



Exempt Review of Research

Policy Version# & Date: 2.1; 11/01/2019
Approved by: Human Protections Administrator and
Director of OPRS
AAHRPP REF#: 128
AAHRPP Elements II.2.A., II.2.B.

POLICY:

- I. Research in which activities involving human subjects are limited to one or more of the categories at [45 CFR 46.104\(d\)](#) may qualify for exemption from 45 CFR 46.
- II. Researchers do not have the authority under federal guidance and UIC policy to independently determine that research involving human subjects is exempt. The research must be submitted to OPRS for review of a claim of exemption and receive written documentation of the exemption from OPRS prior to initiation.
- III. The following individuals may review and approve claims of exemption: IRB Chairs, IRB members designated by the Chair, OPRS Director, Associate Directors, Assistant Directors, and Coordinators designated by the IRB Chair and/or Director.
- IV. When a proposal has received documentation of an exemption, continuing IRB review is not required.
 - A. Exemptions granted prior to January 21, 2019 were given an expiration date three-years after the exemption was granted.
 1. Investigators who wish to continue these proposals must submit a new Claim of Exemption to continue the research at the end of the three-year period as the expired exemption will be administratively closed by OPRS.
 - B. Exemptions granted on or after January 21, 2019 are not given an expiration date.
 1. Every three years, the PI will be asked to complete an Institutional Status Report. If the PI does not submit an Institutional Status Report, the research may be administratively closed by OPRS.
 - C. The PI will receive an annual reminder regarding the need to submit amendments, prompt reports, and a final report as applicable based on UIC policy, federal regulations, and sponsor guidelines.
- V. General considerations in making a claim of exemption:
 - A. The research meets the definition of research involving human subjects and meets one or more of the exemption criteria;
 - B. The research cannot involve prisoners as participants except for research aimed at involving a broader subject population that only incidentally includes prisoners [45 CFR 46.104(b)(2)];



- C. Research activities involving children are limited as described under 45 CFR 46.104(b)(3);
- D. Exemption category 6 is the only category that may pertain to FDA-regulated research [21 CFR 56.104];
- E. The proposed recruitment procedures and consent process are appropriate;
- F. Adequate provisions exist, when applicable, to protect privacy interests of subjects and maintain the confidentiality of the data;
- G. The research cannot involve human embryonic stem cells.

VI. [UIC Policy](#) limits exemptions to the following categories of research:

- A. Category 1. 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 education content or the assessment of educators who provide instruction. This includes:
 - 1. Most research on regular and special education instructional strategies, and
 - 2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45 CFR 46.104(d)(1)]
- B. Category 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; OR
 - 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. [45 CFR 46.104(d)(2)]
 - 3. NOTE: If the research in this category involves children as participants, the activities can not include [45 CFR 46.104(b)(3)]:
 - a) Survey procedures;
 - b) Interview procedures; OR
 - c) Observation of public behavior where the investigators participate in the activities being observed.
- C. Category 3. 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; OR



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.
 3. Benign behavioral interventions are brief in duration. Also, the intervention must be harmless, painless, and not physically invasive. Further, the intervention must not be likely to have a significant adverse lasting impact on the subjects. The investigator should have no reason to believe that the interventions will be offensive or embarrassing to the subjects, and should take into consideration the subject population, the context of the research, the topic, and other characteristics of the study.
 - a) 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.
 4. 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. [45 CFR 46.104(d)(3)]
- D. Category 4. 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 only involves the collection and analysis of identifiable health information when that use is regulated under the HIPAA Privacy Act (45 CFR 160 and 164). Disclosure of any UIC Protected Health Information (PHI) requires a Data Use Agreement.
 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.* [45 CFR 46.104(d)(4)]

5. Additional guidance:

- a) Secondary research refers to re-using identifiable information or identifiable biospecimens that are collected for some other "primary" or "initial" activity. The information or biospecimens that are covered by this exemption would generally be found by the investigator in some type of records or tissue repository.
- b) Publicly available means that the general public can obtain the data or biospecimens. Sources are not considered publicly available if access to the data or biospecimens is limited to researchers.
- c) Under this exemption, an investigator who records information, including information about biospecimens, in a manner in which the identity of the subject cannot be readily discovered, is not permitted to re-identify the information or contact the subject. Therefore, information recorded in this manner cannot be collected longitudinally.
- d) Exemption from IRB review does not represent an exemption from HIPAA requirements for a waiver of authorization when the research involves the use or access of PHI.

E. Category 5. Research and demonstration projects which are conducted or supported by a Federal department or agency or otherwise subject to the approval of department or agency heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and which are designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs, including:
 - a) Procedures for obtaining benefits or services under those programs;
 - b) Possible changes in or alternatives to those programs or procedures; or
 - c) Possible changes in methods or levels of payment for benefits or services under those programs.
2. 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.
3. 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. [45 CFR 46.104(d)(5)]



F. Category 6. Taste and food quality evaluation and consumer acceptance studies, if:

1. Wholesome foods without additives are consumed; or
2. 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 Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [45 CFR 46.104(d)(6), 21 CFR 56.104(d)]

VII. Although exempt research is not subject to the federal regulations at 45 CFR 46, the UIC policy requires all research involving human subjects, including exempt research, to be performed responsibly and in accordance with the ethical guidelines of the [Belmont Report](#). Researchers performing exempt research are expected to institute appropriate protections, including obtaining informed consent as appropriate and implementing measures to protect privacy and confidentiality.

