

REQUIRED RESEARCH TRAININGS:

RASCAL:

- TC0019 - HIPAA: Health Insurance Portability Accountability Act Research Training Course
- TC6500 - HICCC Clinical Protocol and Data Management Investigator Standard Operating Procedure Training

REDIRECTED TO CITI:

- TC0087 - Human Subjects Protection (HSP) Training
- TC0094 - Responsible Conduct of Research (RCR) Training
- TC3450 - Good Clinical Practice (GCP) Training
 - FDA-Regulated Research
 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
 - Human Subjects Protection Biomed
 - RCR Biomedical
 - Research with Minors - BIOMED

Go to RASCAL: www.rascal.columbia.edu

1. Click **Conflict of Interest**

COLUMBIA UNIVERSITY | Rascal

rascal.columbia.edu

COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

 **COLUMBIA UNIVERSITY | RASCAL**
Research Compliance and Administration System

Login

RASCAL

Human Subjects (IRB) Animal Care (IACUC) Proposal Tracking Consent Forms HIPAA Forms

Hazardous Materials Training Center **Conflict of Interest** Administration My Rascal

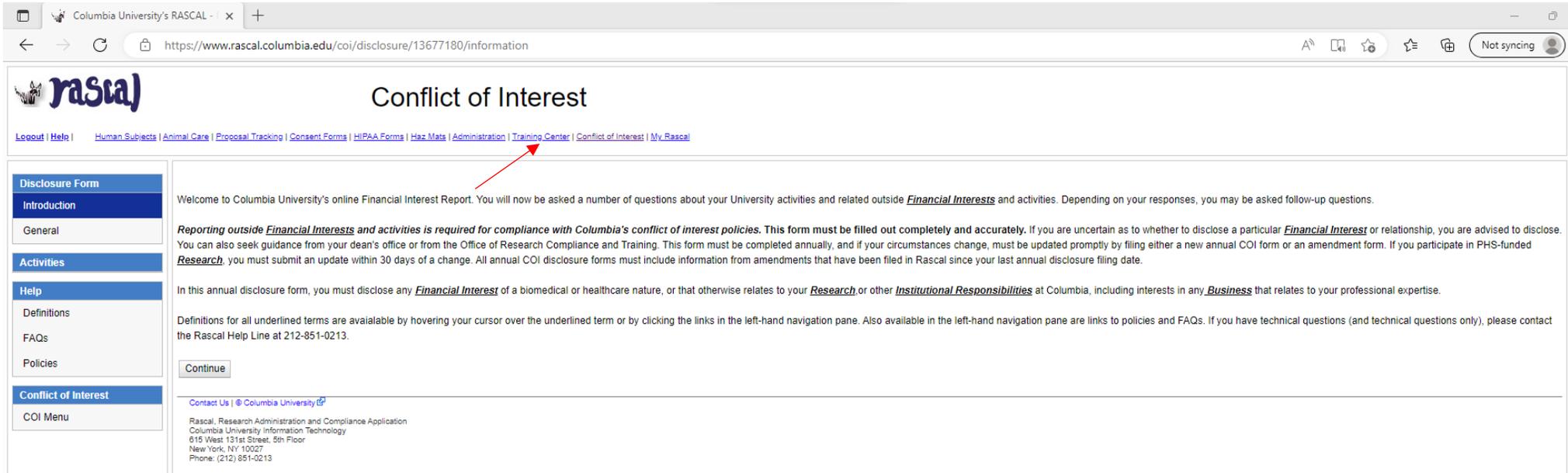
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 **COLUMBIA UNIVERSITY**
IN THE CITY OF NEW YORK

Rascal, Columbia University Information Technology
915 West 131st Street, 5th Floor, New York, NY 10027
Phone: (212) 691-0213

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2. Click Training Center



The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/coi/disclosure/13677180/information>. The page title is "Conflict of Interest" and features the Rascal logo. A navigation menu includes links for "Logout", "Help", "Human Subjects", "Animal Care", "Proposal Tracking", "Consent Forms", "HIPAA Forms", "Haz Mats", "Administration", "Training Center", "Conflict of Interest", and "My Rascal". A red arrow points to the "Training Center" link. The main content area contains a "Disclosure Form" section with a "Continue" button. The "Introduction" sub-section provides a welcome message and instructions. The "Help" sub-section provides definitions for underlined terms. The "Conflict of Interest" sub-section provides contact information for Rascal.

Disclosure Form

Introduction

Welcome to Columbia University's online Financial Interest Report. You will now be asked a number of questions about your University activities and related outside **Financial Interests** and activities. Depending on your responses, you may be asked follow-up questions.

Reporting outside Financial Interests and activities is required for compliance with Columbia's conflict of interest policies. This form must be filled out completely and accurately. If you are uncertain as to whether to disclose a particular **Financial Interest** or relationship, you are advised to disclose. You can also seek guidance from your dean's office or from the Office of Research Compliance and Training. This form must be completed annually, and if your circumstances change, must be updated promptly by filing either a new annual COI form or an amendment form. If you participate in PHS-funded **Research**, you must submit an update within 30 days of a change. All annual COI disclosure forms must include information from amendments that have been filed in Rascal since your last annual disclosure filing date.

Help

In this annual disclosure form, you must disclose any **Financial Interest** of a biomedical or healthcare nature, or that otherwise relates to your **Research** or other **Institutional Responsibilities** at Columbia, including interests in any **Business** that relates to your professional expertise.

Definitions for all underlined terms are available by hovering your cursor over the underlined term or by clicking the links in the left-hand navigation pane. Also available in the left-hand navigation pane are links to policies and FAQs. If you have technical questions (and technical questions only), please contact the Rascal Help Line at 212-851-0213.

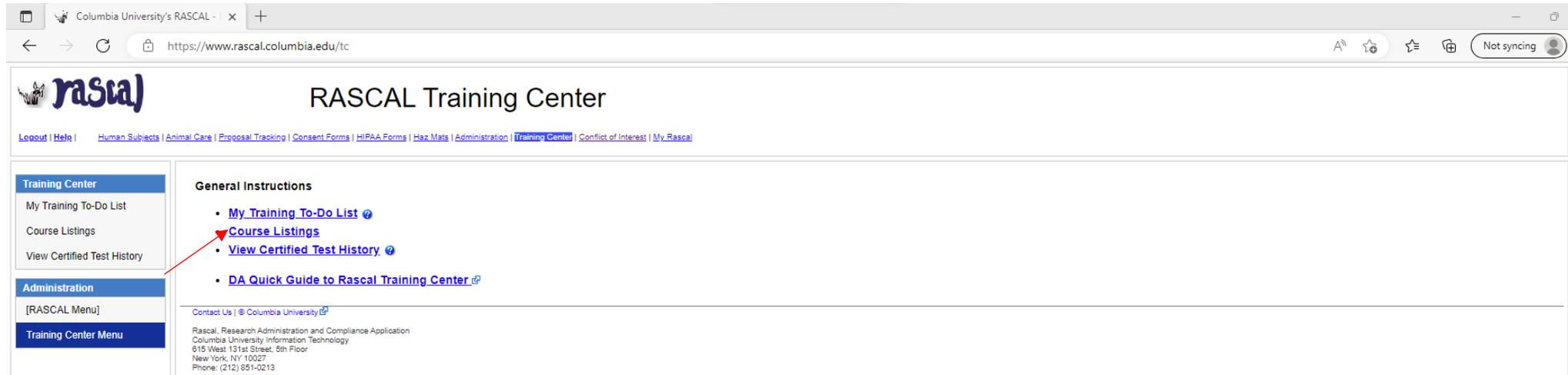
Conflict of Interest

COI Menu

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Rascal, Research Administration and Compliance Application
Columbia University Information Technology
615 West 131st Street, 5th Floor
New York, NY 10027
Phone: (212) 851-0213

