

A LESSON ON (NEW) STREAMLINED IRB TRAINING REQUIREMENTS & RECORDS MANAGEMENT



Nazneen Ali, PhD, CIP
Human Research Protection Program (HRPP) Education and Communication Specialist

OBJECTIVES

2

1. Detail automated features that facilitate seamless (a) institutional affiliation and transfer of module credits in CITI and (b) CITI to eIRB+ systems integration
2. Outline new, streamlined *Human Research Protections (IRB)* training course requirements
3. Share tips on routine human research protections training management
4. Introduce a new supplementary educational tool designed to support classroom instruction and study team training

AGENDA

3

1. Key Concepts & Tools
2. Preparatory to Training
3. Training: New Curriculum
4. Checking Training Records
5. Troubleshooting
6. Supplementary Education



KEY CONCEPTS & TOOLS

KEY CONCEPTS

5

HRP Training

Northwestern requires individuals involved in the [conduct of human research](#) complete human research protections (HRP) training every three years.

Affiliate (n)

A [Northwestern “affiliate”](#) is a individual who conducts research with SRALab, Central DuPage Hospital, and Northwestern Memorial HealthCare

CITI Program

The [Collaborative Institutional Training Initiative \(CITI\) Program](#) is the industry standard HRP training provider.

Affiliate (v)

To [affiliate](#) is a CITI process that identifies institutional training requirements and allows a learner to transfer records across institutions.

eIRB+

In addition to housing human research applications, eIRB+ is an electronic platform that stores researcher training records.

Integration

Integration is a backend system to system process that runs twice every 24 hours to migrate CITI training records into corresponding eIRB+ profiles.

HUMAN RESEARCH PROTECTIONS (HRP)



GOOD CLINICAL PRACTICE (GCP)

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

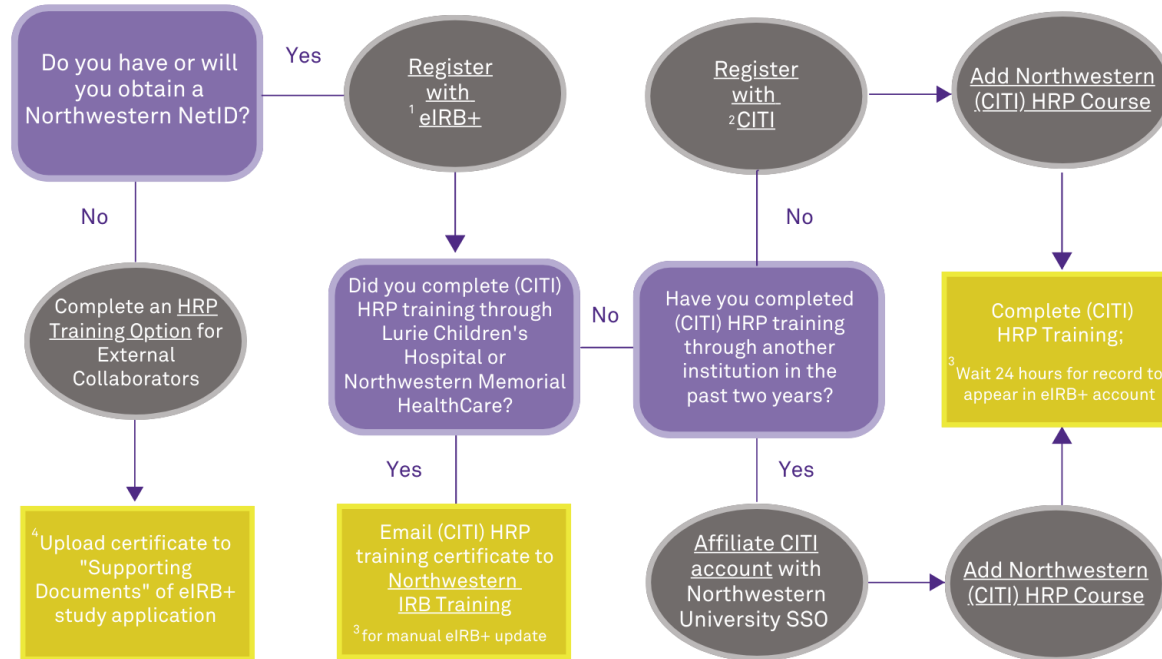
INFORMATION PRIVACY & SECURITY (IPS)

