



SOP: IRB Staff Training (Initial and Ongoing)

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-901	Executive Director, IRB Office Northwestern University	3/25/2020	Page 1 of 3

1 PURPOSE

- 1.1 This procedure outlines the high-level process for initial and continuing training requirements for IRB Office staff members.
- 1.2 The process begins when the IRB Office staff member is appointed to a position within the IRB Office.
- 1.3 The process is ongoing and continuous during the staff member's length of employment within the IRB Office.

2 PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 In accordance with Human Research Protection Program Plan (HRP-101) and the terms of the Federal Wide Assurance (FWA), the Northwestern University IRB Office Staff must receive initial and continuing training in alignment with their job responsibilities.

4 RESPONSIBILITIES

- 4.1 The IRB Executive Director or designee establishes the core educational and training requirements for IRB Office staff. IRB Office staff will receive initial and ongoing training regarding IRB review and oversight of human research, Northwestern University's Human Research Protection Program policies and the relevant procedures and guidelines.
- 4.2 The IRB Manager and/or IRB Lead is responsible for ensuring that each direct report receives the appropriate training required to execute their job responsibilities.

5 PROCEDURE

- 5.1 Onboarding Education and Training
 - 5.1.1 Each IRB Office staff member will receive training upon initial appointment to their position within the IRB Office, in accordance with the following outline. The duration of the initial onboarding process may take approximately [but not less than] six weeks and will be guided by the staff member's direct supervisor. In determining the appropriate length of the initial onboarding process, consideration will be given to the staff member's background, level of expertise and the position's requirements.
 - 5.1.2 Phase I: Content and Observation
 - 5.1.2.1 During the orientation/onboarding process and beyond, the new staff member will be informally mentored by their manager, supervisor and peers. Additionally, as needed or requested an assigned mentor will be available to serve as an ongoing resource to the new staff member during the onboarding period and beyond.
 - 5.1.2.2 Complete Northwestern University [New Employee Onboarding](#) requirements and other Human Resource- related and transition activities as applicable.
 - 5.1.2.3 Become oriented with the following:
 - 5.1.2.3.1 [The Belmont Report](#)
 - 5.1.2.3.2 [HHS regulations](#)
 - 5.1.2.3.3 [FDA regulations](#)
 - 5.1.2.4 Complete Human Subject Protections Training (i.e. CITI Course: Biomedical Research and/or Social Science and Behavioral Science Research).



SOP: IRB Staff Training (Initial and Ongoing)

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-901	Executive Director, IRB Office Northwestern University	3/25/2020	Page 2 of 3

- 5.1.2.4.1 If training was completed at another institution, the training documentation should be provided to the IRB Education Lead to verify it meets the Northwestern University requirements.
- 5.1.2.5 Review all Standard Operating Procedures relevant to the staff member's responsibilities.
- 5.1.2.6 Attend and observe at least two IRB panel meetings.
- 5.1.2.7 Become oriented with the IRB Office website and Northwestern-related electronic systems, including but not limited to eIRB+, Northwestern Box, OnBase, Outlook calendars, Kronos, etc.
- 5.1.2.8 Review past webinars and archived IRB Brown Bag Presentations as identified by the staff member's direct supervisor.
- 5.1.2.9 Visit both IRB offices on the Chicago and Evanston campuses to meet and shadow colleagues.
- 5.1.3 Phase II: Application and Learning
 - 5.1.3.1 During this phase the IRB Office staff member, under direction of their supervisor/manager, will be given the opportunity to apply knowledge obtained from Phase I, which will include activities specific to their role. (i.e. IRB Submission Reviews, IRB Compliance Activities, External IRB Administrative Review, etc.).
 - 5.1.3.2 Demonstrate understanding of the Human Research Protection Program and key IRB-related concepts.
- 5.2 Continuing Education and Training
 - 5.2.1 Each IRB Office staff member will engage in the following continued training opportunities:
 - 5.2.1.1 Human Subject Protections Training refresher every 3 years (i.e. CITI Course: Biomedical Research and/or Social Science and Behavioral Science Research refresher courses).
 - 5.2.1.2 Attend at least 4 continuing education opportunities per calendar year, including but not limited to: Webinars, Workshops and Institutional Continuing Education Opportunities (e.g. Advisory Council for Clinical Research (ACCR), Northwestern University Research Administration Professionals (NURAP), Northwestern University Knowledge at Noon, etc.).
 - 5.2.1.2.1 Depending on the unit budget and upon request from IRB Office leadership, attendance may be supported at one or more human research-related conferences (regional and/or national) for ongoing professional growth and development and maintenance of the relevant expertise (e.g. Certified IRB Professional (CIP) certification). Attendance selection will be at the discretion of the executive director and direct supervisor.
 - 5.2.1.3 Continued training of electronic systems including system updates/changes that are implemented which directly impact the IRB Office staff member's role.
 - 5.2.1.4 Continued review of all Standard Operating Procedures within the IRB Office, including updates/changes which directly impact the IRB Office staff member's role.
 - 5.2.1.5 Participation in educational training activities facilitated by the IRB Executive Director or designee for staff development and training. (e.g. monthly All-staff meetings, annual IRB Member Retreat, etc.)



SOP: IRB Staff Training (Initial and Ongoing)

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-901	Executive Director, IRB Office Northwestern University	3/25/2020	Page 3 of 3

5.2.1.6 IRB staff are encouraged to obtain the Certified IRB Professional (CIP) certificate after 2 years of employment.

6 MATERIALS

6.1 GENERAL DOCUMENT: [Human Research Protection Program Plan \(HRP-101\)](#)

7 REFERENCES

7.1 None