# **CITI PROGRAM Instructions for Inova Health System**





The Collaborative Institutional Training Initiative (CITI Program) provides computer based research ethics education and regulatory compliance training to the research community at <u>https://www.citiprogram.org</u>.

Individuals +

Inova Health System (Inova) requires that all investigators and key personnel engaged in the conduct of human subjects research be certified via the CITI Program Human Subjects Protections (HSP) Course at least every three years and the Conflict of Interest (COI) course every four years as outlined in ORI policy #3.03.

Additionally, individuals who facilitate research at Inova Health System including IRB Members and Office of Research staff be certified via the appropriate CITI Program course as outlined in ORI policy #3.03 at least every three years.

The NIH Policy on Good Clinical Practice Training requires that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP with NIH-sponsored research. <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html</u>. This training is also required for investigators and key personnel involved in FDA-regulated studies at Inova Health System.

Please review the ORI policy #3.03 for training requirements. An appendix with CITI Training Matrix is also attached to the policy to offer a snapshot of trainings available with expiration periods.

\*Inova - Human Research Protections Office (HRPO) reserves the right to require updated or additional trainings for non-Inova researchers in order to maintain compliance.

# **Courses include:**

- Human Subjects Protections (HSP)
  - o Biomedical Researchers
  - o Social-Behavioral-Educational Researcher
- Good Clinical Practice (GCP)
- Conflicts of Interest (COI)
- Responsible Conduct of Research (RCR)
- Biosafety/Biosecurity
- IRB Member
- Office of Research (ORI) Team
- IRB Administration
- Institutional/Signatory Official
- Clinical Trial Billing Compliance
- NIH Recombinant DNA Guideline (rDNA)
- Community Engaged Research
- Protocol Registration (ClinicalTrials.Gov)
- Export Compliance

The courses are designed so that you may enter and exit courses as often as needed to complete the selected curriculum and it is saved after each exit.

A completion report certificate is available for printing at the end of each course and a copy of the certificate is sent to the Inova CITI Program administrator, if "Inova Health System" is selected as your institution.

If you have previously completed CITI through another institution, please affiliate your account with Inova Health System. please skip to the section titled "Returning Users."

#### **New User Registration**

Go to <u>www.citiprogram.org</u> to register for CITI online training. **Registration Step 1a: Click "Register" as shown below** 



Step 1b: In the "Select your organization affiliation" box, enter "Inova Health System"Check the boxes to agree to terms, privacy policy



Registration Step 2: Enter your personal information and email addresses.

indicates a required field.		
* First Name	* Last Name	
Jane	Doe	
* Email Address	* Verify email address	
jane.doe@inova.org	jane.doe@inova.org	
jane.doe@inova.org We urge you to provide a second access the first one. If you forget address. Secondary email address	jane.doe@inova.org email address, if you have one, in case messages are blocked or you lose the your username or password, you can recover that information using either e Verify secondary email address	ability to mail

For Inova employees: Please use your Inova email address

# **Registration Step 3: Complete username, password and security question**

' indicates a required field.	
/our username should con a12b34cd". Once created,	sist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as your username will be part of the completion report.
* User Name	
JaneDoe	
a12b34cd".	
* Daceword	* Vorify Decemend
* Password	* Verify Password
* Password	* Verify Password
* Password ••••••• Please choose a security qu nformation, you will have * Security Question	* Verify Password uestion and provide an answer that you will remember. NOTE: If you forget your login to provide this answer to the security question in order to access your account.
Password     Please choose a security qu     nformation, you will have     Security Question     What color was your first	* Verify Password  westion and provide an answer that you will remember. NOTE: If you forget your login to provide this answer to the security question in order to access your account.
* Password Please choose a security qu nformation, you will have * Security Question What color was your first * Security Answer	* Verify Password

# **Registration Step 4: Enter country of residence and mark preference for marketing emails.**

* Country of Residence	
Search for country: Enter full or partial name (e.g., "United States") OR your country's two or three character abbreviation (e.g., "US", "USA"), then pick from the list of choices provided.	
United States	
* May we contact you to provide information about other courses and services after you complete your CIT Program coursework? 🥹	
• Yes	
ONO	

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?
CITI is pleased to offer CE credits and units for purchase to learners qualifying for CE eligibility while concurrently meeti their institutions training requirements.
CE credits/units for physicians, psychologists, nurses, social workers and other professions allowed to use AMA PRA Category 1 credits for re-certification are available for many CITI courses – with that availability indicated on course and module listings. <b>Please register your interest for CE credits below</b> by checking the "YES" or "NO" dots, and, when applicable, types of credits you wish to earn at bottom of page. Please read texts entered for each option carefully.
Yes
At the start of your course, you will be prompted to click on a "CE Information" page link located at the top of your grade book and to VIEW and ACKNOWLEDGE accreditation and credit designation statements, learning objectives, faculty disclosures, types, number and costs of credits available for your course.
⊖Yes
No
The CE functionality will not be activated for your course. Credits and units will therefore not be available to you for purchase after you start your course. You can change your preference to "YES" before such time however by clicking on the "CE Credit Status" tab located at the top of your grade book page.
No

