

Exempt Review of Research

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310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

POLICY:

- I. Research in which activities involving human subjects are limited to one or more of the categories at 45 CFR 46.101(b) [38 CFR 16.102(b)] may qualify for exemption from 45 CFR 46.
- II. PIs do not have the authority under federal guidance and UIC policy to independently determine that research involving human subjects is exempt. PIs must submit the research to OPRS for review of a claim of exemption and receive written documentation of the determination from OPRS before initiating the research.
 - A. For research conducted at UIC and other non-VA performance sites, the following individuals may review and approve claims of exemption: IRB Chair, IRB member designated by the Chair, IRB Assistant Directors, experienced IRB Coordinators, and the OPRS Director or Associate Director. Experienced coordinators are individuals who have reviewed exemptions for at least 6 months under the supervision of an IRB Assistant Director and Chair and who have been judged by them to be qualified.
 - B. For VA Research, the review and approval of claims of exemption is performed by the Chair for UIC IRB#4 or an IRB member designated by the Chair.
- III. When a proposal has received a written determination that it is exempt, continuing IRB review is not required. The proposal receives a 3 year expiration date, after which the investigator will need to re-submit or close the study. To implement this policy and procedure, the appropriate UIC OPRS staff will use the RiSC action "Admin Closure" to close exempt protocols that have been active for more than 3 years per the previous policy and procedure and require re-submission when applicable. The action "Admin Closure" will also be used for exempt protocols that have expired but in which the investigator does not re-submit or close the study. The action "Admin Closure" will not be used for any other purpose. Investigators conducting exempt protocols at the JBVAMC are required to obtain initial JBVAMC R&D approval before initiating the research and must also submit an annual report of research activities directly to the JBVAMC R&D committee.
- IV. General considerations in making a determination of a claim for exemption.
 - A. The research involves no more than minimal risk to participants.
 - B. The research can not involve prisoners as participants. (45 CFR 46.101(i)).

- C. Exemption categories 1-5 do not pertain to FDA-regulated research. (21 CFR 56.104).
 - D. Exemption categories 1-6 apply to research involving pregnant women, fetuses and neonates (45 CFR 46.201(b)), with the exception that VA Research may not involve the fetus as a subject.
 - E. Exemption categories 1 and 3-6 apply to research involving children. Research activities in category 2 are exempt for children only when limited to educational tests or observation of public behavior when the investigators do not participate in the activities being observed. (45 CFR 46.401(b)).
- V. Categories of research activities identified as exempt by UIC:
- A. Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - 1. Research on regular and special education instructional strategies, or
 - 2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45 CFR 46.101(b)(1), 38 CFR 16.102(b)(1)]
 - B. Category 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - 1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;
AND
 - 2. 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, loss of insurability (this later criteria is for VA Research only; 1200.05) or reputation. [45 CFR 46.101(b)(2), 38 CFR 16.102(b)(2)]
 - 3. If the research in this category involves children as participants, the activities can not include (45 CFR 46.401(b)):
 - a) Survey procedures;
 - b) Interview procedures;
 - c) Observation of public behavior where the investigators participate in the activities being observed.
 - 4. Additional guidance.
 - a) This category requires that information is recorded in a manner that:
 - (1) Participants can not be identified, directly or through their responses, demographics, or codes linked to identifiers,
or
 - (2) If participants can be identified, directly or through their responses, demographics, or codes linked to identifiers, any disclosure of the participants' responses outside the research could not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability or reputation.

