AAHRPP Site Visit 2024:
Interview Guide for IRB Members and IRB Office Staff

This guidance document will help you prepare for the AAHRPP Reaccreditation site visit, scheduled for Thursday, August 22, 2024, and Friday, August 23, 2024.

AAHRPP Reaccreditation

The Association for the Accreditation of Human Research Protection Programs (**AAHRPP**), is an international, independent, non-profit organization that reviews and accredits an institution's human research protections program (HRPP). AAHRPP uses a voluntary, peer-driven, educational model to ensure that the Human Research Protection Program meets rigorous standards for quality and protection.

The Northwestern University Human Research Protection Program (HRPP) achieved initial AAHRPP accreditation on December 19, 2016, and full AAHRPP reaccreditation on December 15, 2019. The Northwestern IRB Office is undergoing AAHRPP reaccreditation in 2024.

The primary purpose of AAHRPP accreditation is to strengthen protections for research participants. This voluntary, independent review of our strengths, weaknesses, and opportunities for improvement results in a more cohesive HRPP with the systems in place to protect research participants and advance research more efficiently and effectively. See the IRB Office's **AAHRPP Accreditation Page** for details about the AAHRPP accreditation process.

AAHRPP Site Visit

For the AAHRPP reaccreditation process, the IRB Office provided AAHRPP with a written description of our HRPP policies, procedures, and resources, and a list of all active IRB protocols. During the site visit, representatives from AAHRPP will conduct interviews and review records to ensure that those policies and procedures have been implemented effectively and are being adhered to throughout the University.

The AAHRPP site visitors will conduct virtual interviews with investigators, research study team members, IRB members, IRB Office staff, key research offices, and institutional and organizational officials regarding the Northwestern Human Research Protection Program. AAHRPP will select approximately 100 individuals to be interviewed during the site visit. Anyone who has a role in human research may be selected for an interview. Interviews will be individual or group sessions and are expected to be 20-45 minutes long.

As an IRB member or IRB Office staff, you are an integral part of the Northwestern HRPP. Several IRB members and IRB Office staff will be interviewed.

If you are selected for an interview by AAHRPP, IRB Office staff will notify you via email ahead of time and will provide you with additional information.

We expect questions to be focused on regulatory and ethical issues related to research with human participants, but questions may also relate to your impressions of the HRPP and IRB Panels at Northwestern.

Preparing for the Site Visit
Early preparation is key! You may be familiar with most of the information in this document and we recommend using this guidance to help refresh your understanding.

Each section contains a list of questions you may be asked during the AAHRPP site visit interview.

This document includes sections on the following topics:

Section 1: General Tips

Northwestern University's HRPP reaccreditation largely depends on these interviews. If interviewed, we recommend that you **respond directly to the question asked**. If a question seems unrelated to the type of work you do, please let the interviewer(s) know.

If you are unsure or unable to answer a question, we recommend that you identify the policy, webpage, office, individual, etc. that you could go to for the answer and state that as your response to the interviewer.

Possible General Questions
Role of the IRB
· What does the IRB do? What are your responsibilities as an IRB member? · What is the IRB's reputation on campus? · Is the IRB workload fair? · Why does Northwestern value AAHRPP accreditation? What do you think of it?

You will be expected to:

- Understand the Northwestern University HRPP structure
- Know the HRPP Mission
- Clearly describe your role in the Northwestern University HRPP
- Be familiar with the Northwestern HRPP policies and where to access them
- Understand the **AAHRPP accreditation** process
- Understand and describe the ethical aspects, purpose, and value of your work
- Know where to obtain answers to ethical/regulatory questions
- Know the process for non-compliance reporting at Northwestern
    - **Reportable New Information (RNI)**

- Know **Human Research Protections Training** requirements and resources at Northwestern
- Describe the training you have received as an IRB reviewer
- Understand what constitutes **Conflict of Interest** in research at all levels (i.e., staff, IRB, Institution)
- Understand how a **Conflict of Interest** is managed at Northwestern
- Know the ethics of recruitment and inclusion/exclusion criteria

The mission of the Human Research Protection Program is to protect the rights and welfare of participants. The protection of research participants at Northwestern University is a shared responsibility, with the Institution, researchers, IRB committees, research participants, and the IRB Office working together toward this common goal.

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Section 2: Northwestern University HRPP Policies and Procedures

The following section summarizes key elements of Northwestern University's IRB Office's policies and procedures. We recommend that you review them in preparation for your interview. The source of this information is the: **Human Research Protection Program Plan (HRP-101)**. See also **SOP: Standard Operating Procedures (HRP-071)** which articulates minimum requirements for IRB Standard Operating Procedures (SOPs).