3. Click Course Listings

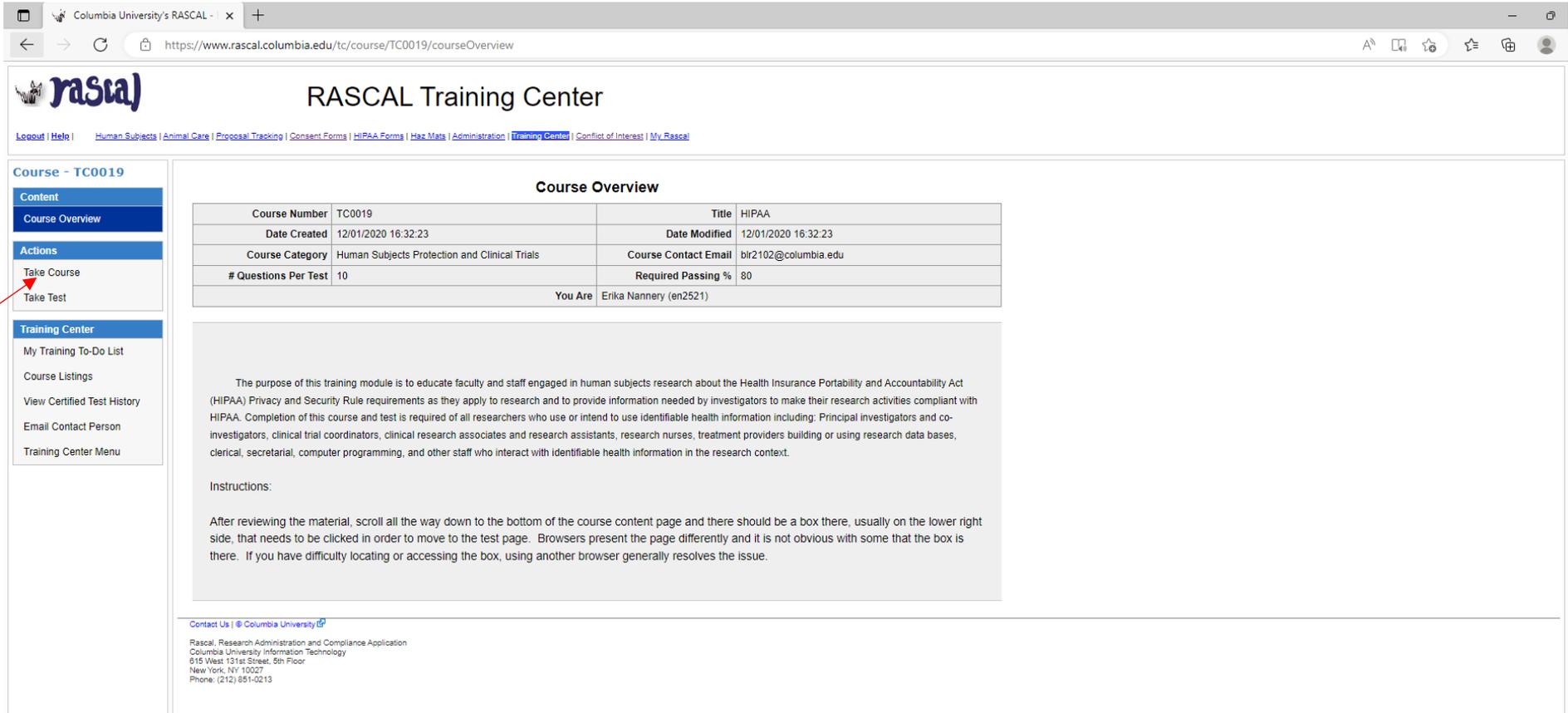


The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc>. The page title is "RASCAL Training Center". The navigation menu includes links for [Logout](#), [Help](#), [Human Subjects](#), [Animal Care](#), [Proposal Tracking](#), [Consent Forms](#), [HIPAA Forms](#), [Haz Mats](#), [Administration](#), [Training Center](#), [Conflict of Interest](#), and [My Rascal](#). The "Training Center" menu is expanded, showing options for [My Training To-Do List](#), [Course Listings](#), and [View Certified Test History](#). A red arrow points to the "Course Listings" link. The "General Instructions" section contains links for [My Training To-Do List](#), [Course Listings](#), [View Certified Test History](#), and [DA Quick Guide to Rascal Training Center](#). The footer includes contact information for Rascal, Research Administration and Compliance Application, located at Columbia University, 615 West 131st Street, 5th Floor, New York, NY 10027, with a phone number of (212) 851-0213.

4. Type and search for **TC0019** (*HIPAA: Health Insurance Portability Accountability Act Research Training Course*) and click **Go**

The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/courseListings>. The page header includes the RASCAL logo and the title "RASCAL Training Center". A navigation menu at the top lists various topics like "Human Subjects", "Animal Care", and "HIPAA Forms". On the left side, there is a sidebar menu with options like "Training Center", "My Training To-Do List", "Course Listings", and "Administration". The main content area is titled "Training Center Course Listings By Topic". Below this title, there is a search bar with the text "Search for a course:" followed by an input field containing "TC0019" and "HIPAA: Health Insurance Portability Accountability Act Research Training Course". A red oval highlights the search input field and the "Go" button. Below the search bar, there is a "Course Category" section with a list of links: "Administration of Sponsored Projects_Effort Reporting", "Animal Care and Use", "Conflicts of Interest_Research Ethics and Responsible Conduct of Research", "Data Management and Security", "Emergency Preparedness", "Environmental Health and Safety", "Human Subjects Protection and Clinical Trials", and "System Tutorials".

