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.

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. Web Address For This Policy
Lehigh University IRB website (IRB Standard Operating Procedures and Policies)

VI. Related Resources

<table>
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<th>University Policies and Documents</th>
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<td>Lehigh University IRB Glossary</td>
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VII. Contacts

<table>
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<tr>
<th>Subject Matter</th>
<th>Office Name</th>
<th>Telephone Number</th>
<th>E-mail/Web Address</th>
</tr>
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<tbody>
<tr>
<td>Policy Clarification and Interpretation</td>
<td>Manager of Research Integrity</td>
<td>610-758-2985</td>
<td><a href="https://research.cc.lehigh.edu/contact-us-0">https://research.cc.lehigh.edu/contact-us-0</a></td>
</tr>
</tbody>
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VIII. 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 human subjects research for IRB review

Read, understand, and follow this policy when preparing applications for submission to the IRB.

Research Integrity office staff

Process IRB reviews and assign end approval dates by calculating them per this policy.

IX. Principles

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 Professor, Associate Professor, or Assistant Professor.
2. Professors of Practice may also 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. 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.
5. 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.
6. Human subjects research conducted by Lehigh University faculty, staff, or students may not commence without advanced approval by the IRB.

X. 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.