Possible Questions About HRPP Policies and Procedures

- Who is the institutional official responsible for overall research at Northwestern University?
- Who is the institutional official/organizational official responsible for the Northwestern HRPP?
- What is the Northwestern HRPP?
- What is your role in the Northwestern HRPP?

Eric Perreault, the Vice President for Research, serves as the **Institutional Official (IO)** for Northwestern University and is responsible for the overall conduct of research at the Institution. They have 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 actionsincluding barring individuals from conducting Human Research at the Institution if the HRPP Institutional Official/Organizational Official concludes such actions are required to maintain compliance.
- Disallow research approved by the Institution's IRB or an external IRB.

In conjunction with the Northwestern University IO, Crista Brawley, the Associate Vice President for Research, serves as the **Institutional Official (IO)/Organizational Official** for the Northwestern University HRPP. She 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 and what Institutions Northwestern will provide IRB services for.
- Ensure that the research review process is independent and free of undue influence.

The HRPP is supported by:

- The Northwestern University Office for Research and its central operating units, including the Institutional Review Board (IRB) Office, Sponsored Research (SR), the Office of Research Integrity (ORI), and Conflict of Interest (COI) Office;
- Academic units, including schools, colleges, and other academic units to which faculty, staff, and trainees engaged in human research are appointed;
- The IRB Panels (Biomedical: Panel A, Panel B, Panel C, Panel D, Panel Q. And Social-Behavioral: Panel E); and
- Key executive and administrative offices, including the Office of General Counsel.

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Section 3: Ethical Conduct of Research and Federal Regulations

Northwestern University fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or overseen by the Institution. All members of the Northwestern community involved in human research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations as well as institutional and IRB Office policies governing human research.

Possible Questions About the Ethical Conduct of Research and Federal Regulations

- What are the three fundamental ethical principles of the Belmont Report?
- When was the first time you heard of the Belmont Report?
- What is the Common Rule (45 CFR 46)?
- What is the Office for Human Research Protections (OHRP)?
- What types of research are regulated by the FDA?
- What is HIPAA and what is its relevance to human research?

The review and conduct of human research at Northwestern University are guided by principles set forth in **the Belmont Report** and performed following Department of Health and Human Services (DHHS) regulations (45 CFR 46 or the "Common Rule"), and Food and Drug Administration (FDA) regulations (21 CFR 50, 21 CFR 56), as well as all other applicable federal, state, and local laws and regulations.

- **The Belmont Report** identifies and summarizes three main ethical principles that should govern human research:
  - Respect for persons (autonomy/voluntary participation/adequate information)
  - Beneficence (risks of research are reasonable in relation to the benefits the research may provide to participants or science)
  - Justice (selection of participants is equitable and representative)
- The **Office for Human Research Protections** (**OHRP**) provides leadership in the protection of the rights, welfare, and well-being of human participants involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP's primary duty is the implementation of 45 CFR 46, a set of regulations for Institutional Review Boards (IRBs) that mirrors the U.S. Food and Drug Administration (FDA) regulations (21 CFR 50 and 21 CFR 56) for clinical trials.
- **The Common Rule (45 CFR 46)** is the federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report. Under the Common Rule, research with human subjects is defined as follows:
  - *Research:* A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
  - *Human Subject*:* A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) information or biospecimens through interaction or intervention with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
    - **At Northwestern, Human **subject** and human **participant** are synonymous terms, and the IRB Office prefers the use of participant over subject.*
- **Common Rule Implementation (Office of Human Research Protections)**
  - The Office of Human Research Protections updated 45 CFR 46, the Common Rule, it went into effect on January 21, 2019, and the Northwestern University HRPP implemented two of the three burden-reducing provisions. This included the elimination of continuing review for non-exempt, non-FDA/non-DoD, minimal risk studies, and clarification of the activities that do not meet the definition of human research. The IRB Office also made relevant updates to the Biomedical and Social and Behavioral protocol templates, as well as consent form templates.
  - Northwestern University's HRPP did not implement Broad Consent because it was optional, and the regulatory agencies have not distributed formal guidance.