HRP TRAINING WEBPAGE



- <https://irb.northwestern.edu/compliance-education/human-research-protections-training/>
- irb.northwestern.edu >
Compliance & Education >
Human Research Protections Training
- Blueprint for today's presentation
- Updated September 2023

Mandatory Human Research Protections (HRP) Training Pathways for Individuals Engaged in Human Research



RESEARCHER GROUPS

9

Northwestern + Affiliates (SRALab, DuPage, NMHC)

Northwestern training

- Northwestern NetID
- CITI training completed with Northwestern
- No need to forward record

Other Institution's training

- Northwestern NetID
- CITI training completed elsewhere
- No need to forward record



Lurie Children's Hospital & NMHC (not covered by MOU)

- Northwestern NetID; must register with eIRB+
- Complete local CITI training
- Email record to IRB Training

Collaborators (Unaffiliated, Community-Based, and External)

- No NetID or local CITI training
- Complete one training option
- Upload record to *Supporting Documents* in eIRB+ application



CHECK

Q1 *Only those on a study team who collect data or biospecimens through intervention or interaction with living individuals for the purpose of research, are required to complete human research protections training.*

True or False.



CHECK

- Q2 *New human research protections training requirements took effect September 1, 2023 for Northwestern and Northwestern- affiliated researchers. What action(s) must researchers take to ensure they are compliant with these requirements?*
- a. *Log into CITI and reaffiliate/register with Northwestern University to reset backend course settings*
 - b. *Ensure their name is on a departmental list of human researchers that is reported to the IRB Office*
 - c. *Enroll in the “Human Research Protections (IRB)” course at time of basic or refresher training*

Northwestern University IRB Office Human Research Protections Training Requirements

PREPARATORY TO TRAINING

1

Register with eIRB+

2

Create/Affiliate CITI
acct using SSO

3

Add HRP course (CITI)

1.

REGISTER WITH EIRB+ (NETID REQUIRED)

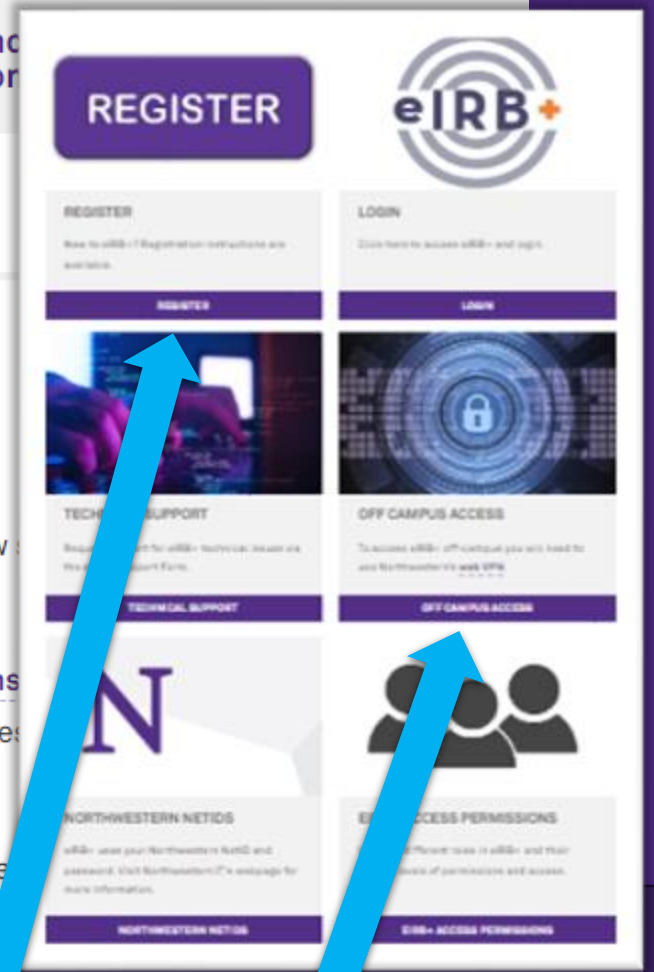
HOME > SUBMITTING TO THE IRB > EIRB+

eIRB+

eIRB+ is Northwestern University's electronic submission and review system. A Northwestern NetID is required to register with eIRB+ profile.

