
Yale University Institutional Review Boards

100 PR.3 Exemption Determinations

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Overview

At the discretion of the IRB, projects meeting the criteria for exemption as described in Policy 100, IRB Review of Research Proposals, may be granted an exemption following review by an experienced IRB member or staff reviewer. This procedure describes the requirements and process for review of projects that may qualify for exemption.

Submission Requirements

If an investigator believes that his or her research activities may qualify for exemption he or she may request such a review by indicating the applicable exemption category when submitting the project to the IRB (See Form 100 FR.4, Exemption Request or Coeus eIRB guide). When submitting a paper submission, two copies of the exemption request along with all attachments should be submitted to the IRB. The IRB chair or other experienced reviewer is responsible for ultimately determining whether or not a study qualifies or is appropriate for exemption.

Ethical Requirements for Exempt Studies

Studies which are deemed exempt by the IRB are still required to adhere to basic ethical principles regarding the ethical treatment of participants and/or their data. Investigators are expected to design exempt studies so that risks to participants are minimized and justified by the anticipated benefits of the research; where prospective participants are informed about the research and voluntarily agree to participate; participant privacy and confidentiality is protected commensurate with confidentiality risks including appropriate data security; and subject selection is equitable.

Ethical requirements also extend to incidental findings arising in the course of research. Researchers should be prepared to respond to any issues that arise in the course of exempt research to ensure the protection of research participants. For example, observational studies may encounter situations of imminent risk to participants, and tissue-based research may identify risk factors for disease. Researchers should consider the types of incidental findings which could arise in a given project, whether it would be possible to contact participants and then identify appropriate responses, if any. See also IRB Guidance on Incidental Findings.

Exemption status also does not obviate other obligations of the investigator such as state mandated reporting requirements for abuse, communicable disease or other applicable state reporting requirements.

Review Process

Research proposals that may qualify for exemption consideration are reviewed by one or more experienced reviewers who may or may not be voting members of the IRB. In no case may a project be reviewed by an individual with a real or perceived conflict of interest. The reviewer will determine whether or not the study meets the exemption categories defined in Policy 100, IRB Review of Research Proposals (see also <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c3>).

An individual may be considered to be an experienced reviewer following a training period under the direction of the IRB Chair or IRB Director in which the individual has demonstrated competence in interpreting the nuances of the exemption categories.

If the research clearly qualifies for exemption, the assigned reviewer will promptly issue an exemption determination in writing. If the research does not clearly qualify, or if participants would benefit from continued IRB oversight, the reviewer may refer the study for expedited review or to a meeting of the convened IRB for review. For example, research involving the psychology subject pool is generally not granted exemption as the recruitment process may lead participants to perceive coercion or undue influence. The reviewer also may seek clarification from the principal investigator. The reviewer may suggest changes to the study design so that the study may qualify for exemption from further IRB review.

Applicability of Common Rule and FDA Exemptions

The FDA has not adopted all of the exemption categories as described in Policy 100: IRB Review of Research proposals. Exempt status shall not be granted when: Categories (1) through (5) apply and research is subject to FDA regulations. FDA regulated research exemptions are limited to taste and food quality evaluations and emergency use of test articles. Research which is otherwise exempt requires IRB approval and oversight if the research is subject to FDA regulations.

Applicability of HIPAA to Exempt Studies

Studies involving the use or disclosure of protected health information are required to comply with HIPAA Policy 5032 Use and Disclosure of Protected Health Information for Research Purposes in addition to IRB policies. Research projects found to be exempt may still require HIPAA authorization or an IRB approved waiver of HIPAA authorization. For example, studies found to qualify for exemption under 45 CFR 101(b)(2) or (b)(4) because they will not include the collection of direct identifiers such as name or street address, may nonetheless include data elements considered to be identifiers under HIPAA such as date of birth or date of service. Investigators should include either a HIPAA authorization or a request for a waiver of HIPAA authorization in the exemption request to the IRB if protected health information will be collected.

Vulnerable Populations

Children

Research involving children may qualify for exemption unless the study involves survey or interview procedures or observation of public behavior where the investigator participates in the activities being observed. (45 CFR 401).

Prisoners

Exemptions are not applicable to research involving persons who are currently known to be incarcerated.

Pregnant women and other potentially vulnerable populations

Research involving pregnant women, individuals with impaired consent capacity or other potentially vulnerable populations may qualify for exemption if they meet the criteria described in Policy 100 IRB Review of Research Proposals.

Psychology Subject Pool

Studies recruiting participants through the psychology subject pool are not granted exemptions as this population 1) may include minors and would be restricted as described above for studies involving children and 2) may perceive undue influence in being recruited in the context of the Introductory Psychology course.

Notification and Documentation Requirements

The reviewer will provide prompt written notification to the investigator regarding the outcome of the review including the exemption category. Investigators will also be informed that changes to the study which would impact the exemption determination are subject to further review by the IRB.

IRB records will include documentation regarding the determination of permissible category for exemption, either through notes included in the IRB file or in IRB minutes.

A list of all human research proposals determined to be exempt is provided to the IRB members at each convened meeting.

Further Review of Exempt Studies

Once a protocol is determined to be exempt, it is not reviewed again unless an amendment request is submitted. There is no continuing review process for exempt research, as long as the criteria for exemption remain satisfied.

Changes to exempt studies which may impact the exemption determination such as proposing to collect identifiers under a 45 CFR 46(b)(4) exemption require submission of an amendment request to the IRB. The IRB or experienced reviewer will determine whether the proposed changes impact the exemption status and if so, the protocol will be reviewed in accordance with IRB Policy 100.

Exemption determinations are considered to be concurred to by the funding agency unless otherwise notified by the agency. Disputes regarding exemption determination will be resolved between the IRB reviewer and the funding agency representative.