- **21 CFR 50** and **21 CFR 56** serve as the regulatory framework for research regulated by the FDA (i.e., research involving drugs, devices, and biologics). This set of regulations is derived from the Common Rule, but there are some notable **differences between FDA and HHS regulations**.
- Other federal and state laws and regulations that apply to research (i.e., Mental Health and Developmental Disabilities Confidentiality Act (**MHDDCA**), Family Educational Rights and Privacy Act (**FERPA)**, Health Insurance Portability and Accountability Act (**HIPAA**), **21st Century Cures Act** and General Data Protection Regulation (**GDPR**), and **National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research**.
- See the IRB Office's **HIPAA, PHI, & PII Page**.
- **Institutional policies and procedures**.

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Section 4: IRB Review

IRBs must obtain sufficient information prior to the review of applications for initial or continuing review so that they can apply and satisfy the requirements for approval of research (see **Worksheet: Criteria for Approval (HRP-314)** for the list of required information).

Possible Questions About the IRB Review

- What is your process for reviewing a study? Do you utilize guidance or written checklists?
- What is the process for scientific review of research at Northwestern?
- Do IRB reviewers consider the scientific validity of studies that they review?
- What are the expedited and exempt review categories? When are they used?
- What is the difference between human research that is exempt from IRB oversight and research determined to be not human-subjects research?
- What is continuing review?
- Do you know what is not part of an IRB review? Can you give examples?
- Are IRB community members recognized as contributing board members?

The IRB considers the following for each application for initial, continuing, or modification review:

1. Does the activity described in the IRB eIRB+ application meet the definition of human research as defined in the Common Rule?
2. Is the activity human research as defined in FDA regulations?
3. Is Northwestern University or one of the affiliates (i.e., Shirley Ryan Ability Lab, NMHC, etc.) engaged?
4. Is the research exempt from IRB oversight?

These determinations are made consistent with the guidance provided on the IRB website. When determining if a project meets the definition of human subject and research, see the IRB website or the **US Department of Health and Human Services Human Subject Regulations Decision Charts** and/or in consultation with IRB administrators or chairs, as appropriate. Review research against these regulations:

- Involves **activities or data subject to other rules or regulations** such as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the Health Information Technology for Economic and Clinical Health Act (HITECH) Security Rule, the Family Educational Rights and Privacy Act (FERPA) or rules of other federal agencies: the review ensures compliance with these regulations or rules.
- **Does not fit the definition of human research**: a designated IRB Office staff member may issue a "non-human research" determination through eIRB+ when the Principal

Investigator submits a **Human Research Determination Form (HRP-503)**.

- Is **Exempt:** an IRB Office staff member reviews the study application following **Worksheet: Exemption Determination (HRP-312)**.

- For other federal and state laws and regulations that apply to research (i.e., Mental Health and Developmental Disabilities Confidentiality Act (**MHDDCA**), Family Educational Rights and Privacy Act (**FERPA**), Health Insurance Portability and Accountability Act (**HIPAA**), **21st Century Cures Act**, General Data Protection Regulation (**GDPR**), and **National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research**., General Data Protection Regulation (**GDPR**), and **National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research**), the review ensures compliance with these regulations or rules.
- See the IRB Office's **Joint Guidance on the Application of FERPA and HIPAA To Student Health Records** and **Guidance for General Data Protection Regulations (GDPR) compliance in the conduct of human research**.

- HIPAA is a separate set of federal regulations that applies to research that uses, creates, or discloses PHI. Protected Health Information (PHI) is any health information that includes any of the 18 elements identified by HIPAA. Read more on the **HIPAA, PHI, & PII Page**.
- There are additional requirements for studies sponsored by the Department of Justice (DOJ), Department of Defense (DOD), Environmental Protection Agency (EPA), etc. See **Worksheet: Additional Federal Agency Criteria (HRP-318**)

- In addition to securing IRB review, researchers may need to secure other approvals or notifications before initiating their research (e.g., Sponsored Research, Conflict of Interest, NM Investigational Drug Service Pharmacy, Institutional Biosafety Committee, etc.) as outlined on the **Additional Reviews** page.

IRBs ensure research is approved only when all of the requirements in **45 CFR 46.111** or **21 CFR 56.111** (for FDA-regulated research) are met. The **criteria for IRB approval and continuing review** are:

A. minimizing risk
B. risk-benefit analysis
C. equitable participant selection
D. informed consent, parental permission, and assent sought
E. Informed consent documented or appropriately waived
F. data monitoring to ensure safety
G. privacy and confidentiality
H. vulnerable populations- additional safeguards

Additional requirements for FDA-regulated clinical trials includes:

A. determining whether an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is required
B. for device studies, making significant/non-significant risk determinations
C. emergency use notification and reporting procedures
D. procedures for reviewing protocols for anticipated additional use in emergency situations
E. waiver of informed consent for certain emergency research, if permitted by the IRB
F. guidelines and procedures for reportable new information; communications, if any, with sponsors and IND and IDE holders

G. test article accountability procedures
H. community consulttations for planned emergency research

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Section 5: Minimizing Risks and Protecting Participants' Rights and Welfare

Minimizing risks to participants and ensuring participants' rights and welfare are integral to the human research protection program.