An eIRB+ profile is required to record the human research protections for all Northwestern affiliates involved in the conduct of human research through Northwestern University. An eIRB+ profile is required for submission and management.

Contact the Department of Information Technology to reactivate an eIRB+ profile.



2.

CREATE OR AFFILIATE CITI ACCOUNT WITH
NORTHWESTERN UNIVERSITY (USING SSO)



Using CITI's single sign-on (SSO) feature not only cuts the clunky manual process of creating/affiliating a CITI account, it practically eliminates opportunities for integration errors, which can affect research timelines and progress.

Single Sign-On (SSO)

The Northwestern University SSO option should *always* be used to create and affiliate accounts with CITI

CITI PROGRAM

LOG IN

CITI - Learner Registration

Steps: **1** 2 3 4

Select Your Organization Affiliation

This option is for persons affiliated with

To find your organization, enter its name in the box below, then pick from the list of choices provided.

Northwestern |

- Northwestern College
- Northwestern Health Sciences University
- Northwestern Oklahoma State University
- Northwestern State University
- Northwestern University
- Northwestern University (SSO) ✓

Northwestern University (SSO) ✓

New to the CITI Program? Read the [getting started guide](#) or watch the [getting started video](#).

[LOG IN](#)[LOG IN THROUGH MY ORGANIZATION](#)[REGISTER](#)

CITI - Learner Registration

Steps: **1** 2 3 4

Select Your Organization Affiliation

This option is for persons affiliated with a CITI Program subscriber organization.

To find your organization, enter its name in the box below, then pick from the list of choices provided. ⓘ

Northwestern University allows the use of Single Sign On (SSO) or a CITI Program username/password for access.

Single Sign On (SSO) requires a username and password issued by Northwestern University.

- I AGREE to the [Terms of Service](#) and [Privacy Policy](#) for accessing CITI Program materials.
- I affirm that I am an affiliate of Northwestern University.

[Log In with Northwestern University](#)

or

[Create a CITI Program account](#)



My Courses

My Records


Welcome, Nazneen

Add Institutional Affiliation

Register as Independent Learner

Affiliate with an Institution

[Home](#) > [Profiles](#) > Affiliate with an Institution

To find your organization, enter its name in the box below, then pick from the list of choices provided. 

If your organization is using Single Sign-On, please find it [here](#).

Northwestern 
Northwestern College
Northwestern Health Sciences University
Northwestern Oklahoma State University
Northwestern State University
Northwestern University 



[LOG IN](#)

[LOG IN THROUGH MY ORGANIZATION](#)

[REGISTER](#)

Organizations listed here use "Single Sign On" (SSO) for CITI Program access.

SSO requires a username and password issued by the organization.

If your organization is not listed here, it does not use Single Sign On. Click on the "Log In" tab (if you already have a CITI Program account) or the "Register" tab (if you are new to CITI Program and creating an account for the first time).

To find your organization, enter its name in the box below, then pick from the list of choices provided. ⓘ

[Continue To SSO Login / Instructions](#)

[See our full list of SSO-enabled organizations](#)

Northwestern

ONLINE PASSPORT

Remember my username

LOG IN



SYSTEMS INTEGRATION: CITI TO EIRB+

24

For Northwestern + affiliate researchers meeting Northwestern IRB training requirements, **a systems integration process pulls training records from CITI into eIRB+ twice every 24 hours**. For that process to be seamless, these fields in the Northwestern CITI profile must match official Northwestern credentials:

Using single sign-on (SSO) to create/affiliate CITI profiles eliminates the opportunity for manual entry errors, which cause systems integration issues down the line

- ✓ **Institutional Username (Northwestern NetID)**
- ✓ Last Name
- ✓ First Name
- ✓ Email Address

3.

