instead*, the PI must contact the IRB only if changes to the project *could alter the exemption determination*

Even when research is exempt from further requirements of federal regulations, these basic ethical standards still apply:

* Prospective participants must be provided enough information to be able to choose whether or not to participate;
* Research data must be handled and stored securely, in compliance with institutional policy;
* Access to research data must be limited to study team members and other authorized personnel; and
* ALL members of the research team must be current on human subjects (CITI) training.

**Revised Common Rule:** Collaboration between the US Department of Health and Human Services and 15 other Federal Departments and Agencies resulted in revisions to 45 CFR 46, Subpart A – “Federal Policy for the Protection of Human Subjects”, or the Common Rule, on January 18, 2017. This is the first revision since its publication in 1991. The explicit goal of these revisions is to reduce administrative burden and better protect subjects in the modern research context.

New exempt categories were added, some were revised, and two new processes were introduced: limited IRB review and broad consent. The pre-2018 rule had six exempt categories in 46.101(b). The revised rule gave exempt categories an entire section, 46.104, and now includes eight categories in 46.104(d) (1-8). However, as previously noted, exempt categories 7 and 8 are not applicable at this time, as AWC is not implementing broad consent.

**Limited IRB Review (for select Exemption Categories)**: The Final Rule introduced a new concept of limited IRB review as a condition of exemption. Certain studies that once required Expedited review by the IRB now meet the criteria for “Limited IRB Review.” Limited IRB review will occur at the same time the proposed research protocol is reviewed for a determination of exemption.

Limited IRB review is required for exempt categories 2 and 3, when:

* The information obtained is recorded by the investigator in such a manner that the identity of the human subject can readily be ascertained, directly or through identifiers linked to the subjects, **AND**
* Any disclosure of the human subjects’ responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, education advancement, or reputation.

[**45 CFR 46.104 Exempt Research**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) ***(follow link for complete list of exempt categories)***

*Exempt categories 7 and 8 are not applicable at this time, as AWC is not implementing broad consent. Of the remaining six categories, Social, Behavioral, and Educational Research, typically falls into categories 1, 2, 3, and/or 4.*

1. Research conducted in established or commonly accepted educational settings, involving 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.
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 criteria is met:
   1. 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;
   2. 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
   3. 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).

*Examples:* An anonymous survey regarding workplace satisfaction. Surveying faculty about a technique or an outcome. Polling students on the frequency of their visits to the campus library. Interviewing managers about a management style or best practice.

1. 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:
   1. 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;
   2. 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
   3. 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).

*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. 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 to allocate a nominal amount of received cash between themselves and someone else.*

*If the research involves deceiving the subjects regarding the nature or purposes 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.*

1. 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:
   1. The identifiable private information or identifiable biospecimens are publicly available;
   2. 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;
   3. 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
   4. 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.

*Examples:* Analyzing de-identified national test scores. Analyzing census data about aging or housing.

1. 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.

*Each federal department or agency conducting or supporting the research and demonstration 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 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.*

1. Taste and food quality evaluation and consumer acceptance studies:
   1. If wholesome foods without additives are consumed, or
   2. 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.

**45 CFR 46.116** [**Informed Consent Process**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116) ***(follow link for more information)***

While federal regulation 45 CFR 46.116 does not apply to studies that met the criteria for exemption and were deemed exempt by the IRB, the study is still considered research with human subjects and, therefore, the ethical principles as outlined in the *Belmont Report,* do still apply. Exempt protocols are still required to obtain informed consent from subjects and should be provided in a language that subjects understand.

As noted in regulation 46.116(b), nine basic elements must be listed on the informed consent form. Depending on nature of research and risks involved, there may be additional required elements, as noted in 46.116(c).

Subjects may not be asked to waive or even appear to waive any of their legal rights. Additionally, they may not be asked to release a researcher, sponsor, or institution from liability for negligence.

The IRB must ensure that appropriate safeguards are in place to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence (vulnerable populations). Vulnerable populations include children (under 18 years old), prisoners, individuals with impaired decision-making capacity, pregnant woman, or economically or educationally disadvantage persons. Additional safeguards for these groups are provided in regulations Subpart B, C, and D.

**Waiver of consent**  
The IRB can [alter or waive the general requirements for consent](https://www2.virginia.edu/vpr/irb/sbs/resources_regulations_subparta.46.116.html) when the following apply:

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration will not adversely affect the rights and welfare of the subjects;
* The research could not practicably be carried-out without the waiver or alteration; and
* Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

[**45 CFR 46.117 Documentation of Informed Consent**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117) **(*follow link for more information)***

When documentation of informed consent is required, these are the two allowable methods:

1. The subject or the subject’s legally authorized representative signs the consent form, either by hand or electronically, containing all the required elements of consent and any additional information necessary to provide complete disclosure. The person who signed the consent form is given a copy as a reference and reminder of the information conveyed.
2. Consent is described orally, in language understandable to the subject, and is documented by an impartial witness. This process uses two documents: (1) a short form written consent document stating that the required elements of consent have been presented orally to the subject or the subject’s legally authorized representative, and (2) a written, IRB-approved summary of what will be said to the subject or the subject’s representative. The subject signs the short form. The witness signs both forms. The person actually obtaining consent signs the summary. Copies of the short form and the summary are given to the subject.

**Note**: English-speaking subjects who have low literacy (nonreaders) can “make their mark” on the informed consent document, as long as it is consistent with applicable state or local laws.

Waivers of documentation are not waivers of the consent process itself. The IRB may waive documentation of informed consent per 46.117(c)(1) under three circumstances:

1. The principal risks are those associated with a breach of confidentiality concerning the subject’s participation in the research, and the consent document is the only record linking the subject with the research. When the requirement for documentation is waived, the IRB may require the researcher to offer the subjects information about the study in writing.
2. Study participation presents minimal risk of harm to the subject and the research involves no procedures requiring consent outside the context of participation in a research study.
3. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

**Non-Research Involving Human Subjects that DOES NOT Require IRB Exemption or Approval**

The following projects fall outside the scope of researchand do notrequire IRB exemption or approval:

* AWC student ratings of instruction;
* Institutional or program evaluations or assessments directly tied to the employee’s primary work or departmental duties (e.g., financial aid regularly examines student records; Institutional Research accesses student success data for learning outcomes assessment purposes; etc.);
* AWC employee performance evaluations;
* Studies conducted by students under the advisement of faculty for classroom instructional purposes only, when information gained is for sharing in the classroom setting only;
* AWC mandated evaluations (program reviews, academic audits, etc.);
* Accreditation mandated assessments and/or evaluations;
* Required AWC grant evaluation activities approved by the grant Program Director, external/internal evaluator, or Office of Institutional Effectiveness and Research.

**Research Involving Human Subjects That DOES NOT Require IRB Approval**

Some projects will involve human subjects as participants but do not require IRB approval. For example:

* Journalism/Documentary/Artistic Activities: Investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism; writing a stage or screen play, poetry, musical, photo display, etc. based on the collected data.
* **Oral History or Case Study:** The project is limited to oral history activities or investigations into an event. Data collected can come from open-ended or one-on-one interviews, but the interviews only document that specific historical event or the experiences of individuals related to an event, without the intent to draw conclusions or generalize findings. These interviews can be with more than one person.
* **Existing Data: G**athering or analyzing data that have already been collected by someone else (i.e., educational data, census data). These data are publicly available and have no identifiers included (e.g., names, addresses, emails, phone numbers, etc.; any information that could specifically identify a person).

Questions about a research activity can be directed to the Office of Institutional Effectiveness and Research at (928) 344-7620 or IERG@azwestern.edu.