	UNIVERSITY RESEARCH POLICY: Expedited IRB Review Responsible Office: Research Integrity			
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of new applications, modifications, continuing reviews (renewals), renewals with modifications, and approval of research that qualifies for expedited 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](#).

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 and/or the Family Educational Rights and Privacy Act (FERPA) and complete the appropriate approval criteria worksheet/checklist to document that all legal requirements are addressed.

Expedited Reviewer Assignment


The Research Integrity office staff assigns IRB committee reviewers. New applications are reviewed by a subcommittee of three reviewers. Continuing reviews and minor modifications are reviewed by one reviewer. The Research Integrity office staff make designated reviewer assignments based on the member's familiarity with IRB issues, experience, availability, and expertise. Designated reviewers notify the Research Integrity office staff when they are unable to complete a review within the designated timeframe, or if they have a conflict of interest. The designated reviewer assignment is documented in IRBNet.

Categories of Expedited Review

IRB reviewers are 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 and informed consent requirements that must be met per 45 CFR §46.111 and/or 21 CFR 56.111. In addition, assigned reviewers are expected to evaluate informed consent documents from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable), and any other relevant ethical or compliance considerations. Reviewers are expected to confirm that the research presents minimal risk and is eligible for expedited review in accordance with this policy and with the [Categories of Research that May Be Reviewed by the Institutional Review Board \(IRB\) through an Expedited Procedure](#), as published by the OHRP, 45 CFR 46.110 and FDA 21 CFR 56.110.

Minor modifications that do not materially affect an assessment of the risks and benefits of the study or do not substantially change the specific aims of the study are eligible for expedited review. Modifications that do not meet this definition will be reviewed at a convened meeting. Examples of minor modifications include the following:

- The addition of research activities that meet the expedited criteria under 45 CFR 46.110 or 21 CFR 56.110.

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- A statistically justified increase or decrease in the proposed human research subject enrollment
- Narrowing the range of inclusion criteria or broadening the range of exclusion criteria.
- Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations
- Properly justified alteration in subject payment or liberalization of the payment schedule.
- Changes to improve the clarity of statements or correct typographical errors, provided that such a change does not alter the content or intent of the statement
- Addition or deletion of study sites
- Minor changes specifically requested by the IRB or other university oversight committees.

Initial expedited review is not applicable to research studies where the subjects are known to be prisoners.

Limited IRB Review for Exempt Protocols (45 CFR §46.111(a)(7))

Expedited review procedures will also be used to complete the limited IRB review required as a condition for exemption under §46.104(d)(2)(iii) and (d)(3)(i)(c).

Under limited IRB review, the expedited reviewer must confirm that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data. The expedited reviewer is provided access to approval criteria worksheets through IRBNet and on the IRB website as guidance to ensure the protocol meets the exemption criteria specified in §46.104(d)(2)(iii) and (d)(3)(i)(c). This determination is documented in IRBNet.


Expedited Review Outcome and Documentation

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

The expedited reviewers only raise those controverted issues or request changes that directly relate to relevant approval criteria as outlined in this policy.

The expedited reviewer documents their determination as follows:

- **Approved:** the approval indicates the expedited reviewer has concluded that the research and consent forms, when applicable, meet the criteria for approval 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. Approval periods are determined per the Approval Periods section below.
- **Modifications Required to Secure Approval:** the expedited reviewer specifies revisions and/or requests additional information that must be submitted by the PI for review before approval 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 expedited reviewer to verify that all approval criteria were met. At the discretion of the expedited reviewer, minor revisions may be reviewed by the Research Integrity office to verify that all approval criteria were met. In these cases, to indicate that the Research Integrity office staff may confirm researchers' responses in lieu of review by the expedited reviewer, the expedited reviewer should choose "Approve with Conditions" in IRBNet.
- **Defer to full committee review:** the expedited reviewer may determine that the research potentially presents greater than minimal risk and requires full review by the IRB at a convened meeting.
- The expedited 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 expedited reviewer will consult with the Research Integrity office to document the rationale for this determination and communicate the determination to the investigator.

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

Approval Periods

Approval periods for research studies assigned an expiration date are determined per IRB Policy: End Approval Dates.

In most cases, minimal risk research will not be assigned an expiration date when approved either at initiation or during the first continuing review submission approved after implementation of this policy.

The following research must be assigned an expiration date:

- Research that receives support from or is subject to FDA regulation or oversight, including research involving data repositories that are intended to be used to support applications to the FDA, and research that involves procedures, devices, or drugs subject to FDA oversight.
- Research that receives support from a Federal agency / sponsor that has not adopted the Common Rule (45 CFR §46).
- Research that receives NIH-issued Certificates of Confidentiality.
- Research that involves federal personnel or involvement of/support from the Department of Veterans Affairs.
- Research involving a [Conflict of Interest](#) for any study personnel.
- Research that involves prisoners as subjects.
- Research that has executed IRB Authorization Agreements in place.
- Research that includes international sites(s) under the supervision of the PI.

At its discretion, the IRB may assign an expiration date to minimal risk research that includes certain activities, including, but not limited to the:

- Inclusion of vulnerable or special populations (e.g. children with special needs).
- Collection of information regarding criminal behavior, substance abuse, and/or mental health.
- Involvement of external sites (e.g. schools).

Expedited reviewers must record their justification for assigning an expiration date to minimal risk research in their review comments during the approval process.


Studies originally reviewed via full board meeting

For renewals or modifications, the IRB reviewer determines if the research that was originally approved by the full-board IRB may now qualify for expedited review. This determination is made based on the risk level or the status of the research and in accordance with the [Categories of Research that May Be Reviewed by the Institutional Review Board \(IRB\) through an Expedited Procedure](#), as published by the OHRP, 45 CFR 46.110 and FDA 21 CFR 56.110.

Studies originally approved via expedited review

For renewals on studies assigned an expiration date and, on all modifications, IRB protocols originally approved by the expedited process are re-evaluated to ensure the submission continues to qualify for expedited review as specified in "[Categories of Research That May Be Reviewed by the Institutional Review Board \(IRB\) through an Expedited Review Procedure](#)." If the research no longer meets these requirements, it will be forwarded for review by a convened IRB Committee and the principal investigator so informed.

New Information and Significant New Findings

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The IRB reviewer evaluates whether any new information/significant new findings obtained during continuing review should be provided to subjects when this information might relate to the subjects' willingness to continue to take part in the research.

Post-approval monitoring requirements

- Investigators are required to obtain IRB approval of any significant changes to the protocol prior to implementing the proposed changes.
- 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.
- Studies approved with an expiration date are required to submit a Continuing Review to the IRB and obtain re-approval prior to the expiration date.

Minimal risk research approved without an expiration date is monitored through annual check-in notices issued by the Research Integrity office. Investigators are required to respond to these notices and the information gathered is used to determine if the research continues to be eligible for continuation without additional post-approval monitoring by the IRB.

Policy Updates

Date	Update
21-Jan-2019	Updated to reflect the implementation of the Revised Common Rule regulations