Description: This job aid describes the UHG Office of Human Research Affairs (OHRA) training requirements for investigators engaged in Human Research with guidance for completing the required courses through the CITI program online.

POLICY

All personnel conducting human research that will be reviewed by the UHG OHRA are required to complete training specific to human subjects research and conflicts of interest. These courses should be completed through the CITI Program online <u>https://www.citiprogram.org</u>.

As the OHRA oversees research being conducted by investigators affiliated with various UnitedHealth Group entities (UHG R&D, Optum, Reliant, Etc...) this policy and guidance is limited to explaining baseline requirements that are common to all departments for which OHRA requests documentation. Depending on your specific affiliation, additional training or periodic renewal of training may be required and should be completed according to your department policy.

The OHRA will request documentation of your completed baseline training for your OnRAMP profile. If your role as research staff does not require creation of an OnRAMP profile, documentation of training should be kept in the research files / regulatory binder / study portfolio or equivalent file per department standards. For especially complex, high risk or high-profile research, OHRA may require additional training prior to approval to begin the research. This will be assessed on a study by study basis.

UnitedHealth Group R&D has created a standing affiliation within the CITI program which anyone can choose in order to take the required baseline courses at no personal cost. This invitation for training extends to those affiliated with any UnitedHealth Group entity as well as external research partners as necessary if their institution does not offer a CITI affiliation. Instructions for using the R&D affiliation are included below with screenshots.

REQUIRED TRAINING

1. Human Subjects Research

- a. To satisfy this requirement the following CITI courses will be accepted:
 - i. Biomedical Research Basic or Refresher
 - ii. Social & Behavioral Research Basic or Refresher
 - iii. Research with data or laboratory specimens only
 - iv. Other equivalent CITI courses covering similar module content
- b. The completed training must align appropriately with the types of studies being conducted.
- c. OHRA only requires completion of this training once. Training does not expire.
- d. You may contact the OHRA directly via email to request review of similar training completed at other academic or industry institutions to avoid re-taking a course. A completion report will be required for this assessment in order to compare modules.

2. Conflicts of Interest (ID 177781)

- a. The Conflicts of interest module(s) completed within the Biomedical Research course do not satisfy this requirement. You will need to complete the CITI Conflicts of Interest Course. This course contains two modules:
 - i. (1) Financial Conflicts of Interest (ID 15070)
 - ii. (2) Institutional Responsibilities as They Affect Investigators (ID 15072)
- b. OHRA requires completion of this training once by all researchers. For any researchers who have conflicts of interest, the training must be refreshed annually for the duration of any protocol for which a conflict exists.
- c. OHRA is not accepting substitutions for this course.

INSTRUCTIONS TO REGISTER AND LOG IN

Go to: https://www.citiprogram.org

If you already have a CITI Profile:

- Click log in to use your existing username and password
- Then click Add Affiliation on the main page and type UnitedHealth Group into the search
- Update your profile questions as needed to demonstrate your affiliation
- Then follow the instructions in the Select Curriculum steps below

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 <u>add an affiliation</u> . If you are no longer associated with a	Affiliate with an Institution
listed institution, you may want to <u>remove an affiliation</u> .	Home > Profiles > Affiliate with an Institution
UnitedHealth Group R&D View Courses	
University of Pennsylvania View Courses	l o find your organization, enter its name in the box below, then pick from the list of choices provided. 👔
Would you like to affiliate with another institution? Add Affiliation	UnitedHealth G
Would you like to remove an existing affiliation? Remove Affiliation	UnitedHealth Group R&D
Independent Learner	
Register as an independent learner to purchase course content. Before you purchase	
a course, please make sure you do not already have access to that course through an	
purchased as an Independent Learner.	
Register as an Independent Learner	

If you are registering for the first time:

- Click Register then follow the registration steps below and continue to the Select Curriculum step



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Registration STEP 1: Do not choose Independent Learner. Type in "UnitedHealth Group R&D" under "Select your Organization Affiliation" and select UnitedHealth Group R&D as soon as the organization appears (costs for this training will be covered). Click both "I AGREE" and "I affirm" statements. Click the blue button to continue.	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. UnitedHealth Group R&D UnitedHealth Group R&D only allows the use of a CITI Program username/password for access. You will create this username and password in step 2 of registration. I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials. I affirm that I am an affiliate of UnitedHealth Group R&D. Continue To Create Your CITI Program Username/Password
Registration STEP 2: Complete your personal information. It is not required to provide a secondary email address.	CITI - Learner Registration - UnitedHealth Group R&D Steps: 1 2 3 4 5 6 7 Personal Information * indicates a required field. * * * * * Last Name *

