



RSCH215 Non-Oncology or RSCH216 Oncology Subject/Patient Management (Pre-requisite RSCH100-Fundamentals)

- Register Subjects to a Study
- Manage Subject Statuses
- Print IRB-Approved Consent Forms
- Scan Signed ICFs into CareConnect
- Document Subject Consent and HIPPA authorization
- Check-In Subject Visits in OnCore
- Pend Research-Specific Orders in CareConnect
- Associate Orders and Visits to Research in CareConnect
- Document SAEs/Deviations
- Print Deviations and SAE Logs
- Generate the Next Actions Report

Mandatory

- Study Coordinators
- Data Managers

Recommended

- Regulatory Coordinators
- Managers/Directors
- Fund Manager

RSCH210 - Study Management (Pre-requisite RSCH100-Fundamentals)

- Manage submissions to IRB
- Manage Study Staff in OnCore
- Create electronic Eligibility Questionnaires
- Track key tasks that are completed to move through different Statuses (Phases) of the study
- Initiate electronic handshakes to help validate and notify centralized teams associated with the Study
- Identify Study Sites
- Manage Study documents, attachments, and notes
- Generate the Next Actions Report

Mandatory

- Regulatory Coordinators

Recommended

- Study Coordinators
- Data Managers
- Managers/Directors
- Fund Managers

RSCH160 - Financials Management (Pre-requisite RSCH100-Fundamentals)

- Associate Fund Account Number and Recharge ID to a study
- Negotiate Budget with Sponsor
- Communicate with centralized teams for Budget updates
- Validate Budget in OnCore
- Configure Invoicing criteria
- Identify trigger points where Invoices can be generated
- Generate Invoices and Documents
- Track Receipts (Payment Reconciliation)
- Conduct Financial Reports
- Generate the Next Actions Report

Mandatory

- Fund Managers

Recommended

- Study Coordinators
- Data Managers
- Managers/Directors
- Regulatory Coordinators

ONCORE JOB TITLES/FUNCTIONS

Principal Investigator (PI)/Investigator

This role includes Principal Investigator, Sub-Investigator, and Co-Investigator.

Primary responsibility for ensuring the ethical conduct of the research study. This includes protecting human subjects' rights, safety and welfare, protocol compliance, and adherence to institutional, state and federal regulations and guidance. The PI is responsible for ensuring informed consent is appropriately obtained from each participant and for appropriately maintaining study records. The PI is also responsible for complying with the financial and administrative policies and regulations associated with the award, overall fiscal management of the project, and conflict of interest disclosure. The PI oversees all aspects of a clinical trial from protocol design, recruitment, data collection, analysis and interpretation of results, but some tasks can be delegated to other research team members (Sub-Investigators and Key Personnel). The PI is responsible for ensuring that all research team members have appropriate education, training and qualifications to assume delegated study tests. All study team members are responsible for ensuring that the conduct of the study is compliant with institutional, state, federal and industry guidance and regulations.

Independent (DIY) Investigator

Investigators who do NOT have research support staff (e.g. coordinators) investigator has privileges to oversee research support staff who will open and close studies, approve calendars/budgets and register subjects.

Director/Manager

Administrative leader of the department/division.

Research Coordinator/ Nurse Coordinator

Oversees and coordinates the daily activities of clinical research studies. They work closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. Research Coordinators/Research Nurses generally manage participant enrollment and ensure compliance with the protocol and other applicable regulations. This includes, but is not limited to, participant recruitment, obtaining informed consent, educating participants on the details of the research study, assessing participant eligibility, facilitating participant care and follow-up per protocol, creating source documentation, assisting in the assessment of toxicities/adverse events and reporting serious adverse events per IRB and sponsor requirements.

Regulatory Coordinator

Responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They are responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards. They often are the keepers of the delegation of authority log for key personnel involved in the study.

Fund Manager

Responsible for providing analytical and fiscal support to the PIs. They administer and manage pre and post award contracts and grants. Responsibilities include the preparation of budgets, ensure compliance, prepare approval forms, administer renewals and continuations, distribute funds according to approved budgets, prepare and approve invoices and post and reconcile against the general ledger.

Data Manager

Responsible for the overall data management of a research study. Data points for analysis must be extracted from multiple source documents and entered into specific databases. Data managers ensure accurate and timely data entry in electronic databases, electronic case report forms (eCRFs) or paper case report forms (CRF). They work closely with sponsor monitors and resolve any data queries that may be generated. They also work closely with the research team in the study development process to identify key data points for collection and analysis for investigator initiated trials.

Research Assistant

Assist the PI and other staff on a clinical trial. Perform various clerical and editorial duties. Can perform research related tasks under supervision.

