

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.2
Policy Title: Institutional Review Board (IRB) - Exemptions

Purpose

The purpose of this policy is to describe circumstances under which an exemption from regulations may be granted, and who may grant said exemption.

Definitions

See policy 2011-007.0 for definition of Exempt.

Policy

Unless otherwise noted, regardless of funding source, the categories of research for which an exemption may be granted are those that have been published in the Human Subject Protection regulation, 45 CFR 46. UConn Health will not use any provision for broad consent should such a provision be adopted in revised regulation. The exemption category regarding 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 and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs pertains only to studies sponsored or funded by the Department of Health and Human Services. Research subject to FDA regulations only qualifies for the exemption regarding Taste and Food quality evaluations. Additional categories may be developed and published by the institution for non-federally funded minimal risk research.

Investigators cannot make the determination as to whether a research project is exempt. Such determination must be made by a representative of the Human Subjects Protection Program (e.g. an IRB Regulatory Specialist (RS), IRB member, Research Compliance Monitor, Educational Specialist). However if an exemption category specifically requires IRB review as a criteria for the exemption, the exemption must be granted by an IRB member. When review by the IRB is required by the exemption category, the research is subject to policies pertaining to suspension/termination of approval. Investigators must obtain exempt determinations prior to the start of the research. The reviewer may require expedited approval or review and approval by the convened board but may not disapprove the project. When requiring expedited or full board review, justification for doing so is to be provided.

In the event of changes to the regulatory categories of research that may be exempt, an exemption made prior to such change will continue to be recognized as a valid exemptions made according to the federal categories of exemption in place at the time the exemption was granted.

The exemptions defined in regulations may be applied to research involving pregnant women, fetuses or neonates if the conditions of the exemption are met.

The exemptions defined in regulations do not apply to research involving prisoners, except for non-federally funded / supported research aimed at involving a broader subject population that only incidentally includes prisoners if the conditions of the exemption are met. If the federal regulations are implemented to allow for this incidental inclusion of prisoners in federally funded/support exempt research UConn Health will also permit this.

The exemptions defined in regulations may be applied to research involving children if the conditions of the exemption are met with the following exclusion.

- For research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview process or observation of public behavior (including visual or auditory recording) children may only be involved when the activity is limited to involving educational tests or the observation of public behavior when the investigators do not participate in the activities being observed.

The reviewer may require a consent process or other protections for exempt research.

All studies approved as exempt are presented for informational purposes on the agenda of the next regularly scheduled meeting of the appropriate panel for which the submission deadline has not passed.

Research which is deemed exempt is not subject to continuing review requirements, even when the criteria for granting the exemption required some level of IRB review. For administrative purposes of maintaining databases and files the HSPP staff will assign an expiration date to exempt research. The expiration date will be the anticipated completion date of the project put forth in the application, or one year from the date the exempt determination is made; whichever is longer. While the exemption is active the research is subject to the Research Compliance Monitoring Program. When the expiration date passes, unless otherwise requested by the PI, the IRB will administratively close the exemption which will remove it from the pool of studies subject to audit. This closure does not invalidate the exemption (e.g. the research may continue as planned). For exemptions granted prior to the implementation of this practice the IRB staff may periodically contact the Principal Investigators (PIs) of exempt studies to determine if the study is still active and obtain expected completion dates in order to implement the same practice.

Procedure

A PI requests exempt status for a research study by indicating within the material provided to the IRB the exemption category that s/he believes is applicable to the study. The PI must also provide all of the other material requested on the IRB application checklist as applicable to the study.

Designated IRB staff will assign requests for exemptions to a RS.* The RS may elect to perform a general screening function prior to performing a formal review. During the screening and/or formal review process, the RS may request that the PI provide additional documents, clarifications, or make corrections before granting the exemption. Such requests for information will be made through the electronic submission system by returning the submission for corrections if requested during the general screening process; or by returning the submission for responses if requested after the formal review is done.

- If corrections are requested as part of a screening process, the review process is set to Returned for Corrections, the study status is set to Initial Screening
- If responses are requested after the formal review, the review process is set to exempt, and the submission outcome is set to Approved Contingent.

The process may repeat if the investigator does not provide adequate responses.

Once all requested additional information is received the RS may grant the exemption. When determining whether to grant the exemption, the RS will review the application and all of the material required for submission for exempt studies as noted in the submission checklist.

The RS documents the final determinations by completing the reviewer form and the form becomes part of the IRB study file.

- If the RS determines the study does not qualify for exemption:
 - the RS will inform the PI by returning the submission with the electronic submission with contingency that directs that study to be resubmitted requesting either expedited or full board review with inclusion of required documents (e.g. consent forms).
- If the RS determines the study qualifies for exemption:
 - the RS will issue to the PI the standard exempt approval letter;
 - the RS will apply the electronic approval stamp to the relevant documents as indicated on the application for exemption checklist;
 - for administrative purposes the RS will assign an expiration date to the exempt research. The expiration date will be either the expected completion date of the research or one year from the date the exempt determination is made, whichever is longer. The expiration date is not stamped on documents.
 - the RS will add the exemption approval to the informational agenda of the next regulatory scheduled board meeting for which the submission deadline has not passed.
 - Any member of the board may request full board review of a study previously deemed exempt. The board will vote and if the vote is in favor of full board review, the Chair will contact the PI, or direct the RS to do so, to withdraw the approval until full board review is conducted. Notification will be done by correspondence through the electronic submission system. This is not considered a suspension or termination of approval that is reportable to institutional officials or agency heads.

While the RS is authorized to grant exemptions, this does not preclude the RS from assigning the task to an IRB member. In such cases the RS may perform a screening function before assigning the task for review by a member. The RS may ask for corrections as noted above. Upon receipt of all responses, the RS would assign the reviewer. Any concerns expressed by the reviewer would be returned to the RS, who in turn would communicate the concerns to the PI as noted in order to obtain the responses. Upon receipt of responses, either the RS or the previously assigned reviewer can then make the determination as to whether the exemption may be granted.

* Note, if there is a regulatory requirement that the IRB review an exemption for purposes of ensuring provisions for privacy/confidentiality are appropriate, the RS must also be a member of the IRB, and if not the RS will assign the review to an IRB member. While the RS is the default reviewer for making exempt determinations, for exemption that do not require IRB review other staff within the HSPP may also be assigned the review.

Related Policies

2009-005.0 - Monitoring of IRB Approved Studies

2011-008.1 - Informed Consent – Process

2011-009.3 – Institutional Review Board – Expedited Reviews

2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

45 CFR 46
21 CFR 56

Document Attributes

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Reviewed and Approved By:

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Date