





# **Human Research Protection Program Plan**

Revised January 30, 2024

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## Scope

Throughout this document, “Institution” refers to Northwestern University.

## Purpose

The Institution is committed to protecting the rights and welfare of participants in Human Research. The purpose of this Plan is to establish the framework for the Institution’s Human Research Protection Program (HRPP) to promote ethical Human Research at the Institution and facilitate compliance with applicable laws, regulations, and policies, and provides information on how to report allegations of non-compliance in Human Research.

The Institution’s HRPP is a comprehensive system to ensure the protection of the rights and welfare of participants in Human Research. The HRPP is based on all key individuals and committees at the Institution fulfilling their roles and responsibilities described in this Plan.

Policies and procedures for the HRPP are available on the following website:

<http://www.irb.northwestern.edu/policies>. Any changes in these policies and procedures are communicated to all key individuals using various mechanisms such as: email, live training, and announcements on the IRB Office website.

## Mission

The mission of the Institution’s HRPP is to protect the rights and welfare of participants involved in Human Research and comply with all applicable ethical and legal requirements.

## Definitions

### Agent

For purposes of this document, an institution’s *employees or agents* refers to individuals who: (1) act on behalf of the Institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual receives compensation.

### Clinical Trial (see HRP-001)

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

### Cooperative Research<sup>1</sup>


Human Research projects covered by a signatory agency of the revised [Common Rule](#) that involve more than one institution and/or site participating in the same research protocol, where each site completes a portion or portions of procedures.

### Engaged in Human Research (see HRP-311)

In general, the Institution is considered engaged in Human Research when the Institution’s employees or agents for the purposes of the Human Research obtains: (1) data about the

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<sup>1</sup> 45 CFR 46.114

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participants of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the participants of the research; or (3) the informed consent of human participants for the research. The Institution follows OHRP guidance on “Engagement of Institutions in Research”<sup>2</sup> to apply this definition and exceptions to this definition.

### **Human Research** (see HRP-310)

Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by USFDA and involves “Human Subjects” as defined by USFDA (“USFDA Human Research”).

### **Human Subject as Defined by DHHS** (see HRP-310)

“A living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through Intervention or Interaction with the individual, and use, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”<sup>3</sup>

For the purpose of this definition:

- **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.


### **Human Subject as Defined by USFDA** (see HRP-310)

“An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.”<sup>4</sup> A human subject includes an individual on whose specimen an investigational medical device is used. When

<sup>2</sup> <http://www.hhs.gov/ohrp/policy/engage08.html>

<sup>3</sup> 45 CFR §46.102(e)

<sup>4</sup> 21 CFR §50.3(g)

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medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

## Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.<sup>5</sup>

## Institutional Review Board (IRB)

Committee authorized to review, approve, require modifications (to secure approval) or disapprove all Human Subject Research at the Institution in accordance with applicable federal, state and local regulatory requirements, as well as Institutional policies and procedures.

## Multisite Study<sup>6</sup>

Non-exempt Human Research funded by the National Institutes of Health (NIH) involving more than one institution and/or site participating in the same research protocol, with each site completing all research activities outlined in the protocol.

## Research as Defined by DHHS

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>7</sup> (see HRP-310)


The following activities are not considered Research as Defined by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
  - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
  - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

<sup>5</sup> See 21 CFR §50.3(d)

<sup>6</sup> NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

<sup>7</sup> 45 CFR 46.102(l).

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- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots.

## Research as Defined by USFDA

Any experiment that involves a test article and one or more human participants, and that meets any one of the following (see HRP-310):

- Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.<sup>8</sup>

## Single IRB (sIRB)

A sIRB is the selected IRB of record that conducts the ethical review for each site participating in a Multisite<sup>9</sup> or Cooperative Research<sup>10</sup> study.

## Ethical Requirements


In the oversight of all Human Research, the Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's IRBs, IRB members and chairs, IRB Office staff, Vice President for Research, Institutional Official/Organizational Official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Participants of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Participants of Research," also known as "The Belmont Report":

- Respect for Persons
- Beneficence
- Justice

<sup>8</sup> See 21 CFR §50.3(c)

<sup>9</sup> NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

<sup>10</sup> 45 CFR 46.114

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## ***Legal Requirements***

The Institution commits to apply its ethical standards as contained in its standard operating procedures and review tools to all Human Research regardless of funding.

All Human Research must undergo review by one of the Institutionally designated IRBs, whether internal or external to the Institution. Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's IRBs and do not need to be submitted to one of the Institution's IRBs, unless there is a question regarding whether the activity is Human Research.

When the Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency that is a signatory of the Common Rule (which includes Subpart A of DHHS regulations at 45 CFR 46), the Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects as defined by DHHS.

When the Institution is engaged in USFDA Human Research, the Institution commits to apply the USFDA regulations relevant to the protection of Human Subjects as defined by USFDA.

This Institution's IRB approves research according to applicable federal and local law for the research conducted within the jurisdiction where the Institution resides. If the applicable law is inconsistent, the IRB will apply the most protective of the applicable laws.

