Ascension Wisconsin IRB Guidance

Exempt Review

The federal Common Rule identifies six categories of research that may be eligible for exemption from IRB review (45 CFR 46.104). The Ascension Wisconsin IRB applies all exemption categories only to protocols determined to be no more than minimal risk.

Ascension Wisconsin does not allow for Investigators or other leaders to determine whether or not a protocol qualifies for exemption from IRB review. Only the Ascension Wisconsin IRB Office can make this determination. The investigator must submit a protocol for review to request IRB exemption approval.

This guidance outlines the new Exempt categories effective 1/21/2019 found in the Common Rule at 45 CFR 46.

Topics covered in this guidance include:

Other Applicable Regulations and Protections

Research that qualifies as exempt must still meet the Ascension Wisconsin ethical standards governing the conduct of human subject research and other institutional requirements.

The HIPAA Privacy Rule (45 CFR Parts 160 and 164) applies to all exempt research that uses protected health information (PHI). Privacy Rule requirements do not apply to exempt research using information that has been de-identified.

The Ascension Wisconsin IRB also applies the FDA regulations exempting from IRB review clinical investigations involving taste and food quality evaluations and consumer acceptance studies and emergency use of test articles (21 CRF 56.104(c) and (d)). The Common Rule exemptions and exemptions allowed by Ascension Wisconsin Policy do not apply to FDA-regulated research.

Submitting an Exempt Protocol for IRB Review

If an investigator believes a research project falls into one of the exemption categories, he or she must submit a protocol to the IRB. Only Research Integrity and Protections staff or the IRB can determine whether the research is exempt from review.

Additionally, the IRB has the right not to exempt a protocol and to IRB review, particularly if the research involves a sensitive population or topic.

An Investigator must submit a request for IRB exemption using the online IRB system, called Mentor. See the Exempt Study Submission Guide for details.

If a protocol is determined to be exempt from review, it is not subject to continuing review or other rules governing human research, such as rules on obtaining and documenting informed consent, unless consent is required by the IRB. After approval, the only time reporting to the IRB is required is if there is a change that could cause the protocol to no longer qualify for exemption and to notify the IRB of study completion/closure.

Exempt Categories

CATEGORY 1 (_.104(d)(1)) (new elements in the revised rule in **bold**)

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. 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.

Comments and Examples

A normal educational setting and practice may include a residency or nurse training programs, professional development workshops or skills development, etc. It is not limited to primary and secondary educational settings.
The proposed research must not deviate from normal educational practice, including random assignment to groups, subject deception or radically new or significantly altered techniques.
This category does NOT apply to studies involving surveys, interviews, questionnaires, or focus groups (see category 2).

Inclusion of vulnerable population (subparts):

- May include pregnant women
- May include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners
- May include children

Example:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

CATEGORY 2 (_.104(d)(2)) (new elements in the 2018 rule in bold)

Research **that only includes interactions involving** educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior **(including visual or auditory recording) if at least one of the following criteria is met:**

(i) **The** information obtained is recorded **by the investigator** in such a manner that **the identity of** the human subjects **cannot readily be ascertained**, directly or through identifiers linked to subjects;
(ii) Any disclosure of the human subjects' responses outside the research **would not** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) **The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).**

Comments and Examples

Observations must be of public behavior in a public setting; classrooms and medical settings are not considered public.

Precautions to protect confidentiality may vary depending on the study, topic or type of data collected. Examples of common practices to protect confidentiality include the following:

- Use a code and remove identifiers from data collection tools, surveys, etc.; Limit access to key code lists
- Destroy contact lists, recruitment materials or other identifiable materials when no longer needed
- Store records in a secure location (like a locked room/ file), consent/HIPAA separate from research data, electronic files on the institutional server/system with password-protection and encryption
- Train research staff in the appropriate methods for storing and managing data

Inclusion of vulnerable population (subparts):

- May include pregnant women
- May include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners
- (2)(i) and (iii) may include children only if the investigator(s) do not participate in the activities being observed; (2)(iii) of this section may not include children

Example:

- Surveying teachers, nurses or doctors about a technique or an outcome
- Conducting a focus group about an experience or an opinion of a community program

CATEGORY 3 (_.104(d)(3)) (new elements in the revised rule in **bold**)

(i) 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:

- **(A) 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;**
- **(B) 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**
- **(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 §46.111(a)(7).**

(ii) 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.

(iii) 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.

Comments and Examples

Examples of benign behavioral interventions 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.

Inclusion of vulnerable population (subparts):

- May include pregnant women
- May include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners

CATEGORY 4 (_.104(d)(4)) (new elements in the revised rule in **bold**)

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- **(i) The identifiable private information or identifiable biospecimens are publicly available;**
- **(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;**
- **(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated 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**
- **(iv) 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.**

Comments and Examples

The "primary" or "initial" activity includes both non-research AND research activities.

Despite exemption, researcher must still work with IRB (also the HIPAA privacy board) if the research activity requires a waiver of HIPAA authorization.

Inclusion of vulnerable population (subparts):

- May include pregnant women
- May include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners
- May include children

Example:

- Medical record reviews where data was extracted from records
- Data analysis of information already collected from court records

CATEGORY 5 (_.104(d)(5)) (new elements in the revised rule in **bold**)

Research and demonstration projects **that** are conducted **or supported by a Federal Department or agengy, 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.

(i) 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.

Comments and Examples
See OHRP's guidance for more details regarding this category. Funding agencies must be notified of the use of this exemption. This exemption is rarely used at Ascension Wisconsin.
Inclusion of vulnerable population (subparts): may include pregnant women; may include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners; may include children.

CATEGORY 6 (_.104(d)(6)) (new elements in the revised rule in **bold**)

Taste and food quality evaluation 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 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Comments and Examples
Also see FDA Exempt Categories 21 CFR 56.104. This exemption is rarely used at Ascension Wisconsin.
Inclusion of vulnerable population (subparts): may include pregnant women; may include prisoners only if the research is aimed at involving a broader subject population that only incidentally includes prisoners; may include children.

CATEGORY 7 (_.104(d)(7)) (new elements in the revised rule in **bold**)

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

Comments and Examples
Broad Consent is not utilized at Ascension Wisconsin

CATEGORY 8 (_.104(d)(8)) (new elements in the revised rule in **bold**)

8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) 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; and(iv) 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.

Comments and Examples
Broad Consent is not utilized at Ascension Wisconsin

References

IRB SOP-208 Review Standards for Research Not Covered by Federalwide Assurance- Flexibility Policy and Procedures
IRB SOP-302: Human Subject Research Exempt from IRB Review
IRB GUIDANCE: Exempt Study Submission Guide

OHRP: 45 CFR 46.104
OHRP: Decision charts

FDA: 21 CFR 56.104