Possible Questions About Minimizing Risks & Protecting Participants' Rights and Welfare

- What is the difference between privacy and confidentiality?
- What additional mechanisms can be put in place to protect research participants?
- What are the different possible levels of risk associated with a study? How is risk level assigned?
- Can sensitive information affect the risk level?
- What are your primary concerns when reviewing a protocol?

The following are some ways to minimize risks to participants and ensure participants' rights and welfare:

- Design and implement protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report.
- Verify procedures are consistent with sound research design by ensuring that the research is reasonably expected to answer the proposed question and that the resulting knowledge is expected to be sufficiently important to justify the research.
- Ensure that recruitment procedures foster the equitable selection of participants.
- Utilize procedures already being performed for diagnostic or treatment purposes, when possible.
- Ensure that appropriate resources are available to conduct the research.
- Establish adequate provisions for monitoring participants to identify adverse events and to review data collected to ensure participant safety, when appropriate.
- Develop plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:
  - *Privacy* – Relates to an *individual* having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
  - *Confidentiality* – Relates to the protection of a participant's *data* that has been shared with the researcher with the expectation that it will be protected and not disclosed.

Put in place additional protections for participants vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, individuals with impaired decision-making, etc.).See IRB Office guidance **Research with Children as Research Participants (HRP-1903).**

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Section 6: Compliance with IRB and Other Review Unit Requirements

Research at Northwestern must be conducted in compliance with the IRB, as well as other institutional and regulatory requirements.

Possible Questions About Compliance with IRB and Other Review Unit Requirements

- What is the process for continuing review?
- What is the difference between an adverse event and a UPIRSO?
- What is non-compliance? When is it considered serious and/or continuing?
- What is the difference between non-compliance and an adverse event?

Below are some requirements that you should be aware of related to this responsibility.

- The continuing review of expedited (when required) or full board-approved research will be conducted with the same thoroughness as the initial review.
- All research with human participants must obtain IRB review and approval or a determination of exemption before work can begin.
- IRB disapproval decisions may be appealed to the IRB, but cannot be overruled by any other institutional official or organization.
- The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of adverse events, non-compliance, and unanticipated problems) must be met and research must be conducted as specified in the IRB-approved protocol.
- No matter how minor, proposed changes to non-exempt human research must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazards to participants.
- Materials must be submitted to the IRB promptly (e.g., requests for changes or modifications, continuing reviews, etc.).

- Research events that meet the IRB reporting criteria as defined on the **Reportable New Information Page**, including unanticipated problems involving risks to participants or others (UPIRSOs) within 5 business days of knowledge or notification of the event.
- Death of an NU/NU Affiliate* Participant that is Unanticipated, Related or Possibly Related, requires Reporting to the IRB within 24 hours of knowledge or notification. *NU/NU Affiliate* Participant*: participants enrolled at NU's affiliate sites (Shirley Ryan Ability Lab and Northwestern Memorial Healthcare) or sites for which NU has agreed to serve as the IRB of Record through a reliance agreement.
- See **Policy: Definitions (HRP-001)** for the following definitions:
    - *Adverse Event (AE):* An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptoms or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.
- Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO): Any information, including any incident, experience, or outcome that meets ALL of the following conditions:
    - is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human participant population being studied;
    - is related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
    - suggests that the research places human participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred

- Potential non-compliance with laws, regulations, or IRB requirements by the research team or others must be reported if the event meets IRB reporting criteria, even if the non-compliance was unintentional or discovered during quality assurance activities (such as post-approval monitoring). See the **Reportable New Information (RNI)** page for definitions and examples.

Researchers can use the IRB Office's **Incident Assessment Tool (HRP-1207)** to document and assess the event. An event meets IRB reporting criteria if the PI assesses that the event had the potential to increase the risk of or cause harm, adversely affect the rights or welfare of participants, or undermine the scientific integrity of the data.