The Institution's Office of General Counsel assists the IRB Office in resolving conflicts among any applicable laws, and also assists the IRB Office in determining who meets the definition of "legally authorized representative," "children," and "guardian" when Human Research is conducted in jurisdictions not covered by policies and procedures.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office, which will provide a determination.

## ***Other Requirements***


When reviewing research that involves community based research, the IRB obtains relevant expert consultation or training, as needed.

All Institutional policies and procedures are followed for the review of all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review (when applicable), and review of modifications to previously approved research
- Post-approval monitoring, when necessary, handling of complaints, non-compliance, and unanticipated problems involving risks to participants or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

Northwestern University's IRBs will conduct reviews of clinical trials involving drugs, devices, or biologics in accordance with ICH-GCP to the extent adopted by the FDA. If a sponsor requires the additional requirements in the ICH-GCP (E6) guidance be followed, the trial will be reviewed following that guidance.



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The Institution prohibits payments to professionals in exchange for referrals of potential participants (“finder’s fees”) and payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments.”)

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

When the Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency whose Common Rule application includes other Subparts of DHHS regulations, the Institution commits to apply the regulations of that agency relevant to the protection of Human Participants.

When Human Research is conducted or funded by the US Department of Justice (USDOJ), the Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (USDOJ), the Institution commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the US Department of Defense (USDOD), the Institution commits to apply the US Department of Defense (USDOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D. The Institution will comply with the terms of the Defense Federal Acquisition Regulation Supplement (DFARS) clause or comparable language used in the agreement with the US Department of Defense (USDOD) Component supporting the research involving human participants.

When Human Research is conducted or funded by the US Department of Education (USED), the Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the US Department of Energy (USDOE), the Institution commits to applying the US Department of Energy (USDOE) O 443.1C, which includes the requirements to apply 10 CFR §745 and Subparts B, C, and D of 45 CFR §46, as applicable, and additional DOE requirements outlined in HRP-318 - WORKSHEET - Additional Federal Agency Criteria.”


When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the US Environmental Protection Agency (USEPA), the Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

When prospective Human Research is subject to the European Union General Data Protection Regulations (GDPR), the relevant components of the HRPP coordinate with the Northwestern GDPR Steering Committee to ensure that the research activities are consistent with institutional policies and interpretations of GDPR.

## ***Scope of Human Research Protection Program***

The Institution abides by its ethical principles, regulatory requirements, and its policies and procedures, for both sponsored and non-sponsored Human Research. All forms of Human Research are overseen.



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## ***Human Research Protection Program Components***

### **Vice President for Research**

The Vice President for Research has the authority to take the following actions:

- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Impose corrective actions up to and including barring individuals from conducting Human Research at the Institution if the Institutional Official/Organizational Official concludes such actions are required to maintain compliance.
- Disallow research approved by the Institution's IRB or an external IRB.

### **Institutional Official/Organizational Official**

The Institutional Official/Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Determine what IRBs the Institution will rely upon.
- Ensure that the research review process is independent and free of undue influence.
- Create policies and procedures related to the HRPP that are binding on the Institution.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the studies. This includes but is not limited to emergency/disaster scenarios, such as natural disasters, man-made disasters, infectious disease pandemics, technological disasters, etc.

### **IRB Office**

The IRB Office, which is responsible for supporting the administration of the IRB, works with the IRB and other University units to ensure compliance with the HRPP.

The IRB Office Executive Director and/or the IRB Office staff have the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the HRPP.
- Allocate resources within the IRB Office budget.
- Periodically review this Plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish and follow policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements.
- Institute regular, effective, educational, and training programs for individuals involved with the HRPP.



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- Ensure that the research review process is independent and free of undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, request that the Vice President of Research remove individuals from involvement in the HRPP.
- Maintain Federalwide assurance (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.
- Establish and follow Institutional written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.
- Approve and rescind authorization agreements for IRBs.
- Evaluate on a case-by-case basis whether the Institution's IRBs can effectively serve as the Single IRB and ensure that the appropriate authorization agreements (reliance agreements) are in place to document respective authorities, roles, responsibilities, and communication between the Single IRB (IRB of Record) providing the ethical review and a participating site relying on the IRB of record.
- Establish Authorization Agreements when the Institution will rely on an external IRB in accordance with established reliance policies and procedures.
- Notify the Institution's researchers (and relying organizations, when applicable) of IRB decisions, and make relevant IRB policies and records available to the Institution's researchers and relying organizations.
- Ensure that the composition of the IRB is appropriate to review the research, including that the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

### IRBs

The list of IRBs designated by the Institutional Official/Organizational Official to be the IRBs relied upon by the HRPP and the scope of review of these IRBs are kept on file in the IRB Office. All Human Research must be approved by one of the IRBs designated by the Institutional Official/Organizational Official. Officials of the Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.

The designated IRBs must follow applicable HRPP policies and procedures, and the designated IRBs have the authority/responsibility to:

- Determine whether an activity is Human Research.
- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution.
- Review the research in accordance with established policies and procedures to determine that the research is ethically justifiable, according to all applicable laws,

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including initial review, continuing review (when applicable), review of modifications to previously approved research, and unanticipated problems involving risks to subjects or others.

