	<b>UNIVERSITY RESEARCH POLICY: Suspension, Termination, or Expiration of IRB Approval</b>			
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## Policy Statement

This policy describes the policy and procedures for the suspension, termination, or expiration of IRB approval.

## Reason for Policy

During the conduct of human subject research, it may become necessary to suspend or terminate some or all research activities associated with an IRB approved protocol. Federal regulations grant the IRB the authority to suspend or terminate IRB approval for research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects (45 CFR §46.113). The IRB may also terminate approval when projects are completed, withdrawn, the IRB approval period has expired, or the project no longer involve human subjects.

## Suspension of IRB Approval

The IRB may temporarily or permanently suspend all or some specific research activities that are not being conducted in accordance with IRB requirements. The IRB may also suspend some or all of the research conducted by the researcher(s) as a result of serious or continuing noncompliance or if there are unanticipated problems involving risk to subjects or others. Studies that are suspended remain active and are subject to all requirements for continuing review.

The IRB determines whether it is necessary to suspend some or all research activities being conducted as part of a previously approved protocol; this determination is made by the committee co-chairs.

A notification of suspension of approval is shared with the principal investigator via IRBNet; this notification includes:

1. List of all suspended research activities;
2. The reason(s) for the suspension;
3. A request for the number of active research subjects and any information necessary to protect their rights and welfare related to the suspension of some or all research activities;
4. Corrective actions that must be addressed by the researcher(s) in order to lift the suspension;
5. Timeline for implementing corrective actions and responding to the IRB.

Any decision by the IRB to suspend some or all research activities shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (the federal agency sponsoring the research, as applicable).


The principal investigator is informed that no suspended research activities may be conducted or resumed until the investigator receives written notification from the IRB that approval has been reinstated.

The principal investigator is directed to submit any request to resume suspended research activities via IRBNet. The request to resume suspended research activities and all corrective actions completed by the principal investigator are reviewed by the committee co-chairs.

If the IRB determines that the principal investigator has satisfactorily addressed the necessary corrective actions, the IRB may elect to lift the suspension. However, if the required corrective actions have not been addressed, the IRB may move to terminate the research or take other actions deemed necessary to protect the rights and welfare of subjects or others. The IRB's decision is shared with the principal investigator via IRBNet.

## Emergency Suspension of Research Activities

In situations where the immediate suspension of some or all research activities is necessary to protect the safety and welfare of subjects, and it is not feasible to convene an emergency meeting of the IRB, the IRB Chair has the authority to suspend any research activities to protect these subjects. The chair's decision to suspend research

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activities for emergency purposes will be communicated to the IRB at the next convened meeting and documented in the minutes of the meeting.

### Termination of IRB Approval

The IRB may terminate approval for research projects that are associated with findings of serious or continuing noncompliance, unanticipated problems involving risk to subjects or others, or findings resulting from continuing review or post-approval monitoring of research activities. Terminated studies are permanently closed and no longer undergo continuing review.

The IRB determines whether it is necessary to terminate approval for a specific research project; this determination is made by the committee co-chairs.

A notification of termination of approval is shared with the principal investigator via IRBNet; this notification includes:

1. The reason(s) for the termination;
2. A request for the number of active research subjects and any information necessary to protect their rights and welfare related to the termination of research activities;
3. Corrective actions that must be completed by the researcher(s) before the research can be re-submitted for review by the IRB;
4. Timeline for implementing corrective actions and responding to the IRB.

Any decision by the IRB to terminate approval shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (the federal agency sponsoring the research, as applicable).

The principal investigator is informed that no research activity associated with the terminated project may be conducted or resumed unless specifically permitted by the IRB in order to protect the rights and welfare of active research subjects. In order to resume terminated research activities, the principal investigator must submit a new research proposal for IRB review and approval, incorporating all of the corrective actions mandated by the IRB as part of the termination notification.

### Termination of Studies No Longer Under IRB Purview

When a project is completed, withdrawn, or past the phase of involving human subjects, the principal investigator must notify the IRB in writing at [inirb@lehigh.edu](mailto:inirb@lehigh.edu). Research projects are considered to no longer involve human subjects and can be closed with the IRB once investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects; including using, studying, or analyzing identifiable private information.

### Expiration of IRB Approval

IRB approval is considered to expire at 11:59pm on the final date of the approval period. In the event IRB approval expires prior to continuing review and approval of the research, all study activities, including subject recruitment, enrollment, intervention, data collection and analysis, must immediately cease. Research activity on the expired project may not resume until continuing review and approval has occurred.

If a project remains expired for over 60 days and no continuing review request has been submitted to the IRB, the project will be considered permanently closed. In order to resume human subjects research activity (including data analysis), a new research protocol will need to be submitted to the IRB and the project will be reviewed as a new research protocol.