**Onboarding for Clinical Research Coordinators**

The following onboarding document should be used when clinical research coordinators are hired in DOP. This plan needs to be presented to the faculty so that they are aware of its existence.

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**Department of Pediatrics Orientation Manual for Clinical Research Coordinators**

**Emory University**

**School of Medicine**

Purpose: This orientation manual was created to serve as a recommendation to principal investigators in the Department of Pediatrics with the on-boarding of new clinical research coordinators.

|  |  |
| --- | --- |
| Name: |  |
| Job Title |  |
| Principal Investigator (s) |  |
| Degree(s) |  |
| Certifications received upon starting the position |  |
| Previous relevant training |  |

**Research Coordinator Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Hire Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Preceptor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Important Contact Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Title** | **Department**  **Institution** | **Phone** | **Email** |
| Claudia Morris, MD | CCTR Co-Director | DOP |  | [claudia.r.morris@emory.edu](mailto:claudia.r.morris@emory.edu) |
| Miriam Vos, MD | CCTR Co-Director | DOP |  | [mvos@emory.edu](mailto:mvos@emory.edu) |
| Liz McCarty | Executive Administrator for Pediatrics & Vice Chair for Administration | DOP | 404-712-8226 | [mmccar2@emory.edu](mailto:mmccar2@emory.edu) |
| Sarah Marie Huban | Director, Clinical Trials | DOP | 404-727-5234 | [ssmit37@emory.edu](mailto:ssmit37@emory.edu) |
| Biorepository | Emory Research Lab  Children’s Clinical and Translational Discovery Core | DOP | 404-727-2342 | [cctdc@emory.edu](mailto:cctdc@emory.edu) |
| Jane Chen | Pharmacy | CHOA | 404-785-1281 | [Jane.chen@choa.org](mailto:Jane.chen@choa.org) |
| Bethany Watson | Lab, Research Tech | CHOA | 404-785-1930 | [Bethany.Watson@choa.org](mailto:Bethany.Watson@choa.org)  [PathVendorMailbox@choa.org](mailto:PathVendorMailbox@choa.org) |
| Cheryl Stone | Manager, PRC | CHOA | 404-785-6453 | [CherylL.Stone@choa.org](mailto:CherylL.Stone@choa.org) |
| Cardiovascular Imaging Research Core (CIRC) | Cardiac Imaging | Cardiology, CIRC | 404-785-CIRC (2472) | [CIRC@choa.org](javascript:void(location.href='mailto:'+String.fromCharCode(67,73,82,67,64,99,104,111,97,46,111,114,103))) |
| Sadama Sinayoku | Radiology Research Coordinator | Radiology | 404-785-2527 | [Sadama.sinayoku@choa.org](mailto:Sadama.sinayoku@choa.org) |
| Stephanie Meisner | Director, Clinical Research | CHOA | [404-785-0400](tel:404-785-0400) | [Stephanie.Meisner@choa.org](mailto:Stephanie.Meisner@choa.org) |
| Amanda Mulligan | Director, Research Administration | CHOA | 404-785-7477 | [amanda.mulligan@choa.org](mailto:amanda.mulligan@choa.org) |
| Jennifer  Shipp | Clinical Research Educator | CHOA | 404-785-9617 | [Jennifer.shipp@choa.org](mailto:Jennifer.shipp@choa.org) |

**Prior to the Employee’s Arrival:**

1. Request Space to the space committee (send request to [Liz McCarty](mailto:mmccar2@emory.edu))
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
2. [Order Computer](https://forms.office.com/Pages/ResponsePage.aspx?id=nPsE4KSwT0K80DImBtXfOProKel5p1tFvHGDKqqkBmJUQjBEVTlMSEtDVDlVUEpUN0NBUlU3SkVUOSQlQCN0PWcu) 
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
3. Request Phone Set-up at desk
   1. Date completed: \_\_\_\_\_\_\_\_\_\_