- C. Category 3. 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 category 2 above, if:
1. The human subjects are elected or appointed public officials or candidates for public office; or
 2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [45 CFR 46.101(b)(3), 38 CFR 16.102(b)(3)]
- D. Category 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, provided:
1. These sources are publicly available, or
 2. The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45 CFR 46.101(b)(4), 38 CFR 16.102(b)(4)]
 3. Additional guidance:
 - a) Publicly available means that the general public can obtain the data/biological specimens. Sources are not considered publicly available if access to the data/specimens is limited to researchers.
 - b) All material that will be used to conduct the research must exist at the time the research is proposed; no on-going or prospective collection of material is allowed.
 - c) Under this exemption, an investigator may review identifiable records, but must record information in the research record in a non-identifiable manner. Moreover, the data must be permanently and completely de-linked at the time of extraction (that is, the investigator will not have any further access to the identifiable records).
 - d) Exemption from IRB review does not also represent an exemption from HIPAA requirements for authorization or waiver of authorization when the research involves the use or access of PHI.
 - e) Research involving the retrospective analysis of medical records qualifies for exemption category 4 when the information extracted from the chart and recorded in the research record does not contain any identifiers, including most of the 18 HIPAA elements (dates of service and geographic codes less specific than street address are allowable), codes derived from any of the HIPAA elements or codes linked to identifiers. The investigator must also receive a waiver of HIPAA authorization from the IRB, as looking at medical records is considered accessing PHI regardless of whether or not identifiers are being recorded.

4. For VA Research, if exemption category 4 is claimed, the investigator may not retain any of the 18 identifiers outlined in the HIPAA Privacy Rule, and the investigator may not have access to any code by which the information may be linked to individuals. When the investigator will review PHI for the research, a waiver of authorization is required.
 5. Research involving the retrospective analysis of medical records does not qualify for a claim of exemption if prospective rather than retrospective data is collected, any of the 18 HIPAA elements, except dates of service and geographic codes less specific than street address, combinations of the elements are entered into the research records, or data contained in the research records are linkable in any way to the identity of the subjects.
- E. Category 5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
1. Public benefit or service programs;
 2. Procedures for obtaining benefits or services under those programs;
 3. Possible changes in or alternatives to those programs or procedures;
or
 4. Possible changes in methods or levels of payment for benefits or services under those programs. [45 CFR 46.101(b)(5), 38 CFR 16.102(b)(5)]
 5. Federal guidance specifies that the following criteria must be satisfied to apply this exemption:
 - a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutritional services as provided under the Older Americans Act);
 - b) The research or demonstration project must be conducted pursuant to specific federal statutory authority;
 - c) There must be no statutory requirement that the project be reviewed by the IRB; and
 - d) The projects must not involve significant physical invasions or intrusions upon the privacy of participants.
 - e) Authorization or concurrence of the Federal funding agency for the exemption determination is needed. For VA Research, determination of exempt status for these research and demonstration projects must be made by the Under Secretary of Health on behalf of the Secretary of Veterans Affairs.
- 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 46.101(b)(6), 38 CFR 16.102(b)(6)]

VI. Although exempt research is not subject to the federal regulations at 45CFR46 (or 38CFR16), 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 an original and one copy of the following documents to OPRS:
 1. Claim of Exemption Application: This form is available on the OPRS website. The website also provides instructions for preparing the form and a list of documents to be submitted with the application;
 2. Protocol;
 3. Federal grant or grant subcontract (if applicable);
 4. Appendices and supplemental documents as needed (e.g., Appendix P, Appendix K, questionnaires, surveys, letters of agreement, limited data use agreements, etc.);
 5. Informed consent and recruitment materials, as appropriate.
- B. The OPRS office/data entry staff checks the submission for completeness, documents receipt of the application, logs the application into the database, and assigns the protocol to the appropriate IRB or OPRS staff.