ADD “HUMAN RESEARCH PROTECTIONS
(IRB)” COURSE TO CITI PROFILE

Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to [add an affiliation](#). If you are no longer associated with a listed institution, you may want to [remove an affiliation](#).

DEMO

Northwestern University

Would you like to affiliate with another Institution?

Would you like to remove an existing affiliation?

View Courses

View Courses

Add Affiliation

Remove Affiliation

“View Courses” in Northwestern University profile and scroll to bottom to “Add a Course”

Learn

- [Add a Course](#)
- [Remove a Course](#)
- [View Previously Completed Coursework](#)
- [Update Institution Profile](#)
- [View Instructions Page](#)
- [Remove Affiliation](#)

CITI Course Enrollment Questions

[View instructions page.](#)

Question 1

Human Subjects Research

If you have NOT taken a required Human Research Protections course in the last three years, select "Human Research Protections (IRB) Basic".

If you have met this requirement in the last three years, select "Human Research Protections (IRB) Refresher".

- Human Research Protections (IRB) Basic
- Human Research Protections (IRB) Refresher

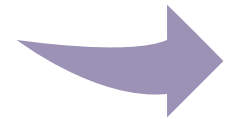
COURSE CREDITS

28



After adding “Human Research Protections (IRB)” course, CITI will transfer credit for modules completed at other institution(s) in **(A)** the past two years that **(B)** match Northwestern course module ID numbers.

NOTE: Outstanding training requirements must be completed.





You are now enrolled in the course(s) you selected.

Show Courses for:

Northwestern University



Institution List

Northwestern University

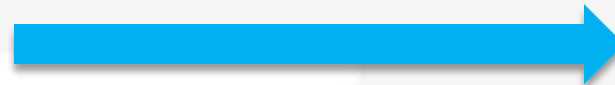
Active Courses

Northwestern University

Human Research Protections (IRB) Basic

Stage 2 - HRP (IRB) Refresher

3 / 9 modules completed



Continue Course

In this example, three previously completed modules met transfer standards and credit for those was automatically recorded in CITI

TRAINING: NEW CURRICULUM

NEW CURRICULUM

1. Simplifies requirements and communications
 - From dual to single track curriculum
 - Reduced number of required modules
 - Clear indication of curriculum, transfers, and outstanding requirements
2. Empowers researchers and teams to manage training records
 - Added refresher enrollment option
 - Reduced dependency on IRB Training review; rely on automated CITI features
3. Course corrects dated processes
 - CITI has updated shifted administrator capabilities exclusively to learners
 - CITI's Single Sign On capability allows for seamless integration of credentials

Curriculum Overview

Level	Track	Old Standards	New Standards
BASIC	Biomedical	17 required	9 required; 5 electives of 11 options
	Social-Behavioral	16 required	
REFRESHER	Biomedical	7 required; 4 optional	9 required; 11 optional
	Social-Behavioral	10 required	



BASIC & REFRESHER

REQUIRED CURRICULUM

33

The following are required at time of basic and refresher trainings:

1. **ID 21087** Human Research Protections at Northwestern University (custom module)
2. **ID 498** History & Ethics of Human Subjects Research
3. **ID 16680** Populations in Research Requiring Additional Considerations and/or Protections
4. **ID 17263** Consent & Cultural Competence
5. **ID 502** The Federal Regulations
6. **ID 503** Assessing Risk
7. **ID 504** Informed Consent
8. **ID 505** Privacy & Confidentiality
9. **ID 5** Records Based Research

