	UNIVERSITY RESEARCH POLICY: IRB Exempt Determinations Responsible Office: Research Integrity		
	ORIGINALLY ISSUED	REVISED	AUTHOR
	12-Mar-2018	29-Nov-2023	M. Dohn
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review and exemption of new research that qualifies for exempt review.

Provision of Materials for Review

The researcher submits a completed package through IRBNet. Instructions for preparing and making submissions to the IRB are available on the [Lehigh University IRB website](#).

Investigators are required to answer questions about the proposed study, which allows the IRB to evaluate the protection of human subjects participating in the exempt study, including information about risk to subjects, subject selection, and provisions for protecting the privacy interests of subjects and the confidentiality of subject data.

When appropriate, investigators are required to include a consent process that describes the study requirements, indicates that it is research, and indicates that participation is voluntary, to ensure that participants are fully informed about the nature of the research project so they can make an informed decision to participate.

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether the study is eligible for review per this policy. If the application does not meet the criteria for review per this policy, the Research Integrity office staff reassign the application to the correct review category or returns the application to the researcher for further clarification.

The Research Integrity office staff note if the application involves application of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the Family Educational Rights and Privacy Act (FERPA), and any other relevant institutional or regulatory requirements, and complete the appropriate approval criteria worksheet/checklist to document that all requirements are addressed.


Exempt Reviewer Assignment

Research Integrity office staff serve as exempt reviewers for new exempt applications. Minor modifications to previously exempted research are reviewed by an expedited IRB committee reviewer under the expedited review process. The exempt reviewer assignment is documented in IRBNet. Exempt protocols requiring limited IRB review as a condition of exemption are also reviewed by an expedited IRB committee reviewer under the expedited review process.

Criteria for Exemption

The exempt reviewer is expected to conduct an in-depth review of all materials and are provided access to approval criteria worksheets through IRBNet and on the [IRB website](#) as guidance to ensure inclusion of regulatory criteria that must be met per 45 CFR 46.104(d)(1)-(6) and any other relevant ethical or compliance considerations. The exempt reviewer determines if the proposed research is exempt from federal policies governing human subject protections. This determination is made in accordance with:

- The criteria for exemption as specified under 45 CFR 46.104(d)(1)-(6)
- The [Lehigh IRB Exempt Determination Criteria Worksheet](#)

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- If subjects are under the age of 18 years, the exemption criteria described in 45 CFR 46.104(d)(2), are not applicable with the exception of research limited to (a) the use of educational tests or (b) to observations of public behavior when the investigator does not participate in the activities being observed. For studies subject to the DoD regulations, no exemptions may be applied when children are involved as participants.
- For protocols that involve interactions with subjects, investigators are required to detail the consent process that includes key elements of consent and is consistent with the principles of the Belmont Report.
 - NOTE: The exemption criteria in 45 CFR 46.104(d) do not apply to studies involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
 - The exemption criteria [with the exception of 45 CFR 46.104(b)(6) / 21 CFR 56.104(d)] do not apply to FDA-regulated research studies.
- For protocols requiring limited IRB review as a condition of exemption under 46.104(d)(2)(iii) and (d)(3)(i)(c), the exempt determination is made only after expedited review limited to confirmation that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

Investigator Communications

Comments or concerns of the exempt reviewer with regard to the exempt status of the research activity are documented and communicated in IRBNet to the principal investigator.

Responses of the principal investigator are reviewed by the exempt reviewer (or another IRB reviewer if the original exempt reviewer is unavailable for an extended time).

Exempt Review Outcome and Documentation


The exempt reviewer makes the final determination as to whether research activities meet the criteria for review and exemption under this policy. Exempt reviewers exercise all of the authority of the IRB except that exempt reviewers may not disapprove the research. The IRB only disapproves research after review by a fully convened committee.

The exempt reviewer only raises those controverted issues or requests changes that directly relate to relevant approval criteria as outlined in this policy.

The exempt reviewer documents their determination as follows:

- Determination of Exempt Status: the approval indicates the exempt reviewer has concluded that the research and consent forms, when applicable, meet the criteria for exemption and the research is minimal risk. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or any findings as described by the PI in the application materials. The exemption is granted without an expiration date.
- Modifications Required to Secure Approval: the exempt reviewer specifies revisions and/or requests additional information that must be submitted by the PI for review before exemption can be granted. The requirements are communicated to the PI and the PI must respond via a response package submission in IRBNet. The response is returned to the exempt reviewer to verify that all exemption criteria were met.
- The exempt reviewer can determine that the activities are not 'human subjects research' per the Lehigh University IRB's definition, and therefore are not the purview of the IRB. In these cases, the exempt reviewer will document the rationale for this determination and communicate the determination to the investigator.

The Research Integrity office promptly issues the commensurate notice to the PI via IRBNet.

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Post-approval monitoring requirements

- For funded protocols previously determined to be exempt, investigators are required to obtain IRB approval of any changes to the protocol prior to implementing the proposed changes.
- For unfunded protocols previously determined to be exempt, IRB approval for changes to the protocol is required *only* when the proposed changes would change the level of risk to participants (e.g., adding the collection of identifiable information, change in the population being studied, adding the sharing of identifiable data with 3rd parties, inclusion of potentially vulnerable population(s), change in research setting, addition of any new intervention/manipulation that does not meet the definition of a Benign Behavioral Intervention¹). Minor modifications such as personnel changes (other than the PI), small changes / corrections to previously approved stimuli / materials, grammatical / wording changes, do not require IRB approval.
- Any proposed change that would lead to a change in review category (from exempt to expedited/full) must be approved by the IRB in advance of these changes being made, regardless of the funding status of the protocol.
- Any unanticipated problem involving risks to subjects or others, and/or serious adverse events must be reported to the IRB per the IRB Policy: Reporting Unanticipated Problems/Adverse Events to the IRB.

Policy Updates

Date	Update
29-Nov-2023, 22-Sep-2023	Updated to clarify amendment requirements for unfunded exempt protocols.
21-Jan-2019	Updated to reflect the implementation of the Revised Common Rule regulations

¹ Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. See [45 CFR 46.104.d.3.i](#)