



# Human Subjects Research Policy Update

Naomi Coll  
Director of Research Policy and Compliance

# Major Policy Updates

1. Activities that meet the HHS or FDA definition of “human subjects research” are subject to IRB oversight
2. Continuing review (annual renewal) is no longer required for minimal risk, unfunded research
3. New informed consent requirements/templates
4. Review by a single IRB is required for NIH-sponsored multisite studies

# Are Federal Regulations Changing?

- The [U.S. Department of Health and Human Services](#) (HHS) and 15 other Federal Agencies are signatories to the Federal Policy for the Protection of Human Subjects (the “Common Rule”). All research supported by any of the [Common Rule agencies](#) is subject to the regulations.
- Revised Common Rule regulations were set to take effect on January 19, 2018, and on January 17, 2018, a six-month delay was announced. The effective date is now July 19, 2018, but there is the potential for subsequent additional delays.
- Until new regulations take effect, Lehigh University will comply with current regulations.

Policy Change 1: Lehigh University uses the DHHS and FDA definitions of “human subjects research” to determine which activities are subject to IRB policy and oversight....

# **DHHS Definition: human subjects**

Living individuals about whom an investigator conducting research obtains either:

1. Data through intervention or interaction, or;
2. Identifiable private information.

# **FDA Definition: human subject**

- Individual who is or becomes a participant in research, either as a recipient of a test article or as a control.
- In the case of research involving a medical device, a human subject also includes an individual on whom a specimen or medical device is used.
- A test article is any drug (including biological product) for human use, medical device for human use, human food additive, color, adaptive, electronic product, or any other article subject to regulation or jurisdiction by the FDA.

# Definition: research

- DHHS: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- FDA: an experiment that involves a test article and one or more human subject that is subject to the IND or IDE regulations or which collects data to be submitted to or held for inspection by the FDA.
  - Research is subject to the IND regulations when it involves any use of a drug except for the use of a marketed drug in the course of medical practice.
  - Research is subject to the IDE regulations when it involves any used of a medical device to determine the safety or effectiveness of that device.

# Activities that meet the definition of “human subjects research” are subject to IRB oversight

Historically, LU policy required IRB review for work that does not meet the definition of HSR, including:

- Institutional research, QA/QI collecting sensitive data
- Students “undertaking a systematic investigation, producing a design or protocol for research, sampling a population, reporting findings”
- Class projects involving research with people outside of class
- Activity that was not a systematic investigation designed to develop or contribute to generalizable knowledge, but the researcher had some intent to publish results



## Lehigh's new policy will apply to activities that meet the definition of human subjects research:

- Research: a **systematic** investigation, including research development, testing, and evaluation, **designed** to develop or contribute to **generalizable** knowledge
- Human subjects: Living individuals about whom an investigator conducting research obtains either: 1) data through intervention or interaction, or; 2) identifiable private information.
  - FDA: the use of drugs or devices in human subjects, and/or the collection of data from humans for submission to FDA.
  - FDA regulations can be harder to apply than DHHS. Please [contact Research Integrity](#) for help determining if your activity is subject to FDA regulations.

# Definition: systematic

“Systematic” means that the activity involves a system, methodical procedure, design, or plan.

# Definition: generalizable

“Generalizable” means that conclusions, facts, or principles derived from particulars (individuals, medical records, etc.) that are applicable to or affect a whole category and enhance scientific or academic understanding.

- The information is broadly applicable or useful outside of the institution.

# Definition: designed

“Designed” in this context refers to the purpose of the activity:

- Activities that are exploratory or intended to train students are not designed to produce generalizable knowledge.

# Definition of “human subjects research”

- Publication or intent to publish is not part of the definition of “human subjects research”.
  - Intent to publish may signify that generalizable results are anticipated.
- Activities that do not otherwise meet the regulatory definition of research will not be considered subject to IRB oversight even if published or intended for publication.
- When in doubt – [contact Research Integrity](#) and we can provide you with a written determination as to whether or not your activity constitutes HSR.

# Definition of “human subjects research”

- **Typically HSR:** doctoral dissertations, honors or graduate theses, pilot studies, clinical investigations, behavioral and social science studies, epidemiological studies, and human genetic research.
- **Not typically HSR:** class-related research activities involving research methodology and course-assigned data collection, quality assurance or quality improvement activities, repository research, tissue banking/databases with stored data or materials, case reports, and institutional, internal, or social process research.