BASIC ELECTIVES

REFRESHER OPTIONAL

34

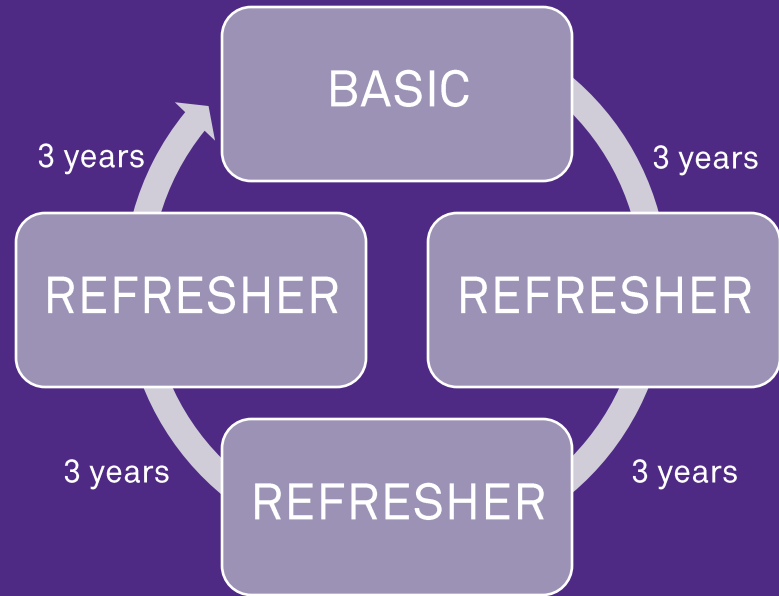
In addition to core modules, basic level training requires 5 electives from the following. **Priority should be given to research relevance.**

1. **ID 12** FDA-Regulated Research
2. **ID 14** Research & HIPAA Privacy Protections
3. **ID 506** Research with Prisoners
4. **ID 507** Research with Children
5. **ID 508** Research in Public Elementary & Secondary Schools
6. **ID 509** International Research
7. **ID 510** Internet-Based Research
8. **ID 10** Research Involving Pregnant Women, Fetuses, and Neonates
9. **ID 17260** Consent with Subjects Who Do Not Speak English
10. **ID 17422** Data & Safety Monitoring in Human Subjects Research
11. **ID 19728** Mobile Apps & Human Subjects Research

Course Standards

35

- 70% required to pass
- All researchers can now self-enroll in Refresher course
- Current completion status stands; no action required until expiration



CHECKING TRAINING RECORDS

Verify individual training in eIRB+ under "My Profile"

Institutional Review Board Office

My Inbox Home IRB

Hello, Nazneen Ali ▾

- My Profile
- Change Password
- Logoff

Ali, Nazneen

Employer: Institutional Review Board (IRB)

37

Training Expiration = Certification Date + 3 years

Training

Training Certification Information:

Training Type	Certification Date	Other Description Note
CITI - Human Research Protections (IRB) Basic	9/1/2023	Northwestern - CITI Integration. 9/12/2023.

Verify research personnel training in eIRB+ under "Study Team Training"

Name	Training Type	Certification Date	Other Description/Notes
	CITI Biomedical	12/14/2020	Northwestern - CITI Integration. 12/14/2020.
	CITI Biomedical	1/11/2022	Northwestern - CITI Integration. 1/11/2022.
	CITI Biomedical Refresher	1/17/2020	Northwestern - CITI Integration. 1/17/2020.
	CITI Biomedical Refresher	5/20/2023	Northwestern - CITI Integration. 5/20/2023.
	CITI Biomedical Refresher	8/15/2022	Northwestern - CITI Integration. 8/15/2022.
	CITI Biomedical Refresher	1/11/2022	Northwestern - CITI Integration. 1/11/2022.
	CITI Biomedical Refresher	4/8/2022	Northwestern - CITI Integration. 4/8/2022.
	CITI Biomedical	9/23/2020	Northwestern - CITI Integration. 9/25/2020.
		10/12/2021	Northwestern - CITI Integration. 10/12/2021.
		5/20/2022	Northwestern - CITI Integration. 5/20/2022.
		12/21/2022	Northwestern - CITI Integration. 12/21/2022.
		8/4/2020	Northwestern - CITI Integration. 8/4/2020.

1. Complete training
2. Wait 24 hours for systems integration
3. Affiliate or login using Northwestern University (SSO)
4. Add HRP course

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI) COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

A CITI Completion Report is a transcript, issued at course completion, containing curriculum information and other details. These differ from Completion Certificates, which hold significantly less information.

Report reflect quiz completions at the time all requirements for the course were met. For more recent quiz scores, including those on optional (supplemental) quizzes, see the Supplemental report.

