Clinical Research Guide for Investigators

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Getting Started

- **Review the Research Handbook-Investigator Guide** The Investigator Guide includes information on where to start, regulatory and institutional requirements, when enrollment can start, navigating research, managing awards, conducting research, hiring and supervising staff, transferring awards/specimens, etc.)

- **Award Transfers**

- **Finding Funding**

- **Grant Writing Resources**

- **Resources and Policies for Emory Research Faculty and Staff**

- **Research Education Programs of the Georgia Clinical & Translational Science Alliance (Georgia CTSA)**

- **Confidentiality/Non-Disclosure Agreements (CDAs/NDAs)**

- **Investigational New Drug IND/ Investigational Device Exemption (IDE)**

  Investigational New Drug (IND)

  An Investigational New Drug Application (IND) is needed in advance of administration of any new drug or biological product that does not have an approved New Drug Application or a Biologics/Products License Application. An IND may be required for a clinical investigation using a marketed drug for a use other than the indications in the approved labeling. Information on INDs and submission help, can be found here: Drug Studies | Emory University | Atlanta GA

  The Office for Research Integrity and Compliance (ORIC) offers one-on-one consultations on IND requirements, protocol review, study start up, SOP development, Expanded Access, IND communications and Audit/FDA Inspection preparation. oric@emory.edu

  Investigational Device Exemption (IDE)

  An Investigational Device Exemption (IDE) is needed to use an investigational device in a clinical study of safety and effectiveness. This request must be secured before administering any new device that is not the subject of an approved Premarket Approval. An IDE may be required for a clinical investigation using a marketed device for a use other than the indications in the approved labeling. Information on IDEs and submission help can be found here: Device Studies | Emory University | Atlanta GA

  The Office for Research Integrity and Compliance (ORIC) offers one-on-one consultations on IDE requirements/application, protocol review, SOP development, Expanded Access, IDE communications and Audit/FDA Inspection preparation. oric@emory.edu

- **Data Use Agreements**

- **Incoming Data Transfer/Use Agreements** (DTA/DUAs): Skip the paper forms and use the form found on Emory contractConnect. The system will collect all of the pertinent information. **The system requires a valid Emory netid.** Send correspondence to ott-mta@emory.edu.
- **Outgoing Data Transfer/Use Agreements** (DTA/DUAs): Skip the paper forms and use the form found on Emory contractConnect. The system will collect all of the pertinent information. **The system requires a valid Emory netid.** Send correspondence to ott-mta@emory.edu.
- **Bi-lateral (reciprocal) Data Transfer/Use Agreements** (DTA/DUAs): Skip the paper forms and use the form found on Emory contractConnect. The system will collect all of the pertinent information. **The system requires a valid Emory netid.** Send correspondence to ott-mta@emory.edu.
- **Data Transfer Agreements Involving Human Subjects** (DTA/DUAs) that are part of an Emory clinical trial agreement, sponsored research agreement, or contract specifically governing human subject interaction/intervention by the Emory investigator where the prime funding agreement is currently under negotiation, send to osp-contracts@listserv.cc.emory.edu.

Include the Sponsor contact information in the email.

- **Training**
  - **CITI Training**
    - Creating a New Account
    - Associating an Existing Account

    **If you plan to conduct research at Children's Healthcare of Atlanta (Children's) and/or using Children's data, you should affiliate your account with Children's. You will receive credit for courses that overlap, but you will be required to take a few extra courses specific to pediatrics/Children's. If you have any trouble with your CITI Account, reach out to Sarah Marie Huban (ssmit37@emory.edu)*

  - **Emory Research Training:**
    - Orientation and baseline training is required for all staff new to Emory or new to clinical research for studies that meet the NIH-definition of a clinical trial (which includes FDA-regulated studies) at Emory. CME/CEU/Nursing credits are issued for several courses and organizations.

      Orientation and core course completion will be required before participation in any research study. If coursework is not completed by the submission of a new study or an amendment (e.g., adding personnel), the IRB will remove the staff from the study, and a hard stop will be imposed by the IRB. They will not be allowed to participate until the coursework is completed by showing a certificate of completion.