**Training (Emory Specific):**

1. [Emory Card](https://www.onecard.emory.edu/emorycard/index.html)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
2. [Parking Account](https://myaccount.parking.emory.edu/Account/Portal)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
3. [HIPAA Training](https://hipaa.emory.edu/home/training.html)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
4. Emory Clinical Research Staff Training (4-5 days)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
5. [ONCORE training](https://ocr.emory.edu/resources/training/courses.html)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
6. [Blood Borne Pathogens Training](https://www.ehso.emory.edu/resources/training/courses.html)\*
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
7. Men[r specimen from CAP to HSRB/torship Program](https://www.pedsresearch.org/research/resources/clinical-research-resources/research-coordinator-resources#tab=tab05) (Mentor Match)
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
8. Compass Training \*
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
9. Emory Express Training\*
   1. Date completed: \_\_\_\_\_\_\_\_\_\_
10. CPR training\*
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
11. Phlebotomy Training\*
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
12. ECG Training\*
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
13. [SAF-T-PAK](https://www.apps.saftpak.com/en-US/account/login) Training\* (Contact Sarah Marie Huban – [sarah.marie.huban@emory.edu](mailto:sarah.marie.huban@emory.edu)) for the online training credentials).
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
14. [Research Participant Stipend Funds Review](https://pedsresearch.org/research/support-services/patient-stipend-funds/)
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
15. Complete CHOA sponsored account via the Non-paid Position process, including EPIC, if needed- see Appendix A.  Contact Jennifer Shipp at [Jennifer.shipp@choa.org](mailto:Jennifer.shipp@choa.org)  to coordinate.
    1. Date completed: \_\_\_\_\_\_\_\_\_\_
16. Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
    1. Date completed: \_\_\_\_\_\_\_\_\_\_

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

**Competency #1\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Conduct all research activities with the highest ethical, legal and scientific standards in accordance with Federal, State, and Institutional regulatory requirements.

* Access and read the Belmont Report
  + <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Complete [CITI training courses for Emory and CHOA](https://about.citiprogram.org/en/homepage/)
  + https://about.citiprogram.org/en/homepage/
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Complete Emory HIPAA modules
  + <http://www.orc.emory.edu/hipaa/HIPAA-training.html>
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Complete Office for Clinical Research Research Staff Training [4-5 days]
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Download Clinical Trials Guidebook from Emory Office of Clinical Trials Audit and Compliance
  + <https://www.ctac.emory.edu/guidebook/index.html>
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Complete CPR training
  + <http://www.ocr.emory.edu/training/courses.html>
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Complete ONCORE training
  + Date completed: \_\_\_\_\_\_\_\_\_\_
* Review principles of Good Clinical Practices and IRB Standard Operating Procedures
  + Review IRB Instructional Videos and download text instructions for future reference
  + <http://irb.emory.edu/Training/webinars.html>
  + Date completed: \_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **Please review the following** | **Check date completed** |
|  |  |
| [How to Access eIRB/Get an eIRB Account](https://irb.emory.edu/resources/training/courses.html) |  |
| [How to Submit a New Study in eIRB](https://oraws2.emory.edu/shared_web/secured_apps/irb_linked_videos/app_irb_linked_video_proc.php?video=IRB90_0201_SubmitStudy&mime=mp4) |  |
| [How to Submit an Amendment in eIRB](https://oraws2.emory.edu/shared_web/secured_apps/irb_linked_videos/app_irb_linked_video_proc.php?video=IRB90_0602_Researcher_CreateMod&mime=mp4) |  |
| [How to Submit a Continuing Review in eIRB](https://oraws2.emory.edu/shared_web/secured_apps/irb_linked_videos/app_irb_linked_video_proc.php?video=IRB90_0601_Researcher_CreateCR&mime=mp4) |  |
| [How to Submit a Reportable Event in eIRB](https://oraws2.emory.edu/shared_web/secured_apps/irb_linked_videos/app_irb_linked_video_proc.php?video=IRB90_0801_SubmitRNI&mime=mp4) |  |

By signing below, I agree that I have reviewed and/or completed the above for competency 1

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency #2\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Collaborate with other departments (within Emory and CHOA) when appropriate to plan & implement the research.

