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

It is the policy of the HSPP that investigators cannot make the determination as to whether a research project is exempt. Such determination must be made by a representative of the IRB office (e.g. an IRB Regulatory Specialist (RS)* or IRB member). Investigators must obtain such 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 deny the project.

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.

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

Exempt research is subject to the Research Compliance Monitoring Program.

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.

For administrative purposes of maintaining databases and files the IRB staff may periodically contact the Principal Investigators (PIs) of exempt studies to determine if the study is still active.

*The RS may also be a member of the IRB, but does not have to be a member in order to grant an exemption.

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, alternating the assignment of new submissions. 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 screen 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.
- 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;
    - 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 approved as 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 will 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.

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:

Signed Richard H. Simon *1 May 2017*

Richard Simon, MD **Date**
Director Human Subjects Protection Office