- Name:
- Institution Affiliation: Ann & Robert H. Lurie Children's Hospital of Chicago
- Institution Email:
- Institution Unit: FSM/Medicine
- Phone:
- Curriculum Group: Human Subjects Research
- Course Learner Group: Human Subject Research for Biomedical Researchers
- Stage: Stage 1 - Basic
- Record ID: 30489660
- Completion Date: 08-Apr-2023
- Expiration Date: 08-Apr-2026
- Minimum Passing Score: 70
- Reported Score*: 92

Should read/indicate *Human Subjects Research, Human Research Protections, Institutional Review Board...*

Northwestern IRB Office has a three-year validation window from Completion Date; note that institutional standards differ

HRP training credit for modules (a) completed within two years of affiliation date (b) with ID numbers matching Northwestern HRP course requirements (see website)

REQUIRED AND ELECTIVE MODULES ONLY

Basic Institutional Review Board (IRB) Regulations and Informed Consent (ID: 3)
Social and Behavioral Research (SBR) for Biomedical Records-Based Research (ID: 5)
Genetic Research in Human Populations (ID: 6)
Research Involving Prisoners (ID: 8)
Research Involving Children (ID: 9)
Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)
FDA-Regulated Research (ID: 12)
Research and HIPAA Privacy Protections (ID: 14)
History and Ethics of Human Subjects Research (ID: 498)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)
Conflicts of Interest in Human Subjects Research (ID: 17464)

DATE COMPLETED SCORE

08-Apr-2023 5/5 (100%)
08-Apr-2023 4/5 (80%)
08-Apr-2023 4/4 (100%)
08-Apr-2023 4/4 (100%)
08-Apr-2023 4/5 (80%)
08-Apr-2023 4/4 (100%)
08-Apr-2023 3/3 (100%)
08-Apr-2023 5/5 (100%)
08-Apr-2023 5/5 (100%)
08-Apr-2023 4/5 (80%)
08-Apr-2023 4/5 (80%)
08-Apr-2023 3/3 (100%)
08-Apr-2023 5/5 (100%)
08-Apr-2023 4/5 (80%)

TROUBLE SHOOTING

TROUBLESHOOTING

1. Check to ensure all necessary steps completed:
 - a. eIRB+ registration
 - b. CITI account affiliation with Northwestern University SSO
 - c. “Human Research Protections (IRB)” course added
 - d. All outstanding training requirements completed
2. If, after 24 hours, CITI to eIRB+ integration does not occur, use SSO to update CITI profile credentials (see website)
3. Sustained issues?

[CITI Support Contact](#)

[eIRB+ Support Form](#)

SUPPLEMENTAL EDUCATION

Northwestern | RESEARCH
INSTITUTIONAL REVIEW

NAVIGATING HUMAN RESEARCH
ETHICS & REGULATORY EX



“NAVIGATING HUMAN RESEARCH ETHICS...”

✓ Course Modules List

1. Introduction
2. Human Research Foundations
3. Key Concepts
4. Understanding Review & Approval
5. Vulnerable Populations
6. Informed Consent
7. HIPAA & Biomedical Research
8. Northwestern Human Research Timeline
9. Compliance & Education
10. Reliance
11. Resources

- MyHR Learn (free)
 - Northwestern NetID required
- Special **Northwestern Human Research Timeline** module on working with our IRB Office!
- Optional supplementary course
 - Does **not** meet IRB Office human research protections training requirement
- 11 modules can be taken/assigned in any combination to meet unique needs
 - Designed as practical tool in course instruction and research team training
- Embedded quizzes solely to support IRB Office education programming
- See [Education webpage](#) for access notes

SPECIAL EVENTS TRAINING

- MyHR Learn course designed to empower research community to meet unique needs regarding HRP and IRB education, *particularly researcher training and course instruction*
- Special event trainings available when IRB Office staff presence is critical
- **Special Event Training Request Form**
 - Submit request five+ weeks in advance of requested date
 - Indicate distinct nature of event and/or audience

BROWN BAG SESSIONS

- Monthly educational events addressing a topic of interest in the world of human research protections
 - Typically, third Wednesday of month, 12-1PM CST
- [Brown Bag Archive](#) offers educational tools to support human research work