* Collaborates with the P.I. to determine the roles and responsibilities of Sub-Investigators and other members of the research team, completing a Delegation of Responsibility Form
  + Can use this Delegation of Authority Log
    - [Delegation of Authority Log](https://www.ctac.emory.edu/_includes/documents/sections/tools/delegation_of_authority_log-2.docx)
      * Date completed: \_\_\_\_\_\_\_\_\_\_
* Laboratory:
  + Meet with research contact at CHOA Lab to review and plan required activities.
  + Provide protocol, lab manual and supplies if a Central Lab is used
  + Completes Hazardous Materials shipping training
    - IATA: [www.ehso.emory.edu](http://www.ehso.emory.edu)
      * Date completed: \_\_\_\_\_\_\_\_\_\_
    - [SAF-T-PAK](https://www.apps.saftpak.com/en-US/account/login) (via Emory DOP):
      * Date completed: \_\_\_\_\_\_\_\_\_\_
* Radiology:
  + Meet with radiology and review policies.
    - * Date completed: \_\_\_\_\_\_\_\_\_\_
* Specimen Courier from CAP to HSRB
  + Meet with director of the biorepository to learn the proper procedures for using the research courier for specimen from CAP to HSRB/
  + Provide SOPs and show employee the lab at CAP and HSRB
    - * Date completed: \_\_\_\_\_\_\_\_\_\_
* Pharmacy:
  + Email/meet with Research Pharmacist to review and plan required activities.
  + Provide Pharmacist with copy of protocol and investigator’s brochure
  + Become familiar with plan Pharmacists have for:
    - Delivery & storage of investigational drug
    - Dispensing
    - Emergency un-blinding procedures
    - Drug accountability
* Nursing:
  + Contact Nursing Director of inpatient unit where research participants will receive care
  + Provide nursing staff with protocol, IRB approved consent documents, data collection forms, and nursing orders
  + Provide in service to nursing staff about research and their role
  + Provide reference materials for nursing staff to access on nursing unit during the course of the research
  + Provide contact information for nursing staff for questions
* Cardiology:
  + Email/meet with CIRC coordinator to review and plan required activities
  + Provide CIRC coordinator with copy of protocol
  + Become familiar with service coverage for outpatient, inpatient, and off hours visits.

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor (Radiology): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: (Laboratory): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor (Samples Courier): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor (Pharmacy): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor (PRC): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor (Cardiology): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency # 3\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Maintain ongoing communication with the IRB throughout all phases of the research; review and submit completed IRB documents as appropriate and in time to meet deadlines.

* Review IRB website
* Review IRB tutorial videos (<https://www.irb.emory.edu/resources/training/courses.html>)
* Access and review Emory IRB policies and procedures
  + <http://www.irb.emory.edu/documents/PoliciesandProcedures.pdf>
* Prepare study submission utilizing the submission checklist below where applicable for initial and subsequent submissions

|  |  |
| --- | --- |
| **Please review the following** | **Check date completed** |
| Final protocol |  |
| Investigator’s Brochure |  |
| Informed consent documents  (consent, assent, HIPAA, Revocation letter)  <https://www.irb.emory.edu/forms/consent/index.html> |  |
| Advertising, patient literature |  |
| Data Collection Forms |  |
| CITI certifications for all study staff |  |
| Amendments |  |
| End of study reports |  |

|  |  |
| --- | --- |
| **Complete the following when appropriate** | **Check date when 1st completed** |
| Report adverse events and protocol deviations as required |  |
| Notify the IRB of ongoing developments in study |  |
| Provide IRB with required Annual Progress Reports and unstamped ICF for yearly approval (progress reports may be more frequent as necessary) |  |
| Submit any changes to the approved protocol to IRB for approval (all protocol revisions including editorial changes) |  |
| Inform IRB of trial completion and submits termination report |  |