      Emory Healthcare (EHC) credentialing is required for Emory clinical research staff who have direct contact with subjects in an EHC facility and/or will need access to patient medical records for EHC subjects, including remote staff who need access to patient's medical records. Direct contact is defined as transporting patients, collecting specimens, obtaining vital signs, obtaining measurements, performing ECGs, phlebotomy, etc.). Investigators who are magnet-designated®, Clinical Research Nurses, Clinical Research Coordinators, or Other key personnel are to contact the EHC Research Credentialing Office, at research.credentialing@emoryhealthcare.org or 404.712.0510. Please review the Clinical Research Role Matrix to understand your roles and responsibilities. https://ocr.emory.edu/_includes/documents/emory-required-training-for-investigators-and-coordinators-v11.pdf

See page 2 for requirements at Emory affiliated sites (AVAMC, CHOA, and Grady).

- OnCore CTMS

  OnCore is a web-based enterprise-wide clinical trials management system (CTMS) that will simplify the management of clinical research and integrate multiple functions including protocol administration, participant tracking, and sponsor invoicing. OnCore CTMS will align with the Emory Healthcare Epic electronic medical record system to reduce redundancy across the enterprise and to enhance patient safety and research billing compliance.

  Studies requiring management in OnCore are the following:

  - All studies with Emory Healthcare or Grady billable items or services - regardless of sponsor/funder - requiring a Prospective Reimbursement Analysis (PRA) or Coverage Analysis (CA)
  - All studies that meet the NIH clinical trial definition regardless of billables (including interventional)
  - All studies where Office for Clinical Research (OCR) performs the invoicing (mainly industry/hybrids)

  OnCore CTMS training is to instinct clinical research staff on how to navigate OnCore consoles for protocol management, subject management, and financial management. The course is an instructor-led demonstration and simulation. Students participate in, practice and complete modules within OnCore. You can register for OnCore Training via Brainer under course name "OnCore Training". For more information about OnCore, visit the OnCore SharePoint site.

- **Environmental Health and Safety:**

  If you intend to work with any of the following in vitro or in vivo, you must complete Biological Registration:

  - Bacteria (infectious and non infectious)
  - Viruses (infectious and non infectious)
  - Fungi (infectious and non infectious)
  - Parasites
  - Human blood, body fluid, cell lines, fixed and unfixed tissue or Other Potentially Infectious Materials (OPIM)
  - Recombinant/synthetic nucleic acid molecules
  - Arthropods
  - Plants
  - Nanoparticles
  - Biological Toxins
  - Other Biological/Infectious Materials (Prions, Parasites, Fungi)
  - Non-Human Primate Material

  Guidance for working with Human Genes, Recombinant DNA, Fruend's Adjuvant, Human Cells and Tissues in Animals, Mammalian Material in Animals and/or Viral Vectors, more information can be found here: https://ehso.emory.edu/guidance/programs/research-safety.html

- **Children's Research Training:** Research Education is required if you are conducting research within the Children's system.

- Reach out to ResearchEducation@choa.org once proposal is ready.
- The Children's Research Education team will direct you to complete the Research Education REDCap form and provide project specific information. Training tracks will be assigned based on this information. All training assigned is required prior to starting research activities. Researchers are encouraged to start trainings as soon as their project has been identified.
    - Track 1: Retrospective Chart Reviews
        - Research Process Training: Computer Based Training (CBT), required for all researchers in the Children's system. A self-paced training module that will typically take an hour to complete.
        - Epic Training: 3 CBTs assigned through Workday. Task will typically take an afternoon to complete. Access is typically issued within 24 hours. *all research activities should be done within the Epic Research Template for auditing purposes*
    - Track 2: Prospectively Enrolling Studies
        - Research Process Training: CBT, required for all researchers in the Children's system. A self-paced training module that will typically take an hour to complete.
        - Epic Training: 3 CBTs assigned through Workday followed by a (approximately) 2-hour Instructor Led Course. Instructor Led portion is offered twice per month, Thursdays 9 am -11 am at the Children's Support Center (1575 Northeast Expwy NE). *all research activities should be done within the Epic Research Template for auditing purposes* This class reviews consenting procedures, consent documentation, linking visits, and other required action items for research staff within Epic. Access is typically issued within 24 hours of completion of the instructor-led course.
        - Clinical Research Administration Orientation: 2-hour instructor led course via WebEx offered the 2nd Tuesday of each month 10 am – 12 pm. Class currently capped at 30 and can permit overflow as needed.
        - CTMS Training: CTMS is Children's Clinical Trial Management System and works in conjunction with Epic. 30-minute instructor-led course via WebEx offered the last Wednesday of each month at 3 pm.

- **Research Sites**

  Hughes Spalding

  Children's Hughes Spalding Hospital is located in downtown Atlanta near Edgewood Avenue and Grady Memorial Hospital. This facility offers many services, including an Emergency Department that is open 24 hours a day.