5. Click Take Course



The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/course/TC0019/courseOverview>. The page title is "RASCAL Training Center". The main content area is titled "Course Overview" and contains a table with the following data:

Course Number	TC0019	Title	HIPAA
Date Created	12/01/2020 16:32:23	Date Modified	12/01/2020 16:32:23
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	blr2102@columbia.edu
# Questions Per Test	10	Required Passing %	80
You Are		Erika Nannery (en2521)	

Below the table, there is a text block describing the purpose of the training module and instructions for taking the course. The purpose is to educate faculty and staff engaged in human subjects research about the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule requirements. The instructions state: "After reviewing the material, scroll all the way down to the bottom of the course content page and there should be a box there, usually on the lower right side, that needs to be clicked in order to move to the test page. Browsers present the page differently and it is not obvious with some that the box is there. If you have difficulty locating or accessing the box, using another browser generally resolves the issue."

The left sidebar contains a navigation menu with the following items:

- Content
 - Course Overview
- Actions
 - Take Course (highlighted with a red arrow)
 - Take Test
- Training Center
 - My Training To-Do List
 - Course Listings
 - View Certified Test History
 - Email Contact Person
 - Training Center Menu

At the bottom of the page, there is contact information for Rascal, Research Administration and Compliance Application, Columbia University Information Technology, located at 615 West 131st Street, 5th Floor, New York, NY 10027, with a phone number of (212) 851-0213.

6. Click OK

The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/course/TC0019/courseOverview>. The page title is "RASCAL Training Center". The main content area is titled "Course Overview" and contains a table with the following data:

Course Number	TC0019	Title	HIPAA
Date Created	12/01/2020 16:32:23	Date Modified	12/01/2020 16:32:23
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	blr2102@columbia.edu
# Questions Per Test	10	Required Passing %	80
You Are	Erika Nannery (en2521)		

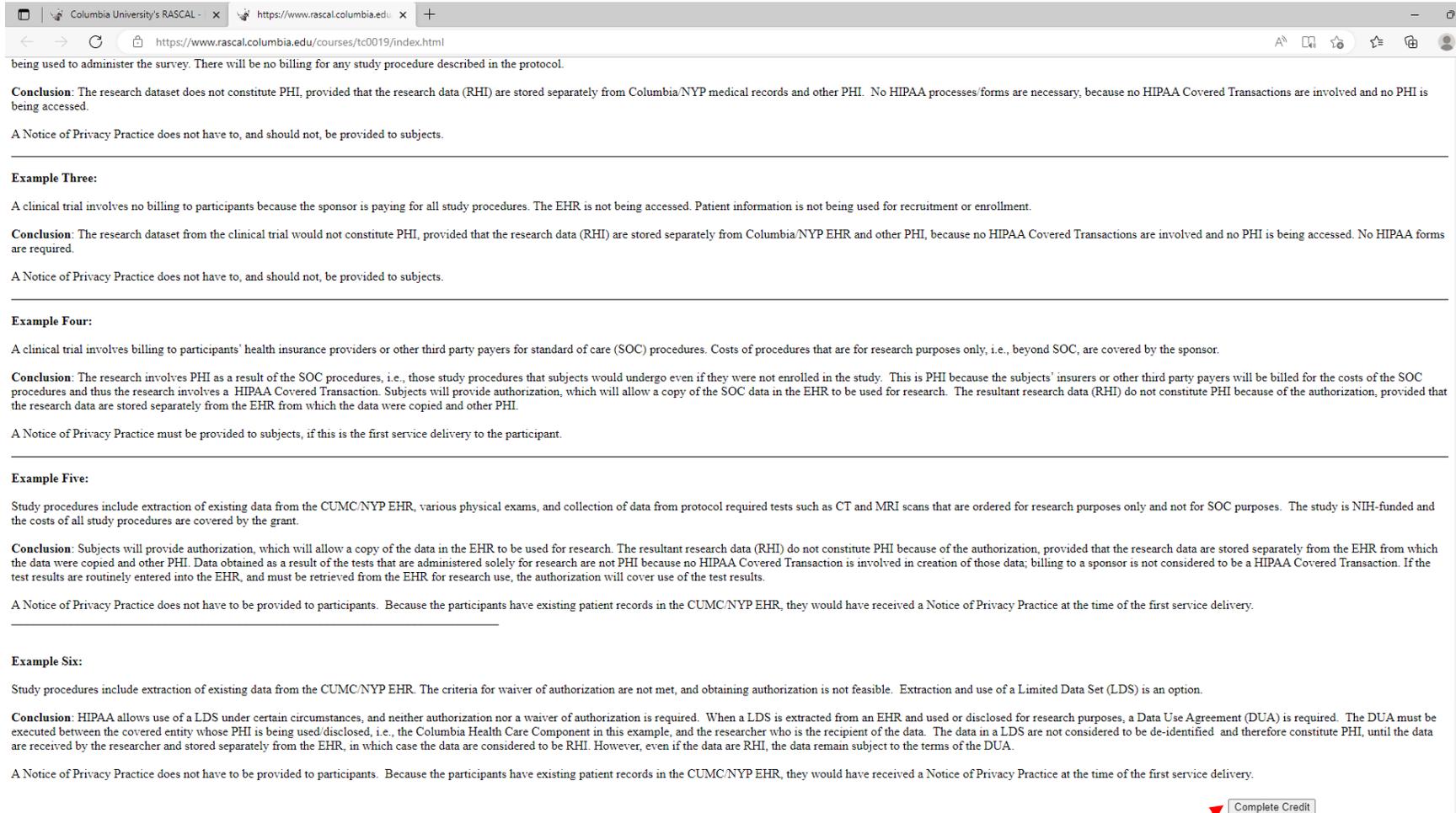
Below the table, there is a section for "Instructions" which is partially obscured by a dialog box. The dialog box contains the following text:

The course content will be opened in a new browser window or tab. Once you have completed the course you can close that window or tab to return to Rascal.

OK

At the bottom of the page, there is contact information for Rascal, Research Administration and Compliance Application, located at 615 West 131st Street, 6th Floor, New York, NY 10027, with a phone number of (212) 851-0213.

7. After reading the training, scroll down and click **Complete Credit**



being used to administer the survey. There will be no billing for any study procedure described in the protocol.

Conclusion: The research dataset does not constitute PHI, provided that the research data (RHI) are stored separately from Columbia/NYP medical records and other PHI. No HIPAA processes/forms are necessary, because no HIPAA Covered Transactions are involved and no PHI is being accessed.

A Notice of Privacy Practice does not have to, and should not, be provided to subjects.

Example Three:

A clinical trial involves no billing to participants because the sponsor is paying for all study procedures. The EHR is not being accessed. Patient information is not being used for recruitment or enrollment.

Conclusion: The research dataset from the clinical trial would not constitute PHI, provided that the research data (RHI) are stored separately from Columbia/NYP EHR and other PHI, because no HIPAA Covered Transactions are involved and no PHI is being accessed. No HIPAA forms are required.

A Notice of Privacy Practice does not have to, and should not, be provided to subjects.

