

 <b>LEHIGH</b> <small>UNIVERSITY</small>	<b>UNIVERSITY RESEARCH POLICY: Human Subjects Research Principal Investigator</b>			
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## I. Policy Statement

This policy describes the university policy for who may serve as the Principal Investigator (PI) on a human subjects research project subject to Institutional Review Board (IRB) review and oversight, and the role and responsibility of the PI.

## II. Reason for Policy

This policy addresses the university's commitment to maintaining an effective, well-functioning, and compliant human research protections program. Under University policy, the Principal Investigator (PI) has the primary responsibility for protecting the welfare and the right of privacy of the individual subject in a research project. The responsibility is shared by the University as an institution and by the sponsor when external support is provided for the project.

## III. Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research; the IRB committee members and chairs; the Institutional Official (IO); Research Integrity office staff.

## IV. Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff
- Deans
- University Vice Presidents

## V. Responsibilities

Responsible Party	List of Responsibilities
Deans or university Vice Presidents	Read, understand, and follow this policy when reviewing and providing approval for human subjects research projects being proposed by non-faculty PIs.  When appropriate per this policy, provide written documentation to the IRB that proposed projects that require special permission for non-faculty PIs that research is in furtherance of university objectives and that you accept responsibility for ensuring the research is conducted in compliance with university research policies and procedures.
Designated reviewer	Apply this policy when conducting reviews of IRB applications.
Lehigh University faculty, staff, and students submitting	Read, understand, and follow this policy when preparing applications for submission to the IRB.  Read, understand, and follow this policy when conducting human subjects research.



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human subjects research for IRB review	
Research Integrity office staff	Process IRB reviews and apply this policy when establishing qualifications of the PI named on the application.  Accept and file written documentation of special permission for non-faculty PIs submitted per this policy. Provide documentation to IRB reviewers upon request.

## VI. Principles

### Who May Serve as Principal Investigator (PI)

1. All research proposals and projects involving human subjects include as principal investigator or co-principal investigator at least one person holding the academic rank of University Faculty (Tenured or Tenure Track Professor, Associate Professor, or Assistant Professor), or Research Faculty.
2. Professors of Practice and Teaching Faculty may serve as principal investigator if the research proposal involves work conducted by students under the supervision of the Professor of Practice in the course of their teaching role.
3. Research involving human subjects must be proposed and conducted within a regular academic department of the University or through the cooperation of multiple academic departments or through a research center.
4. Research Fellows may serve as principal investigator if the research proposal involves work conducted by the Fellow under the terms of a formal collaborative research agreement or sponsored research agreement with Lehigh University. The fully executed agreement outlining the terms must be included with the IRB application.
5. A research proposal may be submitted by an individual who does not qualify as a principal investigator under this policy, or by a non-academic department of the University on the following conditions: (a) the individual proposing to conduct the research is a full-time University employee with the requisite qualifications and research experience necessary to conduct such research; and (b) the research proposal has been approved in writing by the Vice President or Dean to whom such individual or department reports, with such approval (i) indicating that such research is in furtherance of University objectives, and (ii) accepting responsibility for ensuring that such research will be conducted in compliance with University research policies and procedures.

### General Responsibilities of the PI

It is the obligation of the principal investigator to bring any proposed research projects involving the use of human subjects to the attention of the IRB via the Research Integrity office, and to be aware of and follow all applicable policies and procedures for conducting human subjects research. Human subjects research conducted by Lehigh University faculty, staff, or students may not commence without advanced approval by the IRB.

