AAHRPP Site Visit 2024:
Interview Guide for Researchers and Research 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, 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 researcher or research member, you are an integral part of the Northwestern University HRPP. Several researchers or research members 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.

If you were selected for an interview based on a specific type of protocol (e.g., international, device, etc.), please review your procedures for conducting that type of research.

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.

- For example, if a question regarding Food and Drug Administration (FDA) regulations is asked, a social/behavioral researcher should let the interviewer(s) know that drugs or medical devices are not part of their research. Below are examples of the type of general questions you might be asked.

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
About Your Own Project(s)
▪ Describe your study. What are the procedures? How do you recruit? What is the consent process? ▪ What kinds of harms can occur in your study? How do you minimize those harms? ▪ Do you communicate results with your participants after the completion of your research? ▪ How did you interact with the IRB on this study?

Relationship with the IRB

- What is AAHRPP accreditation and why is it important to Northwestern University?
- What is the IRB's reputation on campus?
- What are typical turnaround times?
- How did the IRB prepare you to conduct your research?
- How do you feel about the IRB?
- Do you think IRB reviews are fair?
- What do you think about the IRB and their efforts to protect human research participants?
- Do you know how often the convened (full board) IRB meets?

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
- Know how to document and report non-compliance and research events that occur
  - **Reportable New Information (RNI)**
- Understand and describe the ethical aspects, purpose, and value of your work
- Know the regulatory standards that apply to your research
- Know IRB Office's electronic submission system (**eIRB+: Institutional Review Board (IRB) Office**) terminology, and describe your IRB submissions
- Understand what constitutes **Conflict of Interest** in research.
- Know how a potential **Conflict of Interest** is disclosed and reviewed at Northwestern University
- Describe the **Human Research Protections Training** that is required for all persons engaged in human research (i.e. CITI Training)
- Know how to recruit participants ethically and equitably while adhering to inclusion/exclusion criteria

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 University?
- Who is the institutional official/organizational official responsible for the Northwestern HRPP?
- What are the components of the Northwestern HRPP?
- Where would you go for help on regulatory or ethical issues?

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, 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: Roles and Responsibilities of Investigators and Research Staff

Investigators have primary responsibility for protecting the rights and welfare of humans participating in research. Safeguarding human research participants takes precedence over the goals and requirements of any research endeavor.

Possible Questions About Roles/Responsibilities of Investigators and Research Staff

- What is the PI's primary responsibility in conducting the research?
- What is the Common Rule/46 CFR 46?
- What are the Belmont Principles and when did you first hear of them?
- Are there additional requirements for studies sponsored by the Department of Justice (DOJ), Department of Defense (DOD), Environmental Protection Agency (EPA), etc.?

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

The principal investigator (PI), co-investigator (CO-I), and study team members are expected to understand and adhere to these requirements.

- **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 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, 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/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**, which serve as the regulatory framework for research regulated by the Food and Drug Administration (i.e., research involving drugs, devices, biologics). 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 to Participants and Protecting Their 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 and Protecting Participant's Rights and Welfare

- What is the process of scientific review for your research?
- Do you know the difference between minimal and more-than-minimal risk?
- What is the difference between privacy and confidentiality?
- How do you protect participant privacy and confidentiality of data?
- How/who do you recruit for your research?
- How do you ensure that only participants meeting the inclusion criteria are enrolled?
- What additional mechanisms do you have in place to protect your research participants?

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 *individuals* having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.

  - *Confidentiality* – Relates to the protection of participant *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

Investigators and research staff have a responsibility for ensuring research is conducted in compliance with IRB, as well as other institutional and regulatory requirements.

Possible Questions About Compliance with IRB and Other Review Unit Requirements

- How do you notify the IRB about proposed changes to your research?
- What would you do if you lost your research data and who would you tell?
- Do you know how to report a participant complaint or a problem with your study?
- What is a UPIRSO? Have you ever had one on a study?
- How would you report an adverse event or a UPIRSO?
- Do you know what non-compliance is and when and how to report it?

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 before work can begin.
- The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of adverse events and unanticipated problems) must be met.
- Research must be conducted as specified in the IRB-approved protocol.
- Proposed changes to the 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.
- PIs are responsible for the content of all submissions to the IRB (e.g., eIRB+ application, supporting documents, etc.).
- 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 Obtaining and Documenting Informed Consent

- What are the required elements of informed consent?
- Describe your consenting process. Does the participant get a copy? If yes, when do they get it?
- What is the process for obtaining consent? Who does it? Where are participants approached? Do participants have time to think about it before they agree to participate?
- What would you do if you recruited a non-English speaking participant? How would you consent?
- How do you know if the participant understands the consent document?
- Who answers questions about the research?
- What is a waiver of informed consent?

Informed consent requires full disclosure of the nature of the research and the participant's role in that research, 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 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.
- 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 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 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**:

- A statement that the study involves research;
- Information on the purpose of the research;
- The expected duration of participant 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) should be provided with a copy of the 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 (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

- What do you know about conflict of interest?
- What do you disclose to participants regarding a financial 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 authorized research staff all necessary tasks to carry out research, including specifically:

- Obtaining IRB approval before research begins;
- Obtaining informed consent of participants prior to study enrollment;
- Submitting continuing review in a timely manner;
- Informing the IRB of any disapprovals, suspensions, or terminations to active research studies; and
- Creating and maintaining accurate records.

The PI is also ultimately responsible for proper conduct of the study and fulfillment of related obligations, including specifically:

- Appropriate training for all study team members on protocol and safety issues;
- Cooperating with investigations/inspections by authorized internal oversight activities as well as external reviews; and
- Supporting student researchers and the protection of human participants in the students' research, if applicable.

Possible Questions About Accountability and Additional Administrative Requirements

- Who prepares the IRB application and who submits the application?
- Who communicates with the IRB?

- What are the qualifications of your study team?
- How does your study team work together (delineation of roles)?
- How do you communicate within your team?
- How are you trained in the details of the study protocol?
- How do you ensure that study protocols are followed?
- Do you maintain a regulatory file for the study? Where is it?
- Where are your research records maintained?
- What kind of workload do you have?
- Do you have the appropriate resources to conduct the research properly?
- Do you work on any other studies?

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.

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 kind of training did you receive?
- What training do you require/provide for your research team?
- Were you trained in human research, ethics, and carrying out your research duties?
- How do you verify CITI certification status for yourself and other study team members?

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**