Example Four:

A clinical trial involves billing to participants' health insurance providers or other third party payers for standard of care (SOC) procedures. Costs of procedures that are for research purposes only, i.e., beyond SOC, are covered by the sponsor.

Conclusion: The research involves PHI as a result of the SOC procedures, i.e., those study procedures that subjects would undergo even if they were not enrolled in the study. This is PHI because the subjects' insurers or other third party payers will be billed for the costs of the SOC procedures and thus the research involves a HIPAA Covered Transaction. Subjects will provide authorization, which will allow a copy of the SOC data in the EHR to be used for research. The resultant research data (RHI) do not constitute PHI because of the authorization, provided that the research data are stored separately from the EHR from which the data were copied and other PHI.

A Notice of Privacy Practice must be provided to subjects, if this is the first service delivery to the participant.

Example Five:

Study procedures include extraction of existing data from the CUMC/NYP EHR, various physical exams, and collection of data from protocol required tests such as CT and MRI scans that are ordered for research purposes only and not for SOC purposes. The study is NIH-funded and the costs of all study procedures are covered by the grant.

Conclusion: Subjects will provide authorization, which will allow a copy of the data in the EHR to be used for research. The resultant research data (RHI) do not constitute PHI because of the authorization, provided that the research data are stored separately from the EHR from which the data were copied and other PHI. Data obtained as a result of the tests that are administered solely for research are not PHI because no HIPAA Covered Transaction is involved in creation of those data; billing to a sponsor is not considered to be a HIPAA Covered Transaction. If the test results are routinely entered into the EHR, and must be retrieved from the EHR for research use, the authorization will cover use of the test results.

A Notice of Privacy Practice does not have to be provided to participants. Because the participants have existing patient records in the CUMC/NYP EHR, they would have received a Notice of Privacy Practice at the time of the first service delivery.

Example Six:

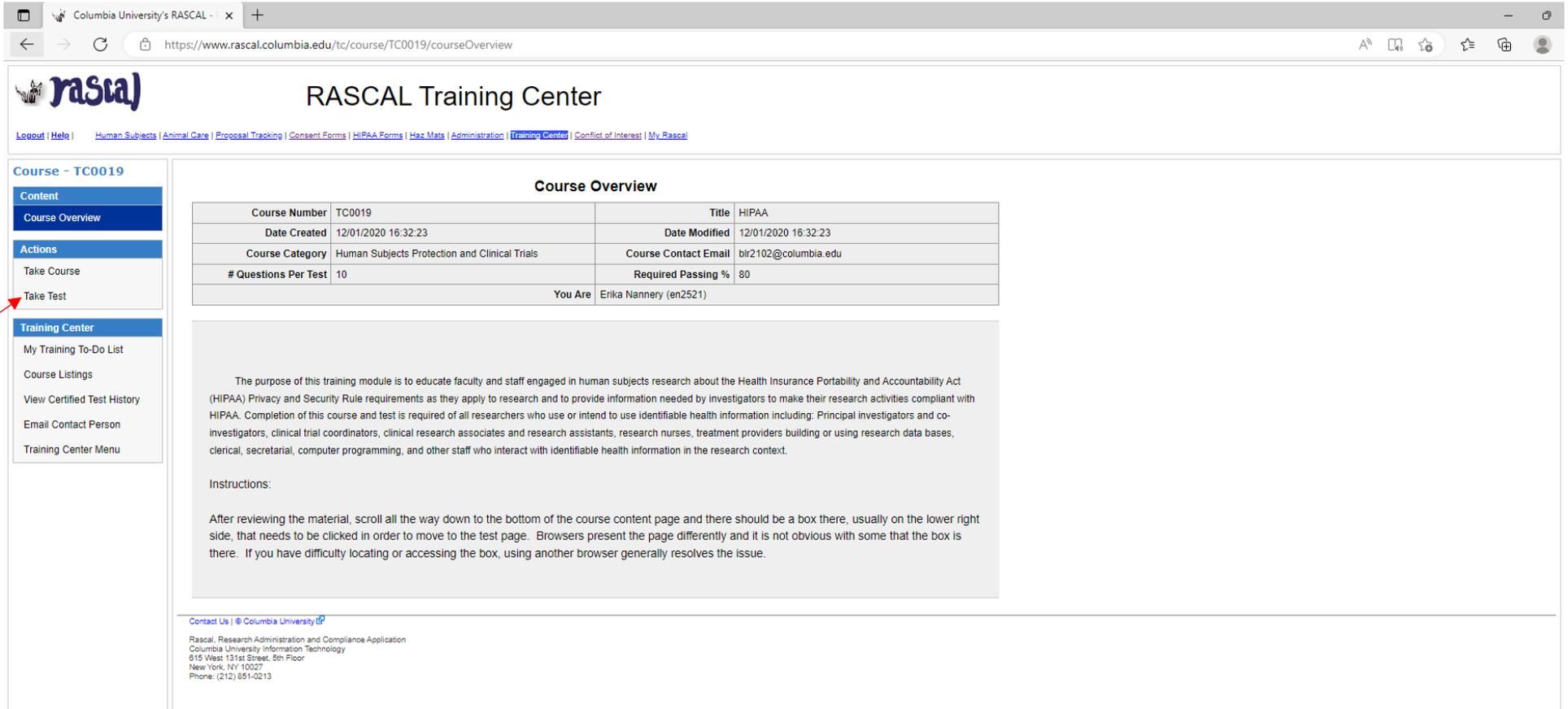
Study procedures include extraction of existing data from the CUMC/NYP EHR. The criteria for waiver of authorization are not met, and obtaining authorization is not feasible. Extraction and use of a Limited Data Set (LDS) is an option.

Conclusion: HIPAA allows use of a LDS under certain circumstances, and neither authorization nor a waiver of authorization is required. When a LDS is extracted from an EHR and used or disclosed for research purposes, a Data Use Agreement (DUA) is required. The DUA must be executed between the covered entity whose PHI is being used/disclosed, i.e., the Columbia Health Care Component in this example, and the researcher who is the recipient of the data. The data in a LDS are not considered to be de-identified and therefore constitute PHI, until the data are received by the researcher and stored separately from the EHR, in which case the data are considered to be RHI. However, even if the data are RHI, the data remain subject to the terms of the DUA.

A Notice of Privacy Practice does not have to be provided to participants. Because the participants have existing patient records in the CUMC/NYP EHR, they would have received a Notice of Privacy Practice at the time of the first service delivery.

[Complete Credit](#)

8. Click Take Test



The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/course/TC0019/courseOverview>. The page header includes the RASCAL logo and the title "RASCAL Training Center". A navigation menu at the top lists various links such as "Logout", "Help", "Human Subjects", "Animal Care", "Proposal Tracking", "Consent Forms", "HIPAA Forms", "Haz Mats", "Administration", "Training Center", "Conflict of Interest", and "My Rascal".

