

# Northwestern University

## Local Context Information

### Institutional Information

- Full Legal Name: Northwestern University
- Institution Category: Private Non-Profit University
- Mailing Address: 633 Clark St. Evanston, IL 60208
- Website: <https://irb.northwestern.edu/index.html>

### OHRP Federalwide Assurance:

- FWA00001549
- FWA Expiration: 12/14/2026
- The FWA has *NOT* been extended to non-federally funded research
- More information can be found at: <https://irb.northwestern.edu/about/index.html>

**IRB Organizations Number:** IORG0000247

### AAHRPP (Association for the Accreditation of Human Research Protection Programs, Inc):

- Initial Accreditation Date: 12/19/2016
- Reaccreditation Date: 12/15/2019
- More information can be found at: <https://irb.northwestern.edu/about/irb-information/aahrpp-accreditation.html>

**Covered Entities:** Northwestern University is not a covered entity under HIPAA, but through Master Agreements the Northwestern University IRB is authorized to serve as the Privacy Board for Northwestern Memorial Healthcare and Shirley Ryan AbilityLab.

**IRB Membership List/Roster:** <https://irb.northwestern.edu/about/irb-information/panels-rosters.html>

**Institutional Review Boards:** 5 biomedical boards and 1 social-behavioral board. Panels A, B, C, D, and E meet monthly and IRB agendas are set two-weeks prior to meeting date. Panel Q meets weekly and reviews biomedical studies that are up for continuing review as well as time sensitive submissions.

- IRB00000418
- IRB00000419
- IRB00000736
- IRB00000420
- IRB00002600
- IRB00005003

**Primary Institutional Affiliations:** The Northwestern University IRB is affiliated and, through Master Agreements, acts as the IRB of record for Northwestern Memorial Healthcare and Shirley Ryan AbilityLab.

- Northwestern Memorial Healthcare:
  - Northwestern Medicine locations: <https://www.nm.org/locations>
  - Northwestern Medical Group locations: <https://nmg.nm.org/locations.html>

- Northwestern Medicine Regional Medical Group locations: <https://rmg.nm.org/CPG/Locations>
- Shirley Ryan AbilityLab locations: [https://www.sralab.org/search?content\\_type=Location](https://www.sralab.org/search?content_type=Location)

### **Illinois Laws to Consider when Reviewing the Northwestern Site (Not an Exhaustive List):**

- The Illinois Medical Studies Act
  - CIVIL PROCEDURE (735 ILCS 5/) Code of Civil Procedure (735 ILCS 5/Art. VIII Pt. 21 heading) Part 21. Medical Studies.
  - The Illinois Medical Studies Act protects information and data used in internal quality control or medical studies by hospital committees or their medical staff. The purpose of the medical study must be to reduce morbidity or mortality, improve patient care, or increase organ and tissue donation. This information and data is privileged and confidential; it is not admissible as evidence nor discoverable in any action of any kind. An institutional review board is considered a hospital committee under the Act. The disclosure of any data or information obtained in any such medical study is unlawful and constitutes a misdemeanor unless disclosure is necessary for the purpose of the study. The consent form should include a disclosure informing the participant that the institutional review board may access and review the participant's information and data, including to ensure that the research study is done in a safe and appropriate manner.
  - See our Northwestern Consent Templates for required language.
- The Illinois Mental Health and Developmental Disabilities Confidentiality Act
  - CIVIL LIABILITIES (740 ILCS 110/) Mental Health and Developmental Disabilities Confidentiality Act.
  - This act governs the use and disclosure of mental health, developmental disabilities, and genetic counseling information. A covered entity cannot disclose this information to a researcher pursuant to a waiver of authorization or consent. A covered entity can however disclose this information as part of a limited data set, to a business associate, or pursuant to a patient's consent. The consent form should consist of a HIPAA-complaint authorization and include (i) the patient's right to inspect and copy the information to be disclosed, (ii) a calendar date expiration, and (iii) a witness signature.
  - See our Northwestern Consent Templates for required language.
- The Illinois Genetic Counselor Licensing Act
  - PROFESSIONS, OCCUPATIONS, AND BUSINESS OPERATIONS (225 ILCS 135/) Genetic Counselor Licensing Act.
  - This act states that the disclosure of genetic counseling information is subject to the Illinois Mental Health and Developmental Disabilities and Confidentiality Act. In the event of a conflict between these acts, the provisions of the Mental Health and Developmental Disabilities Confidentiality Act shall be followed.
- The Illinois Genetic Information Privacy Act
  - PUBLIC HEALTH (410 ILCS 513/) Genetic Information Privacy Act.
  - When using or disclosing genetic-related information under this Act, a covered entity shall do so in accordance with the minimum necessary standard under HIPAA.
- The Illinois AIDS Confidentiality Act
  - PUBLIC HEALTH (410 ILCS 305/) AIDS Confidentiality Act.
  - The disclosure of HIV-related information, when allowed by this Act, shall be performed in accordance with the minimum necessary standard when required under HIPAA.
- The Illinois Nursing Home Care Act
  - HEALTH FACILITIES AND REGULATION (210 ILCS 45/) Nursing Home Care Act.