If you picked "YES", please check below the one type of credit you would like to earn

# **Registration Step 6: Language preference & additional information**

lease provide the following information requested by Inova Health System
* indicates a required field.
Language Preference
English -
* Email Address
We recommend providing an email address issued by Inova Health System or an approved affiliate, rather than a personal one like @gmail, @hotmail, etc. This will help Inova Health System officials identify your learning records in reports.
jane.doe@inova.org
* Verify Email Address
jane.doe@inova.org
* Gender
Female •
* Highest Degree
MD

**Registration Step 7: Selecting your curriculum** Please review the Inova-CITI Training Matrix for a snapshot of required courses and their expiration windows. You must choose a response for each question below.

<form>  Click here to review the inova Health System instruction's page.   Yow instructions page.</form>	Select Curriculum Inova Health System
<form>         View instructions page.         Question 1         Uman Subjects Protections (HSP) course is required for all investigators and key personnel and must be satisfied by completing the appropriate course that most closely reflect the type of research you conduct. This training expires within three years and a refresher course must be taken at that time.         Note: If the researcher conducts both types of research, it is required that only the Biomedical Researcher course be completed.         Please select a course below:         Biomedical Researchers - complete all required modules and any optional modules that pertains to your research.         Social-Behavioral-Educational Researcher - complete all required modules and any optional modules that pertains to your research.         Not applicable at this time.         Decode Clinical Practice (GCP) course is required for investigator and key personnel involved in FDA-regulated studies and clinical trials funded by the National Institutes of Health (NIH).         The training must be re-completed every three years.         If you are required to take the GCP course as described above, please select below:         Instruction is required, Choose one answer.         Must training must be re-completed every three years.         If you are required to take the GCP course as described above, please select below:         Instruming must be re-completed every three years.         If you are required, Choose one answer.         If you are required to take the GCP course.         Instruming must be re-com</form>	<u>Click here</u> to review the Inova Health System instruction's page.
Question 1   Human Subjects Protections (HSP) course is required for all investigators and key personnel and must be satisfied by completing the appropriate course that most closely reflect the type of research you conduct. This training expires within three years and a refresher course must be taken at that time.   Note: If the researcher conducts both types of research, it is required that only the Biomedical Researcher course be completed.   Please select a course below:   The question Is required. Choose one answer.   Social-Behavioral-Educational Researcher - complete all required modules and any optional modules that pertains to your research.   Social-Behavioral-Educational Researcher - complete all required modules and any optional modules that pertains to your research.   Not applicable at this time.   Duestion 1   Question 2   The Good Clinical Practice (GCP) course is required for investigator and key personnel involved in FDA-regulated studies and clinical trials funded by the National Institutes of Health (NIH).   This training must be re-completed every three years.   If you are required to take the GCP course as described above, please select below:   This question is required. Choose one answer.	<u>View instructions page.</u>
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<ul> <li>Social-Behavioral-Educational Researcher - complete all required modules and any optional modules that pertains to your research.</li> <li>Not applicable at this time.</li> <li>Question 2</li> <li>The Good Clinical Practice (GCP) course is required for investigator and key personnel involved in FDA-regulated studies and clinical trials funded by the National Institutes of Health (NIH).</li> <li>This training must be re-completed every three years.</li> <li>If you are required to take the GCP course as described above, please select below:</li> <li>This question is required. Choose one answer.</li> <li>Yes, I am required to complete the GCP course.</li> <li>Not applicable at this time.</li> </ul>	Biomedical Researchers – complete all required modules and any optional modules that pertains to your research.
<ul> <li>Not applicable at this time.</li> <li>Question 2</li> <li>The Good Clinical Practice (GCP) course is required for investigator and key personnel involved in FDA-regulated studies and clinical trials funded by the National Institutes of Health (NIH).</li> <li>This training must be re-completed every three years.</li> <li>If you are required to take the GCP course as described above, please select below:</li> <li>This question is required. Choose one answer.</li> <li>Yes, I am required to complete the GCP course.</li> <li>Not applicable at this time.</li> </ul>	Social-Behavioral-Educational Researcher - complete all required modules and any optional modules that pertains to your research.
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Yes, I am required to complete the GCP course. Not applicable at this time.	This question is required. Choose one answer.
	Yes, I am required to complete the GCP course. Not applicable at this time.