The goal of the Compliance Team within the Northwestern University IRB Office is to enhance the caliber of research and increase the effectiveness of the University's Human Research Protection Program (HRPP) through education and compliance initiatives. Routine post-approval monitoring and for-cause monitoring or audits are performed to ensure the research complies with the federal regulations, guidelines, and institutional policies that govern research. **Post-Approval Monitoring** and **Directed Reviews (For-Cause Audits)** aim to ensure that participants' rights are protected; researchers and staff have educational resources that enable them to fulfill their roles as investigators and study staff; and the research community has access to **Study Support Resources** and other compliance related resources.

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Section 7: Obtaining and Documenting Informed Consent

Informed consent is the voluntary choice of an individual to participate in research based on a complete and accurate understanding of the study. Informed consent is not a single event or document but an ongoing process involving the investigator (or study team member delegated to obtain informed consent) and the research participant.

Possible Questions About Informed Consent

- What are the required elements of informed consent?
- How can a participant obtain information about human protections at Northwestern?
- When reviewing a consent form, what do you look for?
- What does the consent process entail?
- What is the difference between a waiver of consent and a waiver of documentation of consent and an alteration of consent?

Informed consent requires full disclosure of the nature of the research, the participant's role in that research, an understanding of that role by the potential participant, and the participant's voluntary choice to join the study.

For information on obtaining and documenting (if applicable) informed consent, please review the **Consent & Waiver of Consent page**, and the following SOPs: **Informed Consent Process for Research (HRP-090)** and **Written Documentation of Consent (HRP-091).**

General Consent Information:

- Investigators are responsible for obtaining and documenting informed consent before the research begins unless they provide justification for and the IRB waives this requirement.
- Informed consent must be conveyed in language that is understandable to participants or their legally authorized representative.
- Consent must be sought under circumstances that minimize the potential for coercion or undue influence.
- The prospective participant must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate.

- The information must begin with a concise and focused presentation of the key information and in a manner that facilitates comprehension.
- The consent as a whole must present sufficient information and in a manner that facilitates understanding.
- Does not include exculpatory language.
- Time for questions between the initial request for participation and the final decision, as recorded in the consent document, should be allowed.
- The researcher/person obtaining consent must make it clear to participants that their participation is voluntary and that they may withdraw at any time without penalty.
- Consent is documented using a consent form approved by the IRB unless a waiver of informed consent or a waiver of documentation of informed consent is granted.
- Researchers can use the **Documentation of Consent Process Form**.
- The Common Rule (45 CFR 46.116 (a)) outlines the **required elements of informed consent**:
  - A statement that the study involves research;
  - Information on the purpose of the research;
  - The expected duration of participation;
  - A description of the procedures (identification of experimental procedures);
  - A description of reasonably foreseeable risks or harms;
  - A description of any benefits to participants or others;
  - Disclosure of appropriate alternative treatments/procedures, if the research involves clinical treatment;
  - A description of how the confidentiality of records will be maintained;
  - A description of procedures related to compensation for injury, if the research is more than minimal risk;
  - Contact information for the PI and IRB; and
  - A statement that participation is voluntary and that the participant may withdraw at any time with no penalty or loss of benefits.
  - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or
    2. A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- There are also additional elements of informed consent that are to be included as appropriate. OHRP has elements that have not been adopted by the FDA.

- The participant (or their legally authorized representative) must be provided with the opportunity to receive a copy of the signed and dated consent document at the time of consent.
- Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (six years if protected health information will be used or disclosed in connection with the study) or longer if required by the Institution or research sponsor. See **Research Document Retention Requirements for Principal Investigators (HRP-1914)**.
- In some cases, the IRB may waive the requirement to obtain consent or waive the requirement

for documentation of informed consent. To review informed consent waivers, alterations, and exceptions, refer to the worksheets **Waiver or Alteration-Consent Process (HRP-410)** and **Waiver Written Documentation of Consent (HRP-411)**. See also the **Consent & Waiver of Consent** page.

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Section 8: Conflict of Interest Disclosure

A **Conflict of Interest (COI)** is a situation in which an individual's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, their professional judgment in exercising any University duty or responsibility. A COI in research is a significant financial interest that relates to and could directly and significantly affect the design, conduct, or reporting of the research, or present the appearance thereof.

Possible Questions About Conflict of Interest Disclosure

- What is a conflict of interest?
- How does Northwestern assess and manage conflicts of interest?
- What should be disclosed to participants regarding a financial conflict of interest?
- Does the IRB view and approve COI management plans for human research?
- What do you do if you have a conflict of interest related to a protocol you are reviewing?

