NORTHWESTERN
UNIVERSITY

Human Subject Protection Program Plan

Revised August 1, 2015

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Scope

Throughout this document "Institution" refers to Northwestern University.

Purpose

This Institution is committed to protecting the rights and welfare of participants in Human Research. The purpose of this plan is to describe this Institution's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Institution's Human Subject Protection Program is a comprehensive system to ensure the protection of the rights and welfare of participants in Human Research. The Human Subject Protection Program 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 Human Subject Protection Program are available on the following Web site: http://www.irb.northwestern.edu/policies.

Mission

The mission of this Institution's Human Subject Protection Program plan is to protect the rights and welfare of participants involved in Human Research that is overseen by this Institution.

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 is receiving compensation.

Clinical Trial (see HRP-001)

A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious and effective.

Engaged in Human Research (see HRP-311)

In general, this Institution is considered engaged in Human Research when this Institution's employees or agents for the purposes of the Human Research obtain: (1) data about the participants of the research through intervention or interaction with them; (2) identifiable private information about the participants of the research; or (3) the informed consent of human participants for the research. This Institution follows OHRP guidance on "Engagement of Institutions in Research"[1] to apply this definition and exceptions to this definition.

[1] http://www.hhs.gov/ohrp/policy/engage08.html

Human Research (see HRP-310)

Any activity that either:

- Is "Research" as defined by DHHS and involves "Human Participants" as defined by DHHS ("DHHS Human Research"); or
- Is "Research" as defined by USFDA and involves "Human Participants" 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 obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information."[2] For the purpose of this definition:

- *Intervention* means physical procedures by which data 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- *Identifiable Information* means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

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."[3] A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

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.[4]

Research as Defined by DHHS

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[5] (see HRP-310)

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[2] 45 CFR §46.102(f)
[3] 21 CFR §56.102(e)
[4] See 21 CFR §56.102(h)

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.[6]

Ethical Requirements

In the oversight of all Human Research, this Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's Institutional Review Boards (IRBs), IRB members and chairs, IRB Office staff, the Institutional 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

Legal Requirements

This 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 this Institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who 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 Participants.

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[5] 45 CFR 46.102(d). For research conducted within the US Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
[6] See 21 CFR §56.102(c)

When this Institution is engaged in USFDA Human Research, this Institution commits to apply the USFDA regulations relevant to the protection of Human Participants.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office, who 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 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, 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

For clinical trials, this Institution commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6" (ICH-GCP) when required by clinical trial sponsors.

This Institution prohibits payments to professionals in exchange for referrals of potential participants ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")

When this 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. See the applicability table in the footer below.

When Human Research is conducted or funded by the US Department of Justice (USDOJ), this 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), this 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. This Institution will comply with the terms of the 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), this 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), this Institution commits to applying the US Department of Energy (USDOE) O 443.1A and to use "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the US Department of Energy (USDOE) Requirements."

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), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Subject Protection Program

The categories of Human Research overseen may include, but are not limited to:

- International research
- Research conducted or funded by the US Department of Defense (USDOD)
- Research conducted or funded by the US Department of Justice (USDOJ)
- Research conducted or funded by the US Department of Education (USED)
- Research conducted or funded by the US Department of Energy (USDOE)
- Research conducted, funded, or subject to oversight by the US Environmental Protection Agency (USEPA)
- Federally funded research
- Research involving fetuses
- Research involving *in vitro* fertilization
- USFDA-regulated research
- Research involving drugs that require an IND
- Research involving devices that require an abbreviated IDE
- Research involving devices that require an IDE issued by USFDA
- Investigator held abbreviated IDE
- Investigator held IND or IDE
- Research involving pregnant women as participants
- Research involving non-viable neonates
- Research involving neonates of uncertain viability
- Research that plans to or is likely to involve prisoners as participants
- Research involving children as participants
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director
- Research involving a waiver of consent for planned emergency research
- Emergency use of a test article in a life threatening situation
- Activities involving humanitarian use devices

Human Subject Protection Program Components

Institutional Official

The Vice President for Research is designated as the Institutional Official.

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

- Create the Human Subject Protection Program budget.Determine what IRBs the Institution will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Ensure that the research review process is independent and free of undue influence.
- Ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Create policies and procedures related to the Human Subject Protection Program that are binding on the Institution.
- May impose corrective actions up to and including barring individuals from conducting Human Research at the Institution if the Institutional Official concludes such actions are required to maintain compliance.
- Disallow research approved by the Institution's IRB or an external IRB.
- Ensure that the Human Subject Protection Program 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.

The IRB Office

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

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Subject Protection Program.
- Allocate resources within the Human Subject Protection Program budget.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Subject Protection Program.
- 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 Human Subject Protection Program.
- 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 Institutional Official remove individuals from involvement in the

Human Subject Protection Program. Review and sign federal assurances (FWA) and addenda.

- Fulfill educational requirements mandated by OHRP.

IRBs

The list of IRBs designated by the Institutional Official to be the IRBs relied upon by the Human Subject Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the IRB Office.

This Institution may rely upon IRBs of an AAHRPP accredited organization or of an organization that has been appropriately vetted by the Institution.

Reliance on an external IRB requires an Institutional Authorization Agreement for IRB review (IAA) and a local review for compliance with local policies of the Institution.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the Institutional Official. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.
- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' 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.
- Determine whether an activity is Human Research.
- 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.

IRB members and IRB Office staff have the responsibility to follow Human Subject Protection Program policies and procedures that apply to IRB members and staff.

IRB members should report to the Institutional Official or designee any concern about attempts to unduly influence the independence of the IRB.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Subject Protection Program 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.

Other Components of the HSPP

Please see the University's Policy on Human Research Protection Program Compliance

Education and Training

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

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

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:

Biomedical Research
Arthur Rubloff Building, 7th Floor
750 N. Lake Shore Dr.
Chicago, IL 60611
Phone: (312) 503-9338
Email: irb@northwestern.edu

Social and Behavioral Research
Chambers Hall, 2nd Floor
600 Foster St.
Evanston, IL 60208
Phone: (847) 467-1723
Email: irb@northwestern.edu

Approval and Revisions to the Plan

This Human Subject Protection Program Plan is to be approved by the Institutional Official or his/her designee. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official or designee has the responsibility to review this plan to assess whether it is providing the desired results and may amend this plan as deemed necessary.

Approved:

J. T. Walsh

Joseph T. Walsh, PhD, Vice President for Research

29 July 15

Date