The main content area is titled "Course Overview" and contains a table with the following data:

Course Number	TC0019	Title	HIPAA
Date Created	12/01/2020 16:32:23	Date Modified	12/01/2020 16:32:23
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	bir2102@columbia.edu
# Questions Per Test	10	Required Passing %	80
You Are		Erika Nannery (en2521)	

Below the table, there is a text block explaining the purpose of the training module: "The purpose of this training module is to educate faculty and staff engaged in human subjects research about the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule requirements as they apply to research and to provide information needed by investigators to make their research activities compliant with HIPAA. Completion of this course and test is required of all researchers who use or intend to use identifiable health information including: Principal investigators and co-investigators, clinical trial coordinators, clinical research associates and research assistants, research nurses, treatment providers building or using research data bases, clerical, secretarial, computer programming, and other staff who interact with identifiable health information in the research context."

Instructions: "After reviewing the material, scroll all the way down to the bottom of the course content page and there should be a box there, usually on the lower right side, that needs to be clicked in order to move to the test page. Browsers present the page differently and it is not obvious with some that the box is there. If you have difficulty locating or accessing the box, using another browser generally resolves the issue."

At the bottom of the page, there is contact information for Rascal, Research Administration and Compliance Application, Columbia University Information Technology, located at 615 West 131st Street, 5th Floor, New York, NY 10027, with a phone number of (212) 851-0213.

9. Click **I Agree** and take the test

The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/course/TC0019/courseOverview>. The page title is "RASCAL Training Center" and the course is "Course - TC0019".

Course Overview

Course Number	TC0019	Title	HIPAA
Date Created	12/01/2020 16:32:23	Date Modified	12/01/2020 16:32:23
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	blr2102@columbia.edu
# Questions Per Test	10	Required Passing %	80
You Are		Erika Nannery (en2521)	

The purpose of this training module is to educate faculty and staff engaged in human subjects research about the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule requirements as they apply to research and to provide information needed by investigators to make their research activities compliant with HIPAA. Completion of this course and test is required of all researchers who use or intend to use identifiable human subjects research data bases, investigators, clinical trial coordinators, clinical research associates and research assistants, research assistants, research assistants, research assistants, research assistants, clerical, secretarial, computer programming, and other staff who interact with identifiable health information.

Course Attestation

By clicking 'I Agree' and proceeding to the test, I confirm that I have viewed all course materials associated with this module or have attended a corresponding in-person training session on this subject.

Instructions:

After reviewing the material, scroll all the way down to the bottom of the course content page. The box is located in the lower right side, that needs to be clicked in order to move to the test page. Browsers present the page differently and it is not obvious with some that the box is there. If you have difficulty locating or accessing the box, using another browser generally resolves the issue.

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10. Type and search for **TC6500** (*HICCC Clinical Protocol and Data Management Investigator Standard Operating Procedure Training*) and click **Go**

The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/courseListings>. The page header features the RASCAL logo and the title "RASCAL Training Center". A navigation menu includes links for Logout, Help, Human Subjects, Animal Care, Proposal Tracking, Consent Forms, HIPAA Forms, Haz Mats, Administration, Training Center, Conflict of Interest, and My Rascal.

The main content area is titled "Training Center Course Listings By Topic". On the left, there is a sidebar with "Training Center" and "Administration" sections. The "Training Center" section includes links for "My Training To-Do List", "Course Listings", and "View Certified Test History". The "Administration" section includes "[RASCAL Menu]" and "Training Center Menu".

In the center, there is a search box with the text "Search for a TC6500 HICCC CLINICAL PROTOCOL and DATA course: MANAGEMENT INVESTIGATOR STANDARD OPERATING PROCEDURE TRAINING" and a "Go" button. A red oval highlights the search input and the "Go" button, with a red arrow pointing to the "Go" button.

Below the search box, there is a "Course Category" section with a list of links:

- [Administration of Sponsored Projects, Effort Reporting](#)
- [Animal Care and Use](#)
- [Conflicts of Interest, Research Ethics and Responsible Conduct of Research](#)
- [Data Management and Research Security](#)
- [Emergency Preparedness](#)
- [Environmental Health and Safety](#)
- [Human Subjects Protection and Clinical Trials](#)
- [System Tutorials](#)

11. Click Take Course

← → ↻ rascal.columbia.edu/tc/course/TC6500/courseOverview    

 **RASCAL Training Center**

[Logout](#) | [Help](#) | [Human Subjects](#) | [Animal Care](#) | [Proposal Tracking](#) | [Consent Forms](#) | [HIPAA Forms](#) | [Haz Mats](#) | [Administration](#) | [Training Center](#) | [Conflict of Interest](#) | [My Rascal](#)

Course - TC6500

- Content
- Course Overview
- Actions**
 - Take Course
 - Take Test
- Training Center
 - My Training To-Do List
 - Course Listings
 - View Certified Test History
 - Email Contact Person
 - Training Center Menu

Course Overview

Course Number	TC6500	Title	CPDM INVESTIGATOR SOP TRAINING
Date Created	05/03/2022 14:53:32	Date Modified	05/03/2022 14:53:32
Course Category	Conflicts of Interest, Research Ethics and Responsible Conduct of Research	Course Contact Email	fb80@cumc.columbia.edu
# Questions Per Test	14	Required Passing %	80
You Are		Erika Nannery (en2521)	

Investigators who conduct interventional, treatment trials within the HICCC Clinical Protocol and Data Management(CPDM) Office will be required to review the following CPDM SOPs and pass testing with a 80%.. Please review the following SOPs.

CPDM INVESTIGATOR SOP TRAINING LIST

12. Click **OK**

← → ↻ rascal.columbia.edu/tc/course/TC6500/courseOverview

RASCAL Training Center

[Logout](#) | [Help](#) | [Human Subjects](#) | [Animal Care](#) | [Proposal Tracking](#) | [Consent Forms](#) | [HIPAA Forms](#) | [Haz Mats](#) | [Administration](#) | [Training Center](#) | [Conflict of Interest](#) | [My Rascal](#)

Course - TC6500

- Content
 - Course Overview**
- Actions
 - Take Course
 - Take Test
- Training Center
 - My Training To-Do List
 - Course Listings
 - View Certified Test History
 - Email Contact Person
 - Training Center Menu

Course Overview

Course Number	TC6500	Title	CPDM INVESTIGATOR SOP TRAINING
Date Created	05/03/2022 14:53:32	Date Modified	05/03/2022 14:53:32
Course Category	Conflicts of Interest, Research Ethics and Responsible Conduct of Research	Course Contact Email	fb80@cumc.columbia.edu
# Questions Per Test	14	Required Passing %	80
You Are		Erika Nannery (en2521)	

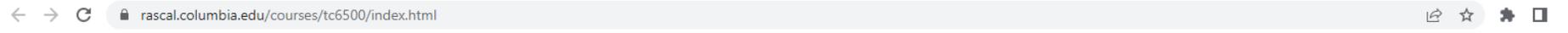
Investigators who conduct interventional, treatment trials within the HICCC Clinical Protocol and Data Management(CPDM) Office will be required to review the following CPDM SOPs and pass testing with a 80%.. Please review the following SOPs.