# Definition of “human subjects research”

- Review the IRB website “[What Types of Activities Require IRB Review](#)”
- Students should confer with faculty advisors when determining if their activity is subject to IRB oversight.
- [Contact Research Integrity](#) for help determining if IRB review is required. We will provide written determinations by request.

# When student, class-related, or internal research activity is not subject to IRB oversight

- It is the responsibility of faculty and staff to ensure that research activity presents [minimal risk](#) to participants, is conducted ethically, and complies with all other institutional and departmental policies.
- When a proposed student activity presents [greater than minimal risk](#), the faculty advisor ***is required to*** seek the advice of the Research Integrity office.
- [Ethical Issues in Research](#) provides guidance on incorporating human subjects protections into all research activities, regardless of whether they are subject to IRB review.



# When student, class-related, or internal research activity is not subject to IRB oversight

“Unregulated” greater than minimal risk activity:

- The [Belmont Report](#) is the ethical foundation for the federal regulations and Lehigh’s institutional policy.
- The ethical principle of “beneficence” holds that the benefits of research must be maximized, and the risks minimized.
- Any activity that presents significant risks to subjects but little or no potential to benefit the individual and/or society at large **is not ethical and may not be conducted by Lehigh faculty, staff, or students** – regardless of whether the activity meets the definition of “human subjects research” and is subject to IRB review.

Policy Change 2: Continuing review (annual renewal) is no longer required for minimal risk, unfunded research

# Continuing review (annual renewal) is no longer required for minimal risk, unfunded research

- New minimal risk, unfunded studies approved by expedited review may be approved without an expiration date.
- Existing, open minimal risk, unfunded studies may be approved without an expiration date at their next renewal.
- Why only unfunded minimal risk research?:
  - Current federal regulations require continuing review for federally sponsored research. The revised Common Rule set to take effect July 19, 2018 does not require continuing review for Common Rule agency-sponsored research. This change allows us to introduce flexibility now, while we wait for new regulations to take effect.

## Continuing review (annual renewal) is no longer required for minimal risk, unfunded research

- Researchers are still required to submit all Amendments and Unanticipated Problems Reports (UPRs) to the IRB.
- Researchers are required to notify the IRB immediately if funding is obtained.
- When the researcher is not required to submit a continuing review, the Research Integrity office will initiate a check-in at one year and ask:
  - Is the study still open?
  - Have any amendments not submitted?
  - Have any UPRs not reported?
  - Has funding been obtained?

# Continuing review (annual renewal) is no longer required for minimal risk, unfunded research:

What do you have to do now?:

- Nothing differently: submit your next continuing review before your study expires or submit your new application per the normal process. The IRB will notify you if it is approved without an expiration date.

# Policy Change 3: New informed consent requirements and templates

# New Informed Consent Requirements

- A revised consent template and revised Required Elements of Informed Consent are available on the [IRB website](#).
- These changes are required in the revised Common Rule, set to take effect on July 19, 2018.
- Lehigh is electing to apply these changes now, since they do not conflict with existing regulations and are expected to be required in July.

# New Informed Consent Requirements

Final consent forms that are over 4 pages long will require a concise summary of study activities, risks, and benefits presented first in the consent form.



# New required elements informed consent:

- Required: disclosure that de-identified data or biospecimens may be shared for future research (or not).
- As applicable:
  - Biospecimens will be used for commercial profit and whether subjects will share in profit.
  - Clinically relevant results will be returned.
  - Research will involve whole genome sequencing.
- Researchers may still request a waiver or alteration of the required elements of informed consent with their IRB application (process does not change).

**Policy Change 4: Review by a single IRB is required for NIH-sponsored multisite studies**

# NIH Single IRB (sIRB) Policy

- All sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH must use a single IRB to conduct IRB review for all sites.
- LU already has a single IRB review process in place (IRB Authorization Agreements for Human Subjects Research under “[IRB Guidance](#)”). There will be no change, other than to require an IAA for NIH-funded multi-site research.
- As of early 2017, Good Clinical Practice (GCP) training and [clinicaltrials.gov](#) registration and reporting is required for NIH-supported [clinical trials](#).
  - See “[GCP Training for NIH-Supported Clinical Trials](#)”

# Questions?

**Contact:**

Naomi Coll

Director of Research Policy and Compliance

[nac314@lehigh.edu](mailto:nac314@lehigh.edu)

610-758-2985