CHECK



CHECK

- Q3 *Dr. Nguyen is enthusiastic about their new appointment at Northwestern University. They registered with eIRB+ and affiliated their CITI profile with the Northwestern SSO as soon as they got their NetID! Today they completed all IRB training requirements, but eIRB+ isn't reflecting their current record. What should Dr. Nguyen do next?*
- A. *Email the IRB Office to ensure their Northwestern CITI profile has all fields accurately filled to support systems integration*
 - B. *Check the Human Research Protections Training webpage for tips on troubleshooting; step 2 on using the SSO always seems to do the trick!*
 - C. *Wait 24 hours for CITI to integrate with eIRB+*



CHECK

Q4 *Finish this sentence (found on Human Research Protections Training webpage): “Automated systems processes no longer require...”*

- A. *... training record be manually updated or supplied via email.”*
- B. *... researchers manually create institutional profiles in CITI.”*
- C. *... be emailed to irbtraining@northwestern.edu”*



CHECK

Q5 *Northwestern researchers may receive credit in CITI for human research protections training completed through another institution for:*

- A. *Modules that meet Responsible Conduct of Research requirements*
- B. *IRB coursework that was completed up to three years prior*
- C. *Modules completed in the past two years that match Northwestern HRP training requirements*
- D. *Training assigned and completed in CITI through a Northwestern entity or organization*



CHECK

Q6 *Saira, a Ph.D. program coordinator for the Department of Psychology, is preparing students for their dissertation work and knows communicating IRB Office requirements is an important aspect of her role. To ensure she has the tools needed to support students' introduction into human research, Saira should:*

- A. *Email IRB Training to request live trainings for the Ph.D. students*
- B. *Consult with tenured faculty who know the IRB process well*
- C. *Use the IRB Office website to identify training requirements and educational tools*



CHECK

Q7 *Using CITI's Single Sign-On feature is critical when creating or affiliating an account with Northwestern because...*

- A. *It ensures CITI pulls necessary information from the researcher's Northwestern eIRB+ profile for record keeping*
- B. *It uses an automated system to create a profile that is then used in systems integration with eIRB+*
- C. *It cuts the amount of time it takes to create/affiliate the institutional profile*



CHECK

Q8 *When transferring credits for previously completed human research protections training from another institution in CITI, researchers must...*

- A. *Create a CITI account, Add HRP course, then complete one of three HRP training courses for external collaborators*
- B. *Affiliate CITI account with Northwestern, complete HRP course, then email training certificate to Northwestern IRB Training*
- C. *Register with eIRB+, Affiliate CITI account with Northwestern (SSO), then add HRP course*
- D. *Wait 24 hours*



CHECK

Q9 *The IRB Office's Human Research Protections Training webpage first organizes information by generalized training requirements and then organizes requirements by:*

- A. *Tenure at Northwestern University*
- B. *Affiliate group indicating which training standards must be met*
- C. *Nature of human research being conducted (biomedical versus social behavioral)*
- D. *Sponsorship category*



CHECK

Q10 Francheska, a newly hired Research Scientist at Northwestern, completed human research protections training at the basic level just two years ago at their former institution. What should Francheska do to avoid taking basic level training again?

- A. Email IRB Training with a request to add the Refresher training to their CITI profile; because they are new to Northwestern, the system will only add the Basic training to their profile when they enroll*
- B. Affiliate with Northwestern University in CITI and select “Human Research Protections (IRB) Refresher” in Enrollment Question 1*
- C. Franny has no choice but to complete Basic level training as a new Northwestern human researcher*



CHECK

Q11 *The new Northwestern IRB course in MyHR Learn is designed for individuals who conduct human research through Northwestern University.*

True or False



CHECK

Q12 *A code used to match CITI records to external systems in the integration process is called:*

- A. *An Institutional Email Address*
- B. *An Institutional Username*
- C. *The Northwestern NetID*
- D. *Northwestern University SSO*

THANK YOU

2022-2023 STATE OF THE IRB
Wednesday, October 18, 2023 | 12 -1PM

Register on the IRB Office Website (Events) or here