[CPDM INVESTIGATOR SOP TRAINING LIST](#)

The course content will be opened in a new browser window or tab. Once you have completed the course you can close that window or tab to return to Rascal.

[COM](#)

13. Click **Click here to start**



 [Click here to start](#)

14. Click through the SOP slides



**Clinical Protocol & Data Management Office
(CPDM)
INVESTIGATOR
STANDARD OPERATING PROCEDURE
TRAINING**

COLUMBIA UNIVERSITY
HERBERT IRVING COMPREHENSIVE CANCER CENTER

COLUMBIA

NewYork-Presbyterian

15. Click Take Test

← → ↻ rascal.columbia.edu/tc/course/TC6500/courseOverview



RASCAL Training Center

[Logout](#) | [Help](#) | [Human Subjects](#) | [Animal Care](#) | [Proposal Tracking](#) | [Consent Forms](#) | [HIPAA Forms](#) | [Haz Mats](#) | [Administration](#) | [Training Center](#) | [Conflict of Interest](#) | [My Rascal](#)

Course - TC6500

- Content
- Course Overview
- Actions
 - Take Course
 - Take Test
- Training Center
 - My Training To-Do List
 - Course Listings
 - View Certified Test History
 - Email Contact Person
 - Training Center Menu

Course Overview

Course Number	TC6500	Title	CPDM INVESTIGATOR SOP TRAINING
Date Created	05/03/2022 14:53:32	Date Modified	05/03/2022 14:53:32
Course Category	Conflicts of Interest, Research Ethics and Responsible Conduct of Research	Course Contact Email	fb80@cumc.columbia.edu
# Questions Per Test	14	Required Passing %	80
You Are		Erika Nannery (en2521)	

Investigators who conduct interventional, treatment trials within the HICCC Clinical Protocol and Data Management(CPDM) Office will be required to review the following CPDM SOPs and pass testing with a 80%.. Please review the following SOPs.

[CPDM INVESTIGATOR SOP TRAINING LIST](#)

16. Click **I Agree** and take the test

← → ↻ rascal.columbia.edu/tc/course/TC6500/courseOverview

RASCAL Training Center

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | **Training Center** | Conflict of Interest | My Rascal

Course - TC6500

- Content
 - Course Overview
- Actions
 - Take Course
 - Take Test
- Training Center
 - My Training To-Do List
 - Course Listings
 - View Certified Test History
 - Email Contact Person
 - Training Center Menu

Course Overview

Course Number	TC6500	Title	CPDM INVESTIGATOR SOP TRAINING
Date Created	05/03/2022 14:53:32	Date Modified	05/03/2022 14:53:32
Course Category	Conflicts of Interest, Research Ethics and Responsible Conduct of Research	Course Contact Email	fb80@cumc.columbia.edu
# Questions Per Test	14	Required Passing %	80
You Are		Erika Nannery (en2521)	

Investigators who conduct interventional, treatment trials within the HICCC Clinical Protocol and Data Management(CPDM) Office will be required to review the following CPDM SOPs and pass testing with a 80%.. Please review the following SOPs.

CPDM INVESTIGATOR SOP TRAINING LIST

Course Attestation

By clicking 'I Agree' and proceeding to the test, I confirm that I have viewed all course materials associated with this module or have attended a corresponding in-person training session on this subject.

COM

17. Type and search for **TC0087** (*Human Subjects Protection Training (includes Minors and FDA where applicable)*) and click **Go**

The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/courseListings>. The page header features the RASCAL logo and the title "RASCAL Training Center". A navigation menu includes links for "Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal".

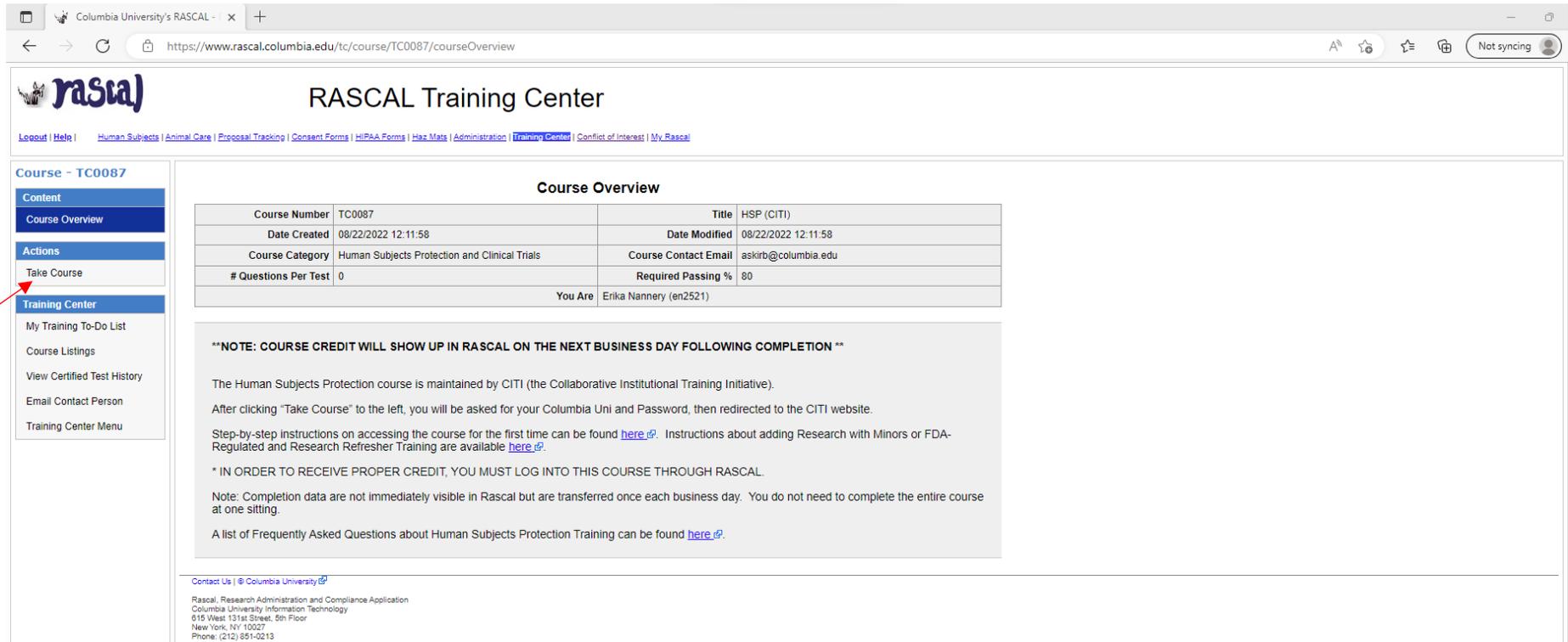
The main content area is titled "Training Center Course Listings By Topic". On the left, there is a sidebar with "Training Center" selected, containing links for "My Training To-Do List", "Course Listings", "View Certified Test History", and "Administration".

