



NORTHWESTERN
UNIVERSITY

Responsible University Official: Vice
President for Research
Responsible Office: IRB Office
Origination Date: July 13, 2015

Human Research Protection Program Compliance

Policy Statement

Northwestern University is committed to protecting the rights and welfare of human research participants and ensuring compliance with all applicable ethical and legal requirements.

Reason for Policy/Purpose

In order to promote ethical human research at Northwestern University and facilitate compliance with applicable laws, regulations and policies, this Policy establishes the framework for the University’s Human Research Protection Program and provides information on how to report allegations of noncompliance in human subject research.

Table of Contents

Page #

| | |
|--------------------------------------|---|
| Policy Statement | 1 |
| Reason for Policy/Purpose | 1 |
| Who Approved This Policy | 1 |
| Who Needs to Know This Policy..... | 1 |
| Website Address for this Policy..... | 1 |
| Contacts..... | 2 |
| Definitions..... | 2 |
| Policy/Procedures | 2 |
| Forms/Instructions | 4 |
| Appendices..... | 4 |
| Related Information | 4 |
| History/Revision Dates | 4 |

Who Approved This Policy

Vice President for Research

Who Needs to Know This Policy

All members of the Northwestern University research community.

Website Address for This Policy

<http://irb.northwestern.edu/sites/default/files/documents/hrpppolicy071315.pdf>

Contacts

If you have any questions on the Human Research Protection Program Compliance Policy, you may:

1. Call the IRB Office at 312-503-9338, or
2. Send an e-mail to <mailto:irbcompliance@northwestern.edu>

Definitions

Human Subject A living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information (45 CFR 46.102(f)); or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control, who may be either a healthy human or a patient (21 CFR 50.3(g)).

Human Subject Research Research, as defined by 45 CFR 46.102(e) or clinical investigation, as defined by 21 CFR 50.3(c).

Institutional Review Board (IRB) Committee authorized to review, approve, require modifications in (to secure approval) or disapprove all human subject research at Northwestern in accordance with all federal, state and local regulatory requirements as well as institutional policies and procedures.

Policy/Procedures

1.0 General Information

Northwestern is committed to protecting the rights and welfare of participants in Human Subject Research. The University has established a [Human Research Protection Program \(HRPP\)](#) to comply with the ethical and legal requirements for the conduct and oversight of Human Subject Research. Northwestern's Office of the Institutional Review Board (IRB Office), which is responsible for supporting the administration of the Institutional Review Board (IRB), works with the IRB and other University units to ensure compliance with the HRPP.

2.0 Reporting Concerns

Any person having concerns about the conduct of Human Subject Research at Northwestern is strongly encouraged to report incidents involving perceived noncompliance through one of the following mechanisms:

- 1) IRB Office:
 - Chicago: (312) 503-9338
 - Evanston: (847) 467-1723
 - irbcompliance@northwestern.edu
- 2) EthicsPoint: [Ethics Point](#) or (866) 294-3545

The University prohibits retaliation against individuals who, in good faith, report alleged noncompliance. See the University's [Policy on Non-Retaliation](#).

The IRB Office and IRB have the responsibility of investigating allegations of noncompliance in Human Subject Research and imposing corrective actions as needed. In addition to audits conducted by the IRB Office in response to reports of alleged noncompliance, the IRB Office also conducts routine post-approval monitoring of Human Subject Research studies in order to review and ensure compliance in the conduct of Human Subject Research at the University.

The Vice President for Research (VPR) may impose additional corrective actions up to and including barring individuals from conducting Human Subject Research at Northwestern University if the VPR concludes such actions are required to maintain compliance with the HRPP.

3.0 Additional Components of the Human Research Protection Program

The IRB Office, in supporting the IRB and administering the HRPP, interacts and coordinates with several units at Northwestern to ensure compliance, including:

- Division/Department Chairs: Oversee compliance in departmental Human Subject Research activities and departmental response to allegations of noncompliance
- School Deans: Aid in fostering and enabling compliant Human Subject Research by receiving and assessing reports of non-compliance and supporting the education and training of personnel
- Office for Sponsored Research: Assists investigators in proposing and managing sponsored programs, including Human Subject Research studies
- Conflict of Interest Office: Oversees and implements conflict of interest policies and procedures and provides guidance and support regarding identified conflicts of interest
- Office for Research Safety: Provides the management and operational support for laboratory health and safety, including coordinating the recombinant DNA safety program and the Institutional Biosafety Committee to ensure the safe, compliant conduct of recombinant DNA research
- Center for Clinical Research: Works closely with clinical and translational researchers, trainees and staff to provide resources, services, and guidance in connection with clinical Human Subject Research

- Office for Research Integrity: Partners with and educates the research community with respect to appropriate practices related to the conduct of research and monitors and corrects noncompliance
- Office of General Counsel: Provides legal advice to the IRB Office, IRB and Office of Research related to policies, procedures and the conduct of Human Subject Research

Forms/Instructions

Appendices

Related Information

[U.S. Department of Health and Human Services, Protection of Human Subjects, 45 CFR 46](#)

[U.S. Food and Drug Administration, Protection of Human Subjects, 21 CFR 50](#)

[Northwestern University Research Roles and Responsibilities](#)

[Northwestern University Policy on Conflict of Interest in Research](#)

[Northwestern University Policy on Institutional Conflict of Interest in Research](#)

[Northwestern University Policy for Reviewing Alleged Research Misconduct](#)

History/Revision Dates

Origination Date: July 13, 2015

Last Amended Date: Month, Day, Year

Next Review Date: July 13, 2016