AAHRPP Site Visit 2024:
Interview Guide for HRPP Administrators

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, as well as 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 a research administrator, you are an integral part of the Northwestern HRPP. Several administrators 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 the conduct of your research, as well as 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. 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 is the IRB's reputation on campus? ▪ What do you think about the IRB and its efforts to protect human participants? ▪ Why does Northwestern value AAHRPP accreditation? What do you think of it?

You will be expected to:

- Understand the Northwestern University HRPP structure
- 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 the process for non-compliance reporting at Northwestern
    - **Reportable New Information (RNI)**
- Know **Human Research Protections Training** requirements and resources at Northwestern
- Know IRB Office's electronic submission system (**eIRB+: Institutional Review Board (IRB) Office**) terminology

- 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

The mission of the Human Research Protection Program (HRPP) 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 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 research at Northwestern?
▪ Who is the institutional official/organizational official responsible for the Northwestern HRPP?

- What is the Northwestern University HRPP?
- What is your role in the Northwestern University HRPP? What research is under your purview?
- What is the guiding philosophy of the HRPP at Northwestern University?
- What does your administration do to support human research activities?

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. He 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 including 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, the Office of Sponsored Research (OSR), the Office of Research Integrity (ORI), and Conflict of Interest (COI) Office;
- Academic units, including schools, colleges, and other 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 is ethical research?
- How do you communicate University values and ethical messages to your associates and institution?
- 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 are OHRP, FDA, and HIPAA?

The review and conduct of research at Northwestern is guided by principles set forth in the **Belmont Report** and performed by Department of Health and Human Services (HHS) regulations (45 CFR 46 or the "Common Rule"**http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm**), 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.
- **Common Rule Implementation (Office of Human Research Protections)**
  - The Office of Human Research Protections updated 45 CFR 46 , the Common Rule, and this 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/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, 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**, 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**).
- 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**.

- 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**).

- **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**.

- In addition to securing IRB review, researchers may need to secure other approvals or notifications prior to 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.

- **Institutional policies and procedures**.

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Section 4: 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 (e.g., personnel, facilities, equipment, etc.).
- 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 enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant persons, individuals with impaired decision-making capacity, etc.).

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Section 5: Compliance with IRB and Other Review Unit Requirements

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

Possible Questions About Compliance with IRB and Other Review Unit Requirements
▪ What does the IRB do? ▪ In a dispute between IRB and a researcher, can an administrator overrule IRB's decision? ▪ How do you handle complaints regarding the IRB system?

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

- 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 and unanticipated problems) must be met and research must be conducted as specified in the IRB-approved protocol.
- Proposed changes to non-exempt human research, no matter how minor, must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazards to participants.
- Materials must be submitted to the IRB in a timely fashion (e.g., 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 subjects 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.
- 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.

- 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.
- 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 6: 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 is the process of consent?
- How can a participant obtain information about human research protections at NU?

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 **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 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 potential for coercion or undue influence.
- Time for questioning between the initial request for participation and the final decision as recorded in the consent document should be allowed.
- It must be made clear to participants that their participation is voluntary and that they may withdraw at any time with no penalty.
- Consent is documented by use of 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**.
- 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.
- Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (seven 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 7: Conflict of Interest Disclosure

A **Conflict of Interest** 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 conflict of interest in research is a

significant financial interest that relates to and could directly and significantly affect the design, conduct or reporting of the funded research, or present the appearance thereof.

Possible Questions About Conflict of Interest Disclosure

- Do you understand the Northwestern COI policies and how COIs may influence the protection of human research participants?
- What is your role in managing conflicts of interest and institutional conflict of interest?

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 NUCOI, 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, management plan information is provided by NUCOI 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 conflict of 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 8: Accountability and Additional Administrative Requirements

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; securing informed consent of participants prior to study enrollment; conducting 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 proper conduct of the study and fulfillment of related obligations.

Possible Questions About Accountability and Additional Administrative Requirements

- Do have access to adequate resources to perform your duties related to human research?
- Does the organization provide support for review and negotiation of contracts?
- To whom do you go for help on issues, be they regulatory or ethical?

IRB Administrators 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.

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

Research participants with a complaint 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 9: Education

The Northwestern IRB Office recognizes the value of ongoing training and educational opportunities for the research community.

Possible Questions About Education

- What education must an investigator complete to be qualified to participate in human research?
- Were you trained in human research/ethics/carrying out research duties, etc.?
- How do you train your staff?
- How do you verify CITI certification status?
- How do university officials keep you informed of new developments in human research regulations?

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 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.

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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

Section 10: 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**