The search section is highlighted with a red oval and contains the following text: "My Training To-Do List" (a link), "*Search for a course:" followed by a text input field containing "TC0087", a dropdown menu showing "Human Subjects Protection Training (includes Minors and FDA where applicable)", and a "Go" button. A red arrow points to the "Go" button.

Below the search bar, the "Course Category" section lists several topics as bullet points:

- [Administration of Sponsored Projects_Effort Reporting](#)
- [Animal Care and Use](#)
- [Conflicts of Interest_Research Ethics and Responsible Conduct of Research](#)
- [Data Management and Security](#)
- [Emergency Preparedness](#)
- [Environmental Health and Safety](#)
- [Human Subjects Protection and Clinical Trials](#)
- [System Tutorials](#)

18. Click Take Course



The screenshot shows a web browser window with the URL <https://www.rascal.columbia.edu/tc/course/TC0087/courseOverview>. The page title is "RASCAL Training Center". The main content area is titled "Course Overview" and contains a table with the following data:

Course Number	TC0087	Title	HSP (CITI)
Date Created	08/22/2022 12:11:58	Date Modified	08/22/2022 12:11:58
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	askirb@columbia.edu
# Questions Per Test	0	Required Passing %	80
You Are		Erika Nannery (en2521)	

Below the table, there is a note: ****NOTE: COURSE CREDIT WILL SHOW UP IN RASCAL ON THE NEXT BUSINESS DAY FOLLOWING COMPLETION ****. The note explains that the Human Subjects Protection course is maintained by CITI and provides instructions on how to access the course and receive credit. It also includes contact information for frequently asked questions.

On the left side of the page, there is a navigation menu with the following items: Content, Course Overview, Actions, Take Course (highlighted with a red arrow), Training Center, My Training To-Do List, Course Listings, View Certified Test History, Email Contact Person, and Training Center Menu.

Contact Us | @ Columbia University

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Columbia University Information Technology
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New York, NY 10027
Phone: (212) 851-0213

19. Click **OK** and you will be redirected to CITI

The screenshot shows the RASCAL Training Center interface. The main content area is titled "Course Overview" and contains a table with the following data:

Course Number	TC0087	Title	HSP (CITI)
Date Created	08/22/2022 12:11:58	Date Modified	08/22/2022 12:11:58
Course Category	Human Subjects Protection and Clinical Trials	Course Contact Email	askirb@columbia.edu
# Questions Per Test	0	Required Passing %	80
You Are		Erika Nannery (en2521)	

Below the table, a note states: ****NOTE: COURSE CREDIT WILL SHOW UP IN RASCAL ON THE NEXT BUSINESS DAY FOLLOWING COMPLETION****. The text explains that the Human Subjects Protection course is maintained by CITI and provides instructions on how to access the course content, including a link to a help page. A modal dialog box is overlaid on the page, containing the text: "The course content will be opened in a new browser window or tab. Once you have completed the course you can close that window or tab to return to Rascal." and an "OK" button. A red circle highlights this dialog box.

At the bottom of the page, contact information for Rascal is provided:

Contact Us | © Columbia University
Rascal, Research Administration and Compliance Application
Columbia University Information Technology
615 West 131st Street, 5th Floor
New York, NY 10027
Phone: (212) 851-0213

20. Once in CITI, click **View Courses**

The screenshot shows the CITI Program website interface. At the top, there is a navigation bar with the CITI PROGRAM logo, menu items for 'My Courses', 'My Records', 'My CE/CMEs', and 'Support', a search icon, and a user profile dropdown for 'Erika Nannery ID 11786917'. Below the navigation bar is a blue banner with the text 'Welcome, Erika' and 'Add Institutional Affiliation Register as Independent Learner'. To the right of the banner are two circular statistics: '0 Courses Completed' and '20 Days of Membership'. Below the banner are two notification boxes. The first notification states: 'Due to planned maintenance, the CITI Program website will be unavailable on Friday November 18 from 9 p.m. to 12 a.m. U.S. Eastern Time (6 p.m. to 9 p.m. U.S. Pacific). We apologize for the inconvenience.' The second notification states: 'CITI Program now supports linking your ORCID® ID.' with a 'Connect your ORCID ID' button and links for 'How to link your ORCID ID' and 'About ORCID'. Below the notifications is the 'Institutional Courses' section, which explains that institutional courses are available to learners with affiliations. It lists 'Columbia University' with a 'View Courses' button highlighted by a red arrow. Below this are buttons for 'Add Affiliation' and 'Remove Affiliation'. The 'Independent Learner' section follows, with a 'Register as an Independent Learner' button. At the bottom, there is a footer with 'SUPPORT' (888.529.5529, 9:00 a.m. - 7:00 p.m. ET, Monday - Friday, Contact Us) and 'LEGAL' (Accessibility, Copyright, Privacy and Cookie Policy, Statement of Security Practices, Anti-Discrimination Policy, Terms of Service) information, along with the CITI PROGRAM logo.

21. Scroll down and click **Add a Course**

Completed Courses

[Learner Tools](#)

You have not recently completed any courses for this Institution. Full records of past completions are available in [Records](#).

Learner Tools for Columbia University

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

SUPPORT

888.529.5929

9:00 a.m. - 7:00 p.m. ET

Monday - Friday

[Contact Us](#)

LEGAL

[Accessibility](#)

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[Privacy and Cookie Policy](#)

[Statement of Security Practices](#)

[Anti-Discrimination Policy](#)

[Terms of Service](#)



22. Select **TC0087**, **TC0094**, **TC3450** and click **Next**

The screenshot shows a web browser window with the URL <https://www.citiprogram.org/members/index.cfm?pagerID=166&qID=4058&qIDverify=51AE6A298AE9212326878BA0615FEF942E01CDCDBDFC90CEEA3CEF69CA98D0BF3615320D9ED28E6BB71504F6E833E6A76FAD7B3AF...>. The page header includes the CITI PROGRAM logo, navigation links for 'My Courses', 'My Records', 'My CE/CMEs', and 'Support', a search icon, and a user profile for 'Erika Nannery ID 11706917'. The main content area has a blue header with the text 'Select Curriculum' and 'Columbia University'. Below this is a section titled 'Question 1' with the question 'Which trainings do you need to complete?' and the instruction 'This question is required. Choose all that apply.' The list of training options includes:

- TC0087 - Human Subjects Protection (HSP) Training**
For all Researchers, Students, and Research Staff conducting research with human subjects.
- TC0094 - Responsible Conduct of Research Training**
Required for some undergraduates, graduate students and postdocs funded by National Science Foundation (NSF) or National Institutes of Health (NIH) grants. Recommended for others, including faculty and research staff.
- TC3450 - Good Clinical Practice (GCP) Training**
This course is primarily for those researchers whose sponsors require GCP training, including NIH clinical trials and certain industry sponsors. NOTE: this course is NOT a substitute for Human Subjects Protection (HSP) Training; all Human Subjects researchers must complete HSP training.
- Webinars**

At the bottom of the form are two buttons: 'Start Over' and 'Next'. A red arrow points to the 'Next' button.