PROCEDURES:

I. Submission.

A. The investigator submits the following documents to OPRS:

1. [Claim of Exemption](#) Application;
2. Appendices and supplemental documents as needed (e.g., [Appendix P](#), [Appendix K](#), letters of agreement, limited data use agreements, etc.);
3. Consent and recruitment materials, as appropriate;
4. Questionnaires, survey instruments, interview questions, discussion guide and/or data collection forms.

II. Review Process.

A. The reviewer uses the review guide to document the review.

B. In making the determination, the reviewer considers whether:

1. The research meets the definition of research involving human subjects and meets one or more of the exemption criteria;
2. If the research involves prisoners, it is aimed at involving a broader subject population that only incidentally includes prisoners;
3. For research conducted under category 2, children can only be involved as described under 45 CFR 46.104(b)(3);
4. If the research is FDA regulated, it is limited to category 6;
5. The proposed recruitment procedures and consent process are appropriate;
6. Adequate provisions exist, when applicable, to protect privacy interests of subjects and maintain the confidentiality of the data;
7. The research cannot involve human embryonic stem cells.

C. The reviewer makes one of the following determinations:

1. Exemption is granted;



- a) For research meeting the criteria for exemption category 4 and involving the review of medical records, the reviewer determines whether a waiver of HIPAA authorization is warranted.
 2. Conditions Required to Secure an Exemption as additional information or clarifications are needed before a final determination can be made;
 3. Proposed activity does not meet the definition of research or research involving human subjects;
 4. Research proposal does not meet the criteria for exemption and must be reviewed by the IRB under expedited or convened review processes;
 5. UIC is not [engaged](#).
- D. Electronic reviews are captured via an electronic signature and date stamp.

III. Communications.

- A. The investigator is notified of the reviewer's determination by e-mail. The communication contains, as applicable,
1. Any issues requiring resolution;
 2. Recommendations for changes in the level of review;
 3. Requests for further information; or
 4. For research granted an exemption, documentation of:
 - a) Date of exemption determination;
 - b) The exemption category(ies);
 - c) Sponsor information, as applicable;
 - d) The investigator's responsibility to submit any changes to the research to OPRS for review and certification prior to implementation;
 - e) If applicable, waiver of HIPAA authorization.

IV. Amendments.

- A. Any proposed changes to an existing exemption must be prospectively submitted to OPRS for review via an amendment application.
- B. Substantive amendments may require a new determination.

V. Expiration.

- A. Exemptions granted prior to January 21, 2019 were given expiration period three-years after the exemption was granted.
1. Investigators who wish to continue these proposals must submit a new Claim of Exemption to continue the research at the end of the three-year period as the expired exemption will be administratively closed by OPRS.
- B. Studies granted exemptions from IRB review on or after January 21, 2019 are not issued an expiration date.
1. Every three years, the PI will be asked to complete an Institutional Status Report. If the PI does not submit an Institutional Status Report, the research may be administratively closed by the OPRS.



- C. PIs will receive an annual reminder regarding the need to submit amendments, prompt reports, and a final report as applicable based on UIC policy, federal regulations, and sponsor guidelines.

REFERENCES:

21 CFR 56.104

45 CFR 46.104(b), 45 CFR 46.104(d)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 04/21/09	1.0, 08/08/08	Revised Section V.D.4. to include language regarding PHI/HIPAA in VA research under category 4.
1.2, 06/18/09	1.1, 04/21/09	Revised Section IV to permit amendments, rather than modifications, with respect to exempt research.
1.3, 07/21/09	1.2, 06/18/09	Revised Section III to reflect that OPRS staff is using the RiSC action "Admin Closure" for exempt protocols that have been active for more than 3 years in certain limited circumstances.
1.4, 05/14/12	1.3, 07/21/09	Revised to specify that the reviewer signs the review guide and is a voting member of the IRB.
1.5, 09/22/15	1.4, 05/14/12	Revised to remove language regarding the VA. Removal of language regarding the inclusion of Claims of Exemptions in the meeting agendas and minutes. Inclusion of language to electronic review.
1.6, 12/02/16	1.5, 09/22/15	Addition of language regarding the logging of the submissions as IRB 7 in RiSC for administrative purposes. Addition of hyperlinks.
2.0, 01/21/19	1.6, 12/02/16	Revision of the policy to incorporate regulatory changes based on 2018 Requirements of 45 CFR 46.
2.1, 11/01/19	2.0, 01/21/19	Clarification regarding exemptions that were granted a three-year period versus an open ended period with a three-year status report.