- Research in nursing homes in the State of Illinois requires additional state approvals. Please note if you are conducting nursing home research outside the State of Illinois you may need additional approvals. Please contact the IRB Office for assistance.

### **Research Team Qualifications and Training:**

- Northwestern University requires all individuals involved in the conduct of human subjects research to complete human subjects protection training and to recertify every three years. More information can be found at: <https://irb.northwestern.edu/compliance-education/human-research-protections-training/citi-training.html>
- All study team members must be trained on requirements specific to each individual research protocol. The PI retains responsibility for overseeing these activities.
- The responsibilities of the Northwestern PI in multi-site studies are outlined in the [Investigator Manual \(HRP-103\)](#) pages 23-25.

### **Oversight of Compliance:**

- The goals of the Compliance and Education Unit within the Northwestern University IRB Office are to enhance the caliber of research performed at Northwestern University and those investigators relying on the Northwestern University IRB for review. We strive to increase the effectiveness of the university's Human Research Protection Program (HRPP) through program oversight, education, and compliance initiatives. We accomplish these by ensuring research at Northwestern complies with the federal regulations, state laws, and institutional policies that govern human research. The IRBs compliance and education program aims to ensure educational resources and guidance materials are available to all staff; that researchers and their teams have the study support tools and resources needed to perform compliant research; and to assess human research projects to ensure the participants' rights and welfare are fully protected. The IRB Office Compliance Unit performs routine post-approval monitoring, directed reviews (for-cause audits), and education/training. The Compliance Unit conducts these activities across the entire portfolio of non-exempt human subject research, including studies for which the Northwestern University IRB has ceded review to an external IRB.
- More information can be found at: <https://irb.northwestern.edu/compliance-education/index.html>

### **Routine Site Visits:**

- There have been no Food and Drug Administration (FDA) or Office for Human Research Protections (OHRP) site visits of Northwestern University's Institutional Review Board in the past 5 years.

### **Conflict of Interest Review (COI):**

- Northwestern University's COI Office requires all individuals involved in the conduct of human research to submit financial disclosures at least annually, or more often if they change, through an online tracking system. COI Office activities are integrated into our electronic IRB submission system and must be completed before issuing IRB approval, or IRB acknowledgement for studies ceding review to an external IRB. The COI Office conducts these activities across the entire portfolio of non-exempt human subject research including those projects for which the Northwestern University IRB has ceded review to an external IRB. More information can be found at: <https://www.northwestern.edu/coi/>

### **Ancillary Reviews:**

- Ancillary reviews are conducted outside of the purview of the IRB Office. Please refer to the Northwestern study team for study-specific details.

### **Research with Non-English Speaking Individuals:**

- Participants who have limited or no English proficiency may be enrolled in research studies provided study teams have resources to communicate effectively during the recruitment process, while obtaining consent, and for the duration of the study. More information can be found at: <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/short-forms/index.html>

### **Research with Children:**

- The age of majority in Illinois is 18. Guidance on research with children can be found at: <https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html>
- Language involving pregnancy testing in minors can be found in the Northwestern consent templates: <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/biomedical-social-behavioral-consent-templates/index.html>

### **Research Involving Legally Authorized Representatives, Children, and Guardians:**

- More information can be found in the Northwestern SOP “HRP-013 Legally Authorized Representatives, Children, and Guardian”: <https://irb.northwestern.edu/resources-guidance/sops/>

### **Research Involving Consent of Adults with Impaired Decision-Making Capacity:**

- More information can be found in the Northwestern checklist “HRP-417 Adults with Impaired Decision-Making Capacity”: <https://irb.northwestern.edu/resources-guidance/checklists-worksheets/index.html>

### **Data Security Policies from Feinberg School of Medicine:**

- <https://www.feinberg.northwestern.edu/it/policies/information-security/index.html>

### **Institutional Contacts:**

Requests for signature by institutional contacts should be submitted in eIRB+ so the Northwestern IRB Office can determine the appropriate signatory.

- **Institutional Official for Research**

**Name:** Crista Brawley, PhD, CCRP

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- **IRB Executive Director**

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- **IRB Associate Director, Compliance and Reliance**

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- **Reliance Contact**

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- **IRB Panel Chair**

**Name:** Maureen Moran, MPH  
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- **Quality Improvement Contact**

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