23. Click **Biomedical** and click **Next**



Question 2

2. Please choose the appropriate Human Subjects Protection course based on your Human Subjects research.

This question is required. Choose one answer.

- Biomedical**
Includes most health sciences research, such as clinical research, epidemiological research, and most other research involving tissues, fluids, radiographic scans, biomedical information, or treatment and/or diagnosis of individuals.
- Social and Behavioral**
Includes research involving behaviors, cognitive function, or social interactions, such as research conducted in the social sciences, humanities, Department of Psychology, the School of Social Work, the Business School, Engineering and some research on the CUMC campus.
- Human Subjects Protection training in Russian**
- Human Subjects Protection training in Spanish**
- IRB Chair

24. Click **YES** for research with children and click **Next**

Columbia University's RASCAL - x CITI - Collaborative Institutional x +

https://www.citiprogram.org/members/index.cfm?pageID=166&qID=4059&qIDVerify=E3A93EC4D87BE48E6CAD09BE0017CEBB3164DD6F319C72D96F80CDEA1D9C19D3173801F3BC5B440787A9438DA06ACFDC1A2A52696... A Not syncing

PROGRAM ID: 11706917

Select Curriculum

Columbia University

Question 4

3. Do you conduct research with children? If "YES" then you must complete the module on "Research with Minors."

This question is required. Choose one answer.

Yes

No

Start Over Next

25. Click **Yes** for FDA Regulated Research and click **Next**

The screenshot shows a web browser window with two tabs: "Columbia University's RASCAL -" and "CITI - Collaborative Institutional". The address bar shows the URL: <https://www.citiprogram.org/members/index.cfm?pageID=166&qID=4064&qIDverify=634C9F091B7E4996012E1FFE939D816F3A062E974E9ECD1CCD31787E1B2368FF965F5A90B547486ED1376AAE042BBED5FC437621DFC1...>

The page header includes the CITI PROGRAM logo, navigation links for "My Courses", "My Records", "My CE/CMEs", and "Support", a search icon, and a user profile dropdown for "Erika Nannery ID 11706917" with a language selector set to "English".

A blue banner reads "Select Curriculum" with "Columbia University" below it.

The main content area is titled "Question 7" and contains the following text:

4. Do you conduct FDA-regulated research? If "YES" then you must complete the module on "FDA-Regulated Research."

This question is required. Choose one answer.

There are two radio button options: "Yes" (which is selected) and "No". A red arrow points to the "Yes" radio button.

At the bottom of the question area are two buttons: "Start Over" and "Next". A red arrow points to the "Next" button.

26. Click **Biomedical (includes NIH trainees)** for RCR Course and click **Next**

The screenshot shows a web browser window with two tabs: 'Columbia University's RASCAL' and 'CITI - Collaborative Institutional'. The address bar shows the URL: <https://www.citiprogram.org/members/index.cfm?pageID=166&qID=4069&qIDverify=92CFE6530CEA603DF61A5050307AF3566916C17DE3E9CA5AE310A951C99523D9DE94A9668750CD84614E93365F63A6F6B3C92DC5F99...>

The main content area has a blue header with the text 'Select Curriculum' in gold and 'Columbia University' in white below it.

Below the header, the text 'Question 11' is centered. Underneath, it says 'Please choose the most appropriate RCR course based on your research/role.' and 'This question is required. Choose one answer.'

There are five radio button options:

- Biomedical (Includes NIH trainees)
- Social and Behavioral
- Humanities
- Physical Sciences
- Engineering
- Research Administrators

At the bottom, there are two buttons: 'Start Over' (light gray) and 'Next' (dark blue). Red arrows point to the selected radio button and the 'Next' button.

27. Click **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)** and click **Next**

The screenshot shows a web browser window with the URL <https://www.citiprogram.org/members/index.cfm?pageID=166&qID=13678&qIDverify=D83663632DA136631C3EF679F9A23C87E6055C16250E40CE2C1518C8DCC30CDA1A3DE4DD00AB4CDC6F18C8F5DA1B10EDDC05CAA...>. The page header includes the CITI PROGRAM logo, navigation links for 'My Courses', 'My Records', 'My CE/CMEs', and 'Support', a search icon, and a user profile for 'Erika Nannery ID 11706917'. A blue banner reads 'Select Curriculum Columbia University'. The main content area is titled 'Question 12' and contains the following text: 'Please choose the appropriate Good Clinical Practice course based on your research and sponsor. This question is required. Choose one answer.' Below this are three radio button options. The first option is selected and has a red arrow pointing to it. The second and third options are unselected. At the bottom, there are two buttons: 'Start Over' and 'Next', with a red arrow pointing to the 'Next' button.

English ▾

CITI
PROGRAM

My Courses My Records My CE/CMEs Support

Search

Erika Nannery
ID 11706917

Select Curriculum

Columbia University

Question 12

Please choose the appropriate Good Clinical Practice course based on your research and sponsor.

This question is required. Choose one answer.

- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) -- This course satisfies GCP training requirements for research personnel on clinical trials in the U.S. sponsored by NIH and others. It may also be beneficial for other clinical trial research personnel.
- Good Clinical Practice Course for Clinical Trials Involving Medical Devices -- This course is intended for research personnel involved in device studies and has an international focus.
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) -- This course is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training.

Start Over Next

28. Click **Start Now** for each course under Courses Ready to Begin and complete the courses

The screenshot shows a web browser window with the URL <https://www.citiprogram.org/members/index.cfm?pageID=508&showInstitution=310&message=94#view>. The page header reads "Columbia University".

Active Courses [Learner Tools](#)
You have no active courses for this Institution.

Courses Ready to Begin [Learner Tools](#)

- Columbia University**
FDA-Regulated Research
Stage 1 - BASIC COURSE
0 / 1 modules completed
[Start Now](#)
- Columbia University**
GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
Stage 1 - GCP
0 / 8 modules completed
[Start Now](#)
- Columbia University**
Human Subjects Protection Biomed
Stage 1 - Basic Course
0 / 8 modules completed
[Start Now](#)
- Columbia University**
RCR Biomedical
Stage 1 - RCR
0 / 12 modules completed
[Start Now](#)
- Columbia University**
Research With Minors - BIOMED
Stage 1 - Basic Course
0 / 1 modules completed
[Start Now](#)

Red arrows point to the "Start Now" button of each course card.