* Submit CHOA IRB approval request, if applicable
  + [Complete CHOA IRB Authorization Agreement (IAA)](https://www.choa.org/~/media/files/Childrens/research/irb/university-studies/iaa-form-1-replacing-research-approval-form-emory.docx?la=en)
    - [CHOA IRB Forms](https://www.choa.org/research/institutional-review-board/forms)

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency #4\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Participate in all aspects of the informed consent process.

* In collaboration with the sponsor, principal investigator, and in accordance with Emory IRB policies and procedures, develop the Informed Consent Form (ICF) to submit to the IRB for approval, taking into account sponsor, Federal, State and Institutional requirements. (see competency #3 above)
* Demonstrate ability to perform the following:
  + Obtain participant’s signature and date signed on ICF after reviewing in detail with participant
  + Ensure that person obtaining consent also signs ICF
    - Give participant copy of signed ICF and place copy in participant’s medical record, retaining original in Regulatory Study File and sending copy to Pediatric Research Center.
    - Document in participant’s medical record (EPIC, OTTR or CPG chart) and source document that:
      * Study was thoroughly explained to the participant and they willingly agreed to participate.
      * Adequate time was given for participant to ask questions
      * Date/time ICF was signed by patient
      * Can utilize this Informed Consent Process Note template
        + [Informed Consent Process Note](http://www.ctac.emory.edu/clinical_trial_resources/informed_consent_process_note.doc)
  + Provide participant with updated information throughout the study that may influence their willingness to continue participation
  + Describe vulnerable participants and how informed consent differs when research participants are children
  + In collaboration with study sponsor/PI, revise ICF as necessary when protocol changes or new information emerges and submit for IRB approval

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency #5\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Coordinate conduct of the research study through the various phases: screening/recruitment, enrollment, and completion

Demonstrate ability to perform the following:

***Recruitment and Screening***

* Initiate the screening process and identify potential candidates for enrollment. Potential strategies to utilize include:
  + Review patient medical records against inclusion criteria
  + Present brief overview of study during division journal club or other applicable meetings
    - Can complete training logs at this time
    - [Study-Specific Training Log](https://www.ctac.emory.edu/_includes/documents/sections/tools/study_specific_training_log.docx)
    - [Training Attendance Log](https://www.ctac.emory.edu/_includes/documents/sections/tools/training_attendance_log.docx)
  + Utilize approved letters to referral sources
* Determine participant eligibility
  + Carefully adhere to protocol inclusion/exclusion criteria
  + Can utilize Eligibility Criteria Checklist
    - [Eligibility Criteria Checklist](http://www.ctac.emory.edu/clinical_trial_resources/eligibility_criteria_checklist.doc)
  + Consult with PI regarding final determination of eligibility and document PI approval of participant inclusion

***Enrollment***

* Following consent (see competency #4),
  + Notify sponsor of participant enrollment per outlined sponsor requirements
  + Establish, maintain, and document any communication with the participant
  + Schedule and coordinate all study visits and required procedures or evaluations
  + Complete data collection forms or case report forms for research visits conducted as required by sponsor
  + Maintain and document ongoing communication with any participating departments (ex. Lab, Pharmacy, Radiology, Cardiology, PRC, etc.)
  + Monitor study team compliance with protocol, ethical, and regulatory requirements
    - Document non-compliance as necessary. Can utilize Protocol Deviation Log
    - [Protocol Deviation Log](https://www.ctac.emory.edu/_includes/documents/sections/tools/protocol_deviation_log.doc)
* Maintain and document ongoing communication with the sponsor
* Monitor and document participant safety throughout participation in the study (see competency #6)

***Study Completion***

* Notify research team and participating departments of study completion
* Communicates appropriately with the IRB
* Adhere to sponsor instructions regarding study closure procedures

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency #6\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Ensure participant safety.