# Question 3

Conflicts of Interest (COI) course is required for all investigators and key personnel and designed to satisfy training requirements for Inova Health System and the requirements associated with the U.S Public Health Service (PHS) regulations on financial conflict of interest. This training must be re-completed every four years.

Please select this course if you are an Inova investigator or key personnel engaged in research:

This question is required. Choose one answer.

Conflict of Interest (COI)

Not applicable at this time.

# Question 4

Responsible Conduct of Research (RCR) course is required for all Principal Investigators (PIs). Additionally, all investigators and key personnel engaged in research supported by NSF, NIH and/or USDA-NIFA are required to complete this course. This training must be re-completed every four years.

If you are an Inova PI and/or engaged in research supported by any of the federal agencies above, please select this course:

#### This question is required. Choose one answer.

Responsible Conduct of Research

Not applicable at this time.

# Question 5

Biosafety/Biosecurity (BSS) course is required for laboratory and research personnel who handle biological materials. This training must be re-completed every three years.

If you handle biological materials, please select this course:

#### This question is required. Choose one answer.

Biosafety/Biosecurity

Not applicable at this time.

# Question 6

IRB Member course is required for all Inova IRB members. This training must be recompleted every three years.

If you are either a regular or alternate IRB Member for the Inova IRB, please select this course:

This question is required. Choose one answer.

IRB Member
 Not applicable at this time.



Office of Research (ORI) Team course is required for all ORI team members (excluding HRPO). This training must be re-completed every three years.

If you associated with the Inova Office of Research administrative offices providing support to the Service Lines, please select this course:

This question is required. Choose one answer.

Office of Research (ORI) Team

) Not applicable at this time.

# Question 8

IRB Administration course is required for all Human Research Protections Office (HRPO) team members. This training must be re-completed every three years. If you are a HRPO team member, please select this course:

This question is required. Choose one answer.

IRB Administration

) Not applicable at this time.

Question	9
Queotion	-

Institutional/Signatory Official (IO) course is required for the IO. Training must be recompleted every three years.If you are the IO for Inova, please select this course:

Institutional/Signatory Official
 Not applicable at this time.

Question 10	The courses in
Optional Supplemental courses relevant to other projects are available to	question 10 are <u>not</u>
investigators and key personnel for educational enrichment.	required however, available as supplemental
you are involved in a project related to any of the courses below and are interested	trainings
n gaining further knowledge, please select and add any of the courses below:	
Clinical Trial Billing Compliance	
NIH Recombinant DNA Guideline (rDNA)	
Community Engaged Research	
Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov	
Export Compliance	
Not applicable at this time.	

Note: after making your selections, please click into box below to complete registration.

**Complete Registration** 

## Updating profile to affiliate with Inova Health System as an additional institution

- 1. Go to <u>www.citiprogram.org</u> to log in with previously created username and password.
- 2. Login with your username and go to the Main Menu and click the blue bar at the bottom of the menu
  - a. "Affiliate with another Institution" and enter "Inova Health System" as your current institution.b. Non-Inova researchers may be required to complete additional courses to per Inova training requirements.

Affiliate with an Institut	tion
Home > Profiles > Affiliate with an Institution	
To find your organization, enter its name in the box below, the pick from the list of choices provided. 🥡	en
Inova Health System	Add Inova as Affiliated Institution
✓ I AGREE to the <u>Terms of Service</u> for accessing CITI Program materials.	
✓ I affirm that I am an affiliate of Inova Health System.	Agree with terms and affirm affiliation
Continue	

# FREQUENTLY ASKED QUESTIONS (FAQ)

#### 1. What are the Inova Requirements?

• Review the Office of Research (ORI) Policy #3.03 as well as the Inova CITI Training Matrix for required training.

#### 2. How long does it take to complete each course take? Can I stop and start again later?

• Each course contains multiple modules and each module may take 10 to 30 minutes to complete. You can stop and continue at any time. Save your work before you exit and remember your username and password.

### 3. What should I do after completing the training?

• Completion certificate should be saved and stored within the Research Service Line.

### 4. How do I obtain a copy of the certificate after completion?

• Users may download individual certificates directly from the CITI site by returning to their profile and selecting "view previously completed coursework". The share/print" option is available to download a PDF of completed certificate.

#### 5. Are users reminded when the training is due to expire?

• The CITI website generates automatic reminders to users when their training is due to expire.

# 6. My previous institution used CITI, so I already have an account. Do I need do make a new one?

o No, however, please take action to affiliate your account with Inova Health System.

#### 7. What should I do if I have forgotten my username and password for CITI website?

• Visit the CITI site at <u>https://about.citiprogram.org/en/homepage/</u> to reset the password.

For questions related to CITI Training requirements for Inova Health System, please email <u>hrpp-liaison@inova.org</u>