- Suspend or terminate approval of Human Research not being conducted in accordance with an IRB's requirements, or that has been associated with unexpected serious harm to participants.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research, and request audits of research reviewed.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.
- Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for the use or disclosure of protected health information for research purposes.
- Report to the Institutional Official/Organizational Official or designee any concern about attempts to unduly influence the independence of the IRB.


The Institution's designated IRBs may serve as the Single IRB or IRB of Record for another entity, organization, or individual investigator. When the Institution provides IRB review for other organizations or individual investigators, the HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site.

The Institution may also rely upon external IRBs of an AAHRPP accredited organization or of an organization that the Institution has appropriately vetted. The Institution will comply with the determinations of the reviewing external IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications, and provide local context information (and any relevant updates) to the external IRB.

## Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the HRPP requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of the IRB, the IRB Chair, and the Institutional Official/Organizational Official.
- Develop and implement emergency/disaster response procedures for Human Research protocols impacted by an emergency/disaster. Emergency/disaster response plans must be submitted to the IRB. As applicable, the emergency/disaster response plan must consider protocol-level factors, such as the nature of the research activities, the specific participant population(s), and the location(s) of the study conduct.

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## **Other Components of the HRPP<sup>11</sup>**

The IRB Office, in supporting the IRB and administering the HRPP, interacts and coordinates with several units at Northwestern to ensure compliance. Please see the University's Policy on Human Research Protection Program Compliance for a list of other HRPP components.

## ***Emergency Preparedness***

The organization routinely assesses potential emergency scenarios and threats to institutional operations to improve its emergency preparedness and response plan. The IRB Office Executive Director, or their designee, collaborates with the HRPP Institutional Official and other organizational leadership to develop, implement, and assess emergency preparedness procedures for the HRPP.

Depending on the nature of the event, the IRB Office Executive Director, or their designee, will collaborate with the HRPP Institutional Official and other institutional leadership to determine the types of research that can continue and the types that the organization may need to temporarily postpone. The organization will proactively identify external IRBs on which it can rely on temporarily during an emergency.

The IRB Office staff will work with IT resources and/or electronic system vendors to ensure continuity of operations if electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The IRB Office Executive Director, or their designee, will collaborate with the vendor of the IRB's electronic system to ensure that records are maintained on a secure server that is accessible in the event of an emergency. If paper records are impacted, the HRPP will implement an alternative process for records management, as applicable.

The organization will implement alternative review procedures, including leveraging online and virtual platforms, to minimize disruption of convened IRB review during an emergency. In instances where the convened IRB is unable to meet, and IRB approval for a study may lapse, the IRB Chair can determine whether it is in the best interest of currently enrolled participants to continue research activities during the lapse period.

## ***Education and Training***

Education and training requirements and resources are made available to the Human Research community via the IRB website. To maintain awareness of HRPP policies and procedures, the IRB Office communicates new information, revised materials, and opportunities for continuing education to the Human Research community by way of various email list-serve groups targeted to appropriate audiences.

IRB members, IRB Office staff, and others involved in the review of Human Research must complete the required initial and continuing Human Research training.


Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

## **Emergency Preparedness Training**

HRPP staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans

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<sup>11</sup> [Northwestern University Research Roles and Responsibilities](#)

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for Human Research conducted at the organization. The HRPP emergency preparedness plan will be made available to the Human Research community via the IRB website. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

### ***Questions and Additional Information from the IRB***

For questions, requests for additional information from the IRB Office and/or to provide feedback relating to the HRPP, please contact the IRB Office below:

#### **Biomedical Research IRB Office**

Mailing Address: Arthur Rubloff Building, 7th Floor

750 N. Lake Shore Dr.

Chicago, IL 60611

Phone: (312) 503-9338

Email: [irb@northwestern.edu](mailto:irb@northwestern.edu)

#### **Social and Behavioral Research IRB Office**

Mailing Address: Chambers Hall, 2nd Floor

600 Foster St.

Evanston, IL 60208

Phone: (847) 467-1723

Email: [sbsirb@northwestern.edu](mailto:sbsirb@northwestern.edu)

### ***Reporting and Management of Concerns***

Any person having concerns about the conduct of Human Research at Northwestern is strongly encouraged to report incidents involving perceived non-compliance. Please see the University's Policy on Human Research Protection Program Compliance for the various reporting mechanisms.

### ***Monitoring and Auditing***


In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations, and institutional requirements may conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state, local or institutional. Random audits may also be conducted.

### ***Disciplinary Actions***

The Vice President for Research may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the Vice President for Research such actions are required to maintain the HRPP.

### ***Approval and Revisions to the Plan***

This HRPP Plan is to be approved by the Institutional Official/Organizational Official or his/her designee. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official/Organizational Official or designee has the

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responsibility to review this plan to assess whether it is providing the desired results and may amend this plan as deemed necessary.