At Northwestern University, potential COIs are identified through annual and continual disclosure requirements for investigators in the University's eDisclosure system. Disclosures of investigators are reviewed by the COI office, School Dean's Offices, and/or School-based or University committees in the context of each research project in which an investigator is engaged to determine whether or not a COI exists and, if so, how it will be reduced, managed, or eliminated in the interest of preserving research objectivity and protecting the rights and welfare of human research participants. For research involving human participants for which a COI determination is made, the COI office provides management plan information to the IRB in eIRB+ so that the IRB can assess whether or not the management strategies adequately protect the rights and welfare of human research participants.

The following relationships are examples of situations that may raise questions regarding an apparent or actual conflict of interest in research:

a) An investigator has a consulting or other relationship with a company sponsoring a research project, or a company that manufactures or markets a product under evaluation in the research
b) An investigator has intellectual property interests in a product or method under evaluation in the research
c) An investigator is a founder and has equity interests in a start-up company that owns intellectual property under evaluation in the research

The following are examples of COI management strategies often instituted when an investigator is determined to have a COI related to a specific research project:

a) Disclosure of the related interest to research team members and collaborators
b) Disclosure of the related interest to human research participants in the informed consent document
c) Disclosure of the related interest in press releases, presentations, and publications arising from the research
d) Reduced role of investigator in the research project (e.g., cannot serve as PI, no involvement in enrollment or consent processes, etc.)

e) Independent review of data/independent data analysis

See the **Research Requirements: Conflict of Interest Page**. The **Policy on Conflict of Interest and Conflict of Commitment** represents the overarching university policy on conflicts of interest and commitment for faculty and staff. In addition, the University has specific policies and processes governing conflict of interest in research, both on the individual and institutional level. The Policy on Conflict of Interest and Conflict of Commitment includes specific information on COI in the context of research involving human research participants, specifically the roles and responsibilities of NUCOI, School Dean's Offices, and/or School-based or University committees in reviewing disclosures and making COI determinations on the individual and institutional levels and establishing management plans when COIs do exist and the roles and responsibilities of the IRB in assessing whether or not the management strategies established adequately protect the rights and welfare of human research participants.

Please take some time to review the full policies, using the links below from the **COI website**:

- **Policy on Conflict of Interest in Research**
- **Institutional Conflict of Interest in Research**

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Section 9: Accountability and Additional Administrative Requirements

The IRB Office is primarily responsible for developing and directing the University's Human Participant Protection Program (HRPP), which also involves other offices at Northwestern University. The HRPP's mission is to be a model program of excellence in protecting the rights and welfare of human participants involved in research.

The IRB Office strives to support our staff and panel members to ensure they have access to the training and educational resources they need to succeed.

Possible Questions About Accountability and Additional Administrative Requirements

- Do you think you have access to adequate resources to perform your duties related to the protection of humans in research?
- What sort of support do you receive from Northwestern's administration?
- To whom do you go for help on issues, be they regulatory or ethical?
- How is communication facilitated throughout the HRPP? Is this an effective system?
- Is the IRB workload reasonable?
- Describe your annual evaluation process.

The **Information for Panel Members Page** contains links to relevant general information, guidance, **Tips for Preparing a Review**, and other helpful information.

IRB members, IRB Office staff, and researchers may contact **Crista Brawley**, Associate Vice President for Research, **Eric Perrault**, Vice President of Research, or **Nathalia Henry**, Executive Director of the IRB Office, to obtain answers to questions, express concerns, or share suggestions regarding the HRPP.

IRB Panel Members are encouraged to contact their Panel's assigned IRB Office staff person with any questions.

A compliance team member is assigned to RNIs and compliance issues at panel meetings, and they are also available to contact for guidance.

Each month, the Compliance and Reliance Teams provide the IRB Office and IRB Chairs and Vice Chairs with the Compliance and Reliance Summaries at the IRB Chairs meetings. Sr. IRB analysts bring back relevant topics from the summary to their assigned panels.

Principal investigators must perform or delegate to qualified research staff all necessary tasks to carry out research, including specifically, obtaining IRB approval before research begins; obtaining informed consent of participants before study enrollment; submitting a continuing review in a timely manner; informing the IRB of any disapprovals, suspensions or terminations by other review units; and the creation and maintenance of accurate records. The PI is ultimately responsible for properly conducting the study and fulfilling related obligations.

Please take some time to review the **Human Research Protection Program Compliance Policy (HRP-1001)**.