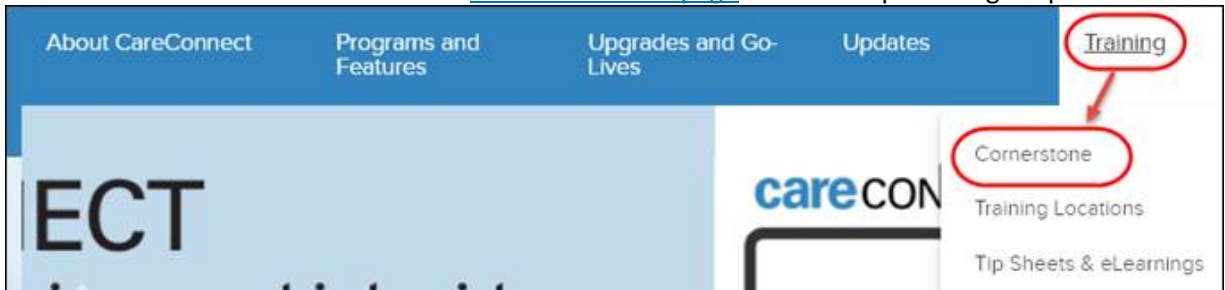
ONCORE COURSE REGISTRATION

Now that the training team has gone live with a new system, Cornerstone, users can now directly register into their courses or have managers register their employees on their behalf. The content below will share tip sheets and links, which you can utilize. The tip sheets will share how to navigate within Cornerstone and how to self-enroll into training sessions.

Cornerstone information provided by the training team:

1. Where to Login

- a. Cornerstone can be accessed from the [CareConnect webpage](#) from the top Training drop-down menu.



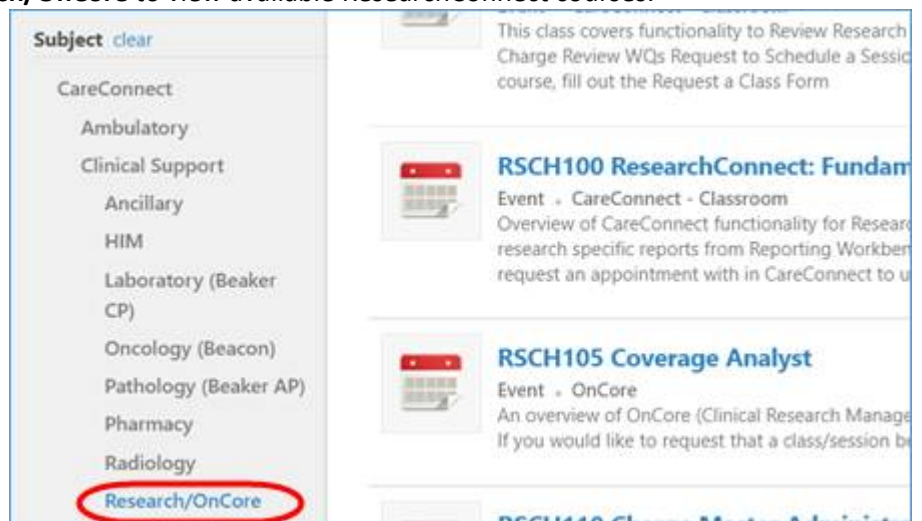
2. Tipsheets for Cornerstone

- a. Training Resources (contains eLearning, Tipsheets, login instructions):
<http://careconnect.uclahealth.org/Training>
- b. How to Browse for Training
 - i. Tipsheet: <http://careconnect.uclahealth.org/workfiles/Cornerstone-Training-Script-Browse-for-Training.pdf>
 - ii. ResearchConnect catalog of courses
 1. Click on **Browse Training** at the top right of the page



a.

2. Under the left **Subject** section, navigate to **CareConnect > Clinical Support > Research/OnCore** to view available ResearchConnect courses.



a.

3. How to Assign Training (Manager)

- a. In-house Course: Tipsheet: <http://careconnect.uclahealth.org/workfiles/Cornerstone-Training-Script-Manager-Assigns-Training.pdf>

- b. eLearning: Tipsheet: <http://careconnect.uclahealth.org/workfiles/Cornerstone-Training-Assign-Online-ELT-Training-to-Employee.pdf>
 - i. Note that eLearnings will not require approval. Investigators can search for ELRSH300 and complete the course.

4. How to Request Training (End-User)

- a. Tipsheet: <http://careconnect.uclahealth.org/workfiles/Cornerstone-Training-Script-Request-Training-for-Manager-Approval.pdf>
 - i. Please note that these requests must be approved by a manager in order for an end-user to be officially enrolled into a class.