Registration STEP 3	
Create a username password	CITI - Learner Registration - UnitedHealth Group R&D
and create security questions	Steps: 1 2 3 4 5 6 7
Be sure to choose a username	
and password you will	Commenter and the second secon
romombor. If you forget either	Create your Osername and Password
vour usornomo or possword	* indicates a required field.
you will need to get help from	Your username should consist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as
the CITI program website	"a12b34cd". Once created, your username will be part of the completion report.
	* User Name
recovering your account.	
	Your password should consist of 8 to 50 characters. Your password IS case sensitive; "A12B34CD" is not the same as "a12b34cd".
	* Password * Verify Password
	Please choose a security question and provide an answer that you will remember. NOTE: If you forget your login information, you will have to provide this answer to the security question in order to access your account.
	* Security Question
	* Security Answer
	Continue To Step 4
Registration STEP 4:	
Enter in your country of	CITI - Learner Registration - UnitedHealth Group R&D
residence.	Steps: 1 2 3 4 5 6 7
Select if you would like CITI to	Steps. <u>1</u> <u>2</u> <u>2</u> <u>3</u> <u>5</u> <u>6</u> 7
provide information about other	* indicates a required field.
courses	
	* 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.
	* May we contact you to provide information about other courses and services after you complete your CITI Program coursework? 🔮
	() Vec
	O No
	Continue To Step 5

Registration STEP 5: Answer the following questions regarding receiving Continuing Education Credit for the completed courses. This is a personal/professional choice. The responses here will not impact your ability to complete required courses discussed in this job aid.	CITI - Learner Registration - UnitedHealth Group R&D Steps: 1 2 3 4 5 6 7 * indicates a required field. * indicates a required field. * 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 meeting 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. Please register your interest for CE credits below 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.
Registration STEP 6: Answer the following questions requested by UnitedHealth Group R&D. Make sure to select the appropriate Department from the drop-down list: - Operations - Other (non R&D) - Research - Science - Venture Please note that a UHG institutional email address is not required if you do not have one. External research partners may use the R&D affiliation to appropriate training without	CTTI - Learner Registration - UnitedHealth Group R&D Steps: 1 2 3 4 5 7 Please provide the following information requested by UnitedHealth Group R&D Indicess a require field. Language Preference Image of the institutional Email Address If available please use an email address issued by UnitedHealth Group R&D, rather than a personal one like @gmail, @hotmail, etc. This will help UnitedHealth Group R&D officials identify your learning records in reports. Enter a valid Institutional Email Address. • Verify Institutional Email Address. • Verify Institutional Email Address. • Department Image: Please use and email Address. • Department Phone
obtaining a UHG email.	Continue To Step 7

INSTRUCTIONS TO SELECT CURRICULUM

As noted above, OHRA only requires completion of 2 courses. After registration or signing into your existing account you will need to Add Courses. You will be brought to a screen to select curriculum. To choose courses you must answer questions. The table below shows the questions that must be answered to meet the requirements for OHRA approval.

All other courses are optional as they pertain to the OHRA policy. If your department or division requires any of these other courses, you are free to take them. You can also take additional available courses that you are interested in learning more about at your convenience. You can return to select more courses under the R&D affiliation at any time. You do not need to complete all courses at one time.

If you return at a later time to add more courses, you will have to answer the questions again in the select curriculum menu in order to access the desired courses.

You must answer Question 1 to take the required Human Subjects Research course.	Human Subjects Research
You should select the specific course that matches the type of research you are involved in most often. The Biomedical version is the most comprehensive.	Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group. <i>Required Course for UHG OHRA Approval</i> Biomedical Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical
If you take the social & behavioral course or the data or lab specimens only courses you may be asked to take the biomedical course in the future if you join a study team supporting a biomedical research project.	 research with human subjects. Social & Behavioral Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects. Research with data or laboratory specimens- ONLY: No direct contact with human subjects. IRB Members: This Basic Course is appropriate for IRB or Ethics Committee members. Not at this time.
You must also answer yes to Question 2 to take the required Conflicts of Interest course	Question 2 Conflicts of Interest (COI) Would you like to take the Conflicts of Interest course? Required Course for UHG OHRA Approval Yes No

When you complete each course, your CITI account will be updated to provide you with a certificate of completion and a completion report in the Records section.

OHRA will request to see a copy of these course completion reports to support the creation or update of your OnRAMP profile for this purpose.

The OHRA staff will update your profile in OnRAMP to reflect the dates of completion of your courses so that when you are added as personnel to a project, it will be clear that your training is complete.