Research participants with complaints about a research project or questions about their rights as a research participant, and members of the research community who are not research participants but would like to offer suggestions about our Human Research Protection Program or would like to obtain more information, may visit the IRB Office's **Concerns & Complaints** page which provides a variety of methods of contact, including:

- Contact the IRB Office at (312) 503-1376 or **IRBCompliance@northwestern.edu**.
- Find specific information on our **Contact Us** page.
- File an anonymous complaint of noncompliance using the **EthicsPoint website**. EthicsPoint is a secure service for the research and academic community that allows the reporter to remain anonymous while reporting possible noncompliance to relevant institutional officials, and receive feedback from those same officials.
- See the **For Participants** page.

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Section 10: Education

The Northwestern IRB Office recognizes the value of ongoing training and educational opportunities for IRB members and staff and understands that an engaging educational program can increase the ability of IRB members and staff to contribute to the HRPP.
The Common Rule and FDA regulations require IRB members to be qualified to complete reviews, but what and how these qualifications should be developed is not outlined.

Possible Questions About Education

- Describe the training you've had to be qualified to review human research projects.
- What sort of continuing education do you receive related to research ethics and human research?
- What ongoing professional meetings/trainings are offered or have you attended?
- How do university officials keep you informed of new developments in human research regulations?

IRB Member Training

The IRB Program for Onboarding and Education of Members (I-POEM) is designed to give new panel members a phased experience in learning and development as key stakeholders in the Northwestern University Human Research Protection Program (HRPP). I-POEM begins with the establishment of basic knowledge that is a cornerstone of the operations

of a successful HRPP and IRB Office, moves into guided hands-on learning through mentorship with senior Northwestern IRB members and persists with ongoing education critical to the continued professional development of board members who serve in an ever-evolving regulatory environment.

Phase II of I-POEM distinguishes it from standard training programs as it transitions learning to focus on applying skills as the IRB member demonstrates knowledge obtained from Phase I of the program. Having learned foundational concepts, ethical considerations, and regulatory policies, new panel members have opportunities in Phase II to practice further tasks related to their review of various submission types. In Phase II of I-POEM, the panel analyst assigns submission(s) to the new member, who has now graduated to IRB "mentee" status. The mentee and their mentor, assigned by the Panel analyst and chair in Phase I of the program, then work together to ensure the mentee gains the breadth of knowledge, skills, and experience appropriate to serve independently.

IRB Member Retreat
Each fall, the Northwestern University IRB Office hosts its annual Keren Patricia Dimah IRB Member Retreat, gathering members from all six of its panels, along with IRB Office staff and leadership, for a conference that centers on the theme(s) of interest to panel members. The conference's goal is the professional development of panel members, and there is marked ancillary benefit to IRB Office staff who gain knowledge through attendance, many of whom prepare sessions for presentation at the retreat.

IRB Member Evaluation
On a rolling basis, the Associate Director, IRB Operations works in concert with the HRPP Program Assistant to evaluate Panel members who have appointment periods ending soon (e.g., within 3 months of appointment term end date) as part of the IRB Panel Member 360 Evaluation & Re-Appointment Process. The Panel members perform a self-evaluation, evaluate their chairperson's performance, and evaluate the performance of the IRB Office staff person assigned to support their Panel. For IRB Members who are also part of the IRB Office staff, the employee's annual Performance Excellence (PEX) is utilized in place of the 360 Evaluation Survey. The chairperson(s) of non-staff IRB members and the IRB staff person assigned to the Panel also evaluate the member's performance.

IRB Staff Training
Each IRB Office staff member will complete the IRB Staff Training and Onboarding Program (ISTOP) upon initial appointment to their position within the IRB Office. The approximate duration of onboarding may be no less than six weeks and is guided by the staff member's direct supervisor, with consideration given to background, position requirements, and office needs.

Phase I of ISTOP familiarizes new staff with job-related content and information and orients them with IRB Office processes, policies, and tools. Phase II presents opportunities to operationalize Phase I knowledge to gain comfort and competence in meeting job requirements.

Human Research Protections Training Requirement
The Collaborative Institutional Training Initiative (CITI) Program provides research ethics education to the Northwestern University HRPP community. Northwestern University requires all individuals involved in the conduct of Human Research to complete Human Research Protections Training and refresh their training every 3 years, and these requirements apply to all persons engaged in human research and listed on the eIRB+ study application.

The **Human Research Protections Training webpage** has detailed information on these requirements and is outlined based on researcher affiliation with Northwestern University.