As a general condition for the approval of a research study, the IRB holds the PI of the study responsible for ensuring that:

- Risks to research subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- Risks to subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result



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- Selection of human subjects is equitable
- Individuals are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each prospective human subject, or his/her legally authorized representative, in accordance with, and to the extent required, by university policies and federal regulations
- Informed consent of human research subjects will be obtained in advance of research participation and appropriately documented in accordance with, and to the extent required, by university policies and federal regulations
- Where appropriate, there is routine monitoring of the data collected to ensure the safety of human research subjects
- The privacy of human research subjects is protected and the confidentiality of data is maintained
- Appropriate additional safeguards are included in the study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g. children, prisoners, pregnant women, cognitively impaired persons, or economically or educationally disadvantaged persons)

#### Specific Responsibilities of the PI

In addition to the general responsibilities outlined above, the IRB also holds the PI responsible for the following specifics, when applicable:

- Promptly responding to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB renewal, when required.
- Ensuring that adequate resources and facilities are available to carry out the proposed research study
- Abstaining from enrolling any individual in a research study (i) until such study is approved in writing by the IRB, (ii) during any period when the IRB or sponsor/PI has suspended study activities, or (iii) following IRB or sponsor/PI-directed termination of the study
- Ensuring that all colleagues, associates, and other personnel assisting in the conduct, reporting, or design of the research are appropriately informed of (i) the study procedures, (ii) informed consent requirements, (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks, (iv) adverse event reporting requirements, and (v) data collection and record keeping critiera
- Conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject
- Requesting IRB approval of any proposed modification to the research protocol or informed consent documents prior to implementing such modifications
- Obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent documents (i.e., unless the IRB has granted a waiver of the consent process) maintaining adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risk/benefit ratio of study participation
- Reporting promptly to the IRB (and, if applicable, to the sponsor and the FDA) any internal or external adverse event that is considered to be 1) unexpected; 2) serious, and; 3) possibly or definitely related to the study
- Reading, understanding, and following the Lehigh University Research Policy: Reporting Unanticipated Problems/Adverse Events to the IRB
- Ensuring that in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible

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- Ensure that human research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study
- Ensuring that all investigators, including students, participating on a research protocol have the appropriate credentials to conduct the portion of the study in which they are involved and have completed all applicable university required training
- Ensuring that the conduct of the research study adheres to the Good Clinical Practice guidelines, if applicable.
- Maintaining adequate and accurate subject research records that reflect adherence to protocol-specific requirements
- Complying with any additional requires for federal agencies or sponsors

## VII. Procedures

1. IRB review of submissions is completed and documented per the IRB review process.
2. When research proposals are submitted by individual staff members or by non-academic departments of the University who are not qualified PIs per items 1 and 2 of the Principles section above, the IRB submission must be accompanied by a letter documenting the requirements in item 4 of the Principles section above. These requests must be approved by the IRB before a human subjects research application can be considered.
3. Once approved, special permission per item 4 in the Principles section above is applicable for subsequent IRB submissions, unless:
  - a. Subsequent projects differ substantially in terms of furtherance of university objectives
  - b. The letter of permission provided by the Dean or Vice President was explicitly extended to a certain project or for a specified period of time.

Once a research project is approved, the PI named on the IRB-approved protocol is responsible per this policy for the ongoing oversight of the research and for protecting the rights and welfare of all participants.

## VIII. Web Address For This Policy

[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

## IX. Related Resources

<b>University Policies and Documents</b>
<a href="#">Lehigh University IRB Glossary</a>

## X. Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address



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Policy Clarification and Interpretation	Research Integrity Manager	610-758-2199	<a href="https://research.cc.lehigh.edu/contact-us-0">https://research.cc.lehigh.edu/contact-us-0</a>
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### XI. Policy Updates

Date	Update
01-Feb-2018	Roles and responsibilities of the PI were added to IX. Principles. General and specific responsibilities involved in implementing the policy were added for Lehigh University staff, students, and faculty submitting human subjects research for IRB review and for Research Integrity office staff. Ongoing responsibilities of the PI were added to X. Procedures.
23-May-2018	Policy formatting changes
22-Aug-2018	Section 4 of "Who May Serve as Principal Investigator (PI)" was added to the Principles section, to include the terms under which Research Fellows are eligible to serve as PI.
27-Mar-2023	Section 4 of "Who May Serve as Principal Investigator (PI)" was revised to clarify the eligibility of Research Faculty and Teaching Faculty to serve as PI.