* Demonstrate ability to perform the following:
  + Effectively monitor participants throughout course of study:
    - Communicate with participant regarding onset of adverse events or worsening or preexisting worsening medical conditions
  + Document and report adverse events appropriately (under the guidance of study PI)
    - [Notify IRB when appropriate per their guidelines](https://www.irb.emory.edu/_includes/documents/sections/guidance_re_chart.pdf)
    - <https://irb.emory.edu/guidance/reportable.html>
  + Provide notification to the IRB and sponsor of any event classified as both serious and unexpected
  + Ensure PI has event details and available test results to assist in event classification and determination of a treatment plan, when appropriate or termination of participation in the research study.
  + Communicate adverse event related information to the participant's routine care providers as appropriate
  + Ensure appropriate event follow-up
  + Submit IND Safety Reports to the IRB per their guidelines
    - <https://irb.emory.edu/guidance/reportable.html>

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency# 7\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Maintain study records according to regulatory and sponsor requirements

* Demonstrate ability to perform the following:
  + File and maintain appropriate and up to date documents in Regulatory File
    - Can utilize this Regulatory Documentation Checklist as a guideline
    - [Regulatory Documentation Checklist](http://www.ctac.emory.edu/clinical_trial_resources/regulatory_documentation_checklist.doc)
  + Accurately complete Case Report Forms (CRFs) or Data Collection Forms (DCFs) in a timely manner as required by sponsor
    - Maintain CRFs/DCFs in a secure location
  + Resolved data queries in a timely manner as required by study sponsor
  + Ensure all data captured on CRFs/DCFs are accompanied by verifiable source documentation
  + Retain documentation of all communication and correspondence with regulatory agencies, IRB, sponsor, research team members, and participant. Study correspondence includes verbal, written, electronic, or faxed communication.
  + Ensure that all source documentation is de-identified before inclusion in participant research record,
    - Additional de-identification of all documentation containing protected health information (PHI) prior of submission documentation to regulatory agencies (including study CRO), the IRB, and/or the sponsor
  + Access additional clinical trial resources and forms as necessary from Office of Research Compliance
    - <http://www.orc.emory.edu/clinical%20trials/Other%20Resources.html>

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency #8\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective: Manages financial aspects of the clinical trial

* Demonstrate ability to perform the following:
  + Arrange for and document participant payments as outlined in the informed consent
    - Obtain W-9 annually and any time participant’s address changes
  + Ensures appropriate registration/billing procedures are followed when participant research visit is conducted at CHOA
    - Pre-register participant visit at least 24 hours in advance
    - Complete study visit tracker within 24 hours of visit completion
      * Document any and all billable activities
  + Maintains finance related documents separate from regulatory and patient files

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Competency# 9\***

*\*These trainings are required if the staff member is expected to perform these tasks. If not applicable to an employee’s role, note “N/A” in the “Date completed” area.*

Learning Objective:Coordinates all activities for study close out

* Demonstrate ability to perform the following:
  + Coordinate study close out procedures in accordance with the protocol
  + Contact study participants with final information and/or instructions
  + Arrange for final disposition of remaining study supplies
  + Arrange for site close out visit from sponsor or sponsor’s representative (CRO)
  + Submit final Progress Report to the IRB
    - Submit CHOA IRB Close-out form
      * [Close-Out Form](https://www.choa.org/-/media/Files/Childrens/research/irb/research-under-irb-review/iaa-closeout-2021.docx?la=en&hash=A6D1F9D2759CFA1D9488E370080AE83D1F75CCD7)
  + Notify the research team, including all participating departments, of study completion
  + [Arrange for record storage](https://portal.filebridge.com/)

By signing below, I agree that I have reviewed and/or completed the above.

Research Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Preceptor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_