  Emory Children's Center – Research Unit ECC-RU

  The Emory-Children's Center Research Unit (ECC-RU) is located on the first floor of the Emory-Children's Center Building, within the Children's Specialty Services Clinic. It is Emory University space, managed by the Department of Pediatrics. The ECC-RU is dedicated to clinical research activities and is available for IRB approved protocols conducted by Emory Department of Pediatrics faculty and their team members. The unit contains a research staff work room, storage room, phlebotomy chair, two exam rooms and one interview room which can also be used as an exam room.

Pediatric Research Unit (PRU)

The Children's Healthcare of Atlanta Pediatric Research Unit (PRU) is located on the 5th floor of the Center for Advanced Pediatrics and improves the ability of pediatric researchers to perform innovative research while providing patients and their families with increased access to leading-edge clinical trials. The Children's Pediatric Research Unit is available for patients coming to Children's for research visits. Depending on the particular research study, participants visit either the outpatient or inpatient unit.

Grady

The Grady Health System, the primary teaching facility of the Emory University School of Medicine, is a Level 1 Trauma Hospital that serves a primarily inner-city, minority, and low-income population from metropolitan Atlanta and Fulton and DeKalb Counties. The Grady Health System includes a general hospital (the largest in Georgia and among the largest in the country), as well as multiple outpatient clinics.

- **Determine which IRB to submit to:** determine where to submit: childrens-emory-routing-flow-08022022-final.pdf

  If your study doesn't fit into this flowchart or if you have questions, reach out to irb@choa.org for guidance.

- **Drafting a Protocol**

  If you are responsible for drafting your protocol, consider which IRB you will need to submit to and use the template from the appropriate institution.

  If you plan to submit to the ***Children's IRB***, use the appropriate template below:

  Full Protocol Template

  Retrospective Chart Review Protocol Template

  If you plan to submit to the ***Emory IRB***, choose the appropriate protocol template:
  https://irb.emory.edu/forms/protocol-templates.html

- **Drafting Consent/Assent Forms**

  If you are responsible for drafting your consent/assent forms, consider which IRB you will need to submit to and use the template from the appropriate institution.

  If you plan to submit to the ***Children's IRB***, use the appropriate template(s) below:

  Consent and HIPAA Authorization Form

  Assent

  Verbal or Electronic Consent/Assent

  If you plan to submit to the ***Emory IRB***, use the appropriate template(s) below:

  CHOA Consent/HIPAA Template

  CHOA Consent/HIPAA Template for Hughes Spalding

  Assent

Verbal/Electronic Consent

Some studies may be eligible for a waiver of consent, a waiver of documentation of consent or Exception from Informed Consent. Work with your IRB analyst early in the process, if you believe your study may fall into one of those categories.

Research Offices and Contacts

Emory

Office	Role	Contact
Institutional Review Board (IRB)	Ensures research with human participants is done safely and that the expected benefits of research balance out the risk to participants.	irb@emory.edu
Institutional Animal Care and Use Committee (IACUC)	Monitors all research activities related to animal use.	iacuc@emory.edu
Office of Sponsored Programs (OSP)	Handles proposals, contracts, and awards; including subcontracts.	osp@emory.edu
Office of Technology Transfer (OTT)	Responsible for some data use agreements and confidentiality agreements. OTT handles the intellectual property rights of the University.	ott@emory.edu OTT Contacts
Research Administration Services (RAS)	Provides faculty assistance with pre- and post-award research administration activities (i.e., proposal, budgets, and financial close out, etc.)	pediatric.ras@emory.edu Portfolio Assignments
Research Grants and Contracts	Provides post-award research administration services (i.e., award set-up, financial status reports, managing collections, etc.)	rgc@emory.edu
Office for Clinical Research (OCR)	Pediatric studies with Emory healthcare billables route to OCR and OCR is used for CT.gov registration.	OCR@Emory.edu
Research Compliance & Regulatory Affairs (RCRA)	Implements processes and policies and provide training to comply with requirements and regulations (i.e., eCOI, Research Misconduct, Export Control, Controlled Substances, etc.)	Contact Us | Emory University | Atlanta GA
Environmental Health and Safety	The Research Safety unit provides consulting services, training programs, and regulatory compliance support to all University community members. This includes but is not limited to the following: review of biological and chemical safety registrations, bloodborne pathogen and laboratory safety training, laboratory signage, and laboratory assessments.	https://ehso.emory.edu/about/research-safety.html