Navigating Human Research & Regulatory Review with the IRB Online Course

As of 2023, the Northwestern University IRB Office began offering Navigating Human Research Ethics & Regulatory Review with the Institutional Review Board Office, a comprehensive educational tool that can be accessed through Northwestern's centralized **MyHR Learn** system. It is designed to meet the varying needs of Northwestern University's human research community members. The 11-module course was developed by IRB Office staff and offers an overview of the most salient topics in human research protections along with tips on conducting that work in the context of Northwestern University. "Navigating," as the course is commonly called, is designed to support classroom learning in ways that support individual learning styles and meet instructional needs. It was created to serve Northwestern's HRPP community, including new IRB Office staff and panel members. Navigating is an optional course that supports general IRB education and does not satisfy the Northwestern human research protections training requirements.

Live Educational Sessions

In addition to Navigating, the IRB Office also offers live educational sessions for the Northwestern HRPP community through various means. IRB Office staff are available for Question and Answer sessions for groups requiring support that extend beyond the Human Research Protections foundations education offered through the Navigating course. Additionally, the Office hosts intensive Special Event Training sessions for groups where IRB Office staff support is critical for professional or academic development. Finally, the IRB Office hosts monthly Brown Bag Lunch & Learn sessions highlighting topics relevant to human research protection.

More information on IRB Office educational resources can be found here: **Education: Institutional Review Board (IRB) Office**.

IRB Learning Library

The IRB Learning Library is an educational resource collection designed to support the professional development of IRB Office staff, IRB panel members, and the Northwestern research community. It contains various virtual and hard copy resources pertaining to the history of and current events in human research protections, Certified IRB Professional (CIP) exam preparation, IRB submission review conduction, IRB submission compilation, Northwestern IRB Office conference submissions, and general professional development content. IRB Learning Library is an ever-growing collection, and access is free but regulated to maintain records of use and track distribution of hard copy materials.

To borrow a hard copy resource from our IRB Learning Library Catalog (firewalled database), email **irbtraining@northwestern.edu**. The IRB Learning Library's physical location is Northwestern University Institutional Review Board Office, Arthur Rubloff Building, 7th floor, 750 N Lake Shore Dr., Chicago, IL 60611. Many library resources (see Catalog) are available electronically and stored in the Northwestern IRB Learning Library Sharepoint folder. These may be accessed and used freely.

The IRB Learning Libary is a shared resource designed by human research protections community members and we welcome contributions of all kinds! Please email **irbtraining@northwestern.edu** with any contributions or ideas for additions to the Library.

IRB Office Communications
As a part of the IRB Office's initiative to share timely resources and information with the research community, the IRB publishes the IRB Bulletin at the beginning of each month and it is posted on the **News & Announcements Page**. This e-newsletter contains relevant updates from the IRB Office on various topics of interest to the research community and is written by members of the IRB Office staff. Additionally, the IRB Office contributes to Transforming Research, the Northwestern University Office for Research's monthly e-newsletter, as part of a shared voice on current events and updates pertinent to research administration at our institution.

IRB Education SOPs:

- IRB Member Training Guide (HRP-111)
  - This training guide is designed to address learning throughout the life cycle of IRB members' service. It documents the onboarding education of new panel members, separated into three phases to scaffold the learning process, as well as continuing education for existing members.
- IRB Member Training (Initial and Ongoing) (HRP- 902)
  - This is a high-level process outline for the onboarding and professional development of IRB panel members
- IRB Staff Training Guide (HRP-1109)
  - This training guide is designed to learning throughout the life cycle of IRB staff personnel tenure. It documents the onboarding education of new Office staff, separated into three phases to scaffold the learning process, as well as continuing education for existing staff.
- IRB Staff Training (Initial and Ongoing) (HRP-901)
  - This is a high-level process outline for the onboarding and professional development of IRB Office staff
- New Hire Onboarding Checklist (HRP-1422)
  - This to-do list is designed to guide the onboarding process for new IRB Office staff personnel.

Remember! Protecting research participants is a shared responsibility.
Northwestern University IRB Office staff are available to answer your questions and to help you have a successful interview. If you have any questions, don't hesitate to contact us at:
IRBCompliance@northwestern.edu

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Section 11: Additional Resources

- **Northwestern University AAHRPP Accreditation Webpage**
- **Northwestern University IRB Office Homepage**
- **Human Research Policies & Guidance**
  - **Protocol Templates & Forms**
  - **Consent Templates & HIPAA Requirements**
  - **Study Support Resources**
  - **Recruitment Materials & Guidelines**
  - **Policies & Guidance**

- **Checklists & Worksheets**
- **SOPs**
- **Association for the Accreditation of Human Research Protection Programs (AAHRPP)**
- **Office of Human Research (OHRP) Protections**
- **Clinical Trials and Human Subject Protection | FDA**