II. Review Process.

- A. The following individuals may review and approve claims of exemption
 1. VA Research: IRB chair or IRB members designated by the Chair.
 2. Research conducted at UIC and non-VA performance sites: IRB Assistant Directors or Coordinators (designated), Director/Associate Director of OPRS, IRB Chair, or IRB member designated by the Chair.
 3. Research involving retrospective analysis of medical records (use of PHI) and meeting the criteria for exemption category 4: Determination of the waiver of HIPAA authorization must be made by the IRB chair or IRB members designated by the Chair.
- B. The reviewer is responsible for notifying the IRB Chair or OPRS Director if they have a conflict of interest as outlined in the UIC HSPP policy [IRB Member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest](#) or if they do not feel qualified to review the proposal.
- C. The reviewer uses the UIC OPRS *Claim of Exemption Guide for Reviewers* form to guide and document the review.
- D. In making the determination, the reviewer considers whether:

1. The research meets the definition of research involving human subjects;
 2. The selection of subjects is equitable;
 3. The research involves no more than minimal risk;
 4. The research involves prisoners;
 5. The research involves children;
 6. The research activities fit one or more exemption categories;
 7. The research is FDA regulated;
 8. The proposed recruitment procedures and consent process are appropriate;
 9. The consent process, when applicable, informs participants of the following:
 - a) The activity is research;
 - b) Name, affiliation, and contact information for the investigator
 - c) Purpose of the research;
 - d) Description of the procedure;
 - e) Participation is voluntary;
 - f) Measures to protect the privacy of subjects and the confidentiality of the research data;
 - g) Description of any reasonable foreseeable risks as well as anticipated benefits;
 - h) Statement that the researcher is available to answer any questions.
 10. Adequate provisions exist, when applicable, to protect privacy interests of subjects and maintain the confidentiality of the data.
- E. The reviewer makes one of the following determinations:
1. Certification of exemption is granted;
 2. Additional information or modifications needed before a final determination can be made;
 3. Proposed activity does not meet the definition of 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. For research meeting the criteria for exemption category 4 and involving the retrospective review of medical records, the reviewer determines whether a waiver of HIPAA authorization is warranted.

III. Communications.

- A. The investigator is promptly notified of the reviewer's determination by e-mail and campus or U.S. 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; and
 4. For research granted an exemption, documentation of:
 - a) The exemption category(ies);

- b) The expiration date of the exemption certification;
 - c) The investigator's responsibility to submit any modifications to the research to OPRS for review and certification prior to implementation;
 - d) Review of any informed consent documents, recruitment materials, or research instruments;
 - e) If applicable, waiver of HIPAA authorization;
 - f) If applicable, Optional Form 310 - Protection of Human Subjects, Assurance Identification/Certification/Declaration.
- B. The IRB is notified of protocols granted an exemption by listing them on the agenda for the next IRB meeting. The meeting minutes related to the agenda also list the protocols granted an exemption during that time period.
- C. For VA Research, the OPRS notifies the JBVAMC R&D committee of the exemption determination by transmitting a copy of the determination letter and IRB minutes to the R&D office.

IV. Amendments.

- A. Any proposed amendments to a project that has received a certification of exemption must be submitted to the OPRS for review and certification of exemption prior to implementation. The proposed amendment is submitted using the amendment submission form. Amendments to research protocols that were granted an exemption are reviewed to determine whether or not the change to the research would alter the exempt status, thus requiring either expedited or convened IRB review.

V. Expiration.

- A. Studies granted exemptions from IRB review are issued an expiration date of three years.
- B. Investigators are sent reminders at 90, 60, and 30 days before the expiration date.
- C. Investigators must either re-submit to continue the research or submit a final report to close the protocol.

REFERENCES:

[21 CFR 56.104\(c\)-\(d\)](#)
[38 CFR 16.101\(b\), 38 CFR 16.301\(a\), 38 CFR 16.401\(b\), 38 CFR 16.101\(b\)\(1\)-\(b\)\(6\)](#)
[45 CFR 46.101\(b\), 45 CFR 46.301\(a\), 45 CFR 46.401\(b\)](#)
[OHRP Guidance on 45 CFR 46.101\(b\)\(5\): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs](#)
[OPRR Guidance on Exempt Research and Research that may Undergo Expedited Review, May 5, 1995](#)
[OHRP Guidance on the Involvement of Prisoners in Research May 23, 2003](#)
[VHA Handbook 1200.05 para.3 and 8, Appendix A](#)

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.