Children's Research Administration Offices

Office	Role	Contact
Children's IRB	Ensures research with human participants is done safely and that the expected benefits of research balance out the risk to participants.	irb@choa.org
Research Administration	Handles proposals, contracts, and awards; including subcontracts. Provides faculty assistance with pre- and post-award research administration activities (i.e., proposal, budgets, and financial close out, etc.)	researchadministration@choa.org

**If you have any issues with responsiveness, feel free to contact Sarah Marie Huban (ssmit37@emory.edu) for assistance.*

Once you have a Protocol/Final Study Documents

If you are **unsure whether your project need IRB review**, review the guidance found here: https://irb.emory.edu/guidance/getting-started/review.html

If you haven't already, determine **where to submit**: childrens-emory-routing-flow-08022022-final.pdf

Do not proceed to the next steps until you have final study documents (i.e., protocol, consent (if applicable), budget (if applicable) and contract (if applicable).

- Skip to Funded Studies routing to Emory
- Skip to Unfunded Studies routing to Emory
- Skip to Funded Studies routing to Children's
- Skip to Unfunded Studies routing to Children's

If you will be conducting research at Hughes Spalding or Grady, click here after reviewing Emory/Children's requirements.

Funded Studies routing to Emory

The following tasks should be done concurrently.

- **Submitting to Emory RAS:**
  - **Complete the Intent to Submit**: https://redcap.emory.edu/surveys/?s=LHX5hbYReH

    Grant Proposals: submit 30 days prior to agency deadline, 60 days prior for complex awards

    Clinical Trials: submit when all documents have been received by the sponsor (FINAL: protocol, contract and budget) and the appropriate division/departmental approvals have been obtained to move forward with the study
- **Submit to the IRB, if applicable**: https://eirbemory.huronresearchsuite.com/
  - New users - Emory IRB uses single sign on (SSO), so you should use your Emory NetID to log in. Once you log in, your account will be created automatically.
  - Guidance on submitting to the IRB can be found here: https://irb.emory.edu/forms/eirb/how-to.html If you have additional questions, reach out to Sarah Marie Huban (ssmit37@emory.edu)
  - Submit this form to the CHOA IRB even when Emory is the IRB of record: CHOA IAA Acknowledgement Form
- **Be aware of contracting requirements.**
  - Contracting - Contract initiation is largely trigged by the Intent to Submit form. However, you should be aware of the requirements for your project (i.e., data use agreement, subcontract). More information can be found on the Office of Sponsored Programs website https://osp.emory.edu/

Unfunded Studies routing to Emory:

The following tasks should be done concurrently.

- **Submit to the IRB, if applicable**: https://eirbemory.huronresearchsuite.com/
  - New users - Emory IRB uses single sign on (SSO), so you should use your Emory NetID to log in. Once you log in, your account will be created automatically.
  - Submit this form to the Children's IRB even when Emory is the IRB of record: CHOA IAA Acknowledgement Form

        - Guidance on submitting to the IRB can be found here: https://irb.emory.edu/forms/eirb/how-to.html If you have additional questions, reach out to Sarah Marie Huban (ssmit37@emory.edu)

- **Be aware of contracting requirements.**
    - If you will have *access to Children's data, but will not conduct research in a Children's location*, you will need a Data Use Agreement (DUA). If you submit the CHOA IAA Acknowledgement Form, Children's will automatically start the process for the appropriate agreement.
    - If you will *conduct research in a Children's location*, you will need a Research Agreement. If you submit the CHOA IAA Acknowledgement Form, Children's will automatically start the process for the appropriate agreement.

Funded Studies routing to Children's

The following tasks should be done concurrently.

- **Complete the Children's Feasibility Review Form:** https://redcap.choa.org/redcap/surveys/?s=K38YM4A7Y7LKM3NY
    - Feasibility Review is required for new sponsored studies (industry, federal, consortium, investigator-initiated, and internally funded). Upon feasibility review approval, the budget (including coverage analysis), contracts, and IRB reviews may occur in parallel.

- **If your study requires Emory services or subcontracting, complete the Intent to Submit**: https://redcap.emory.edu/surveys/?s=LHX5hbYReH
    - Any studies that will require Emory services or sub-contracting will still need to submit into PRISM and Emory's Intent to Submit form after Feasibility approval.

- **Submit to the IRB, if applicable**: https://eirbchoa.huronresearchsuite.com/
        - New users - Emory IRB uses single sign on (SSO), so you should use your Emory NetID to log in. Once you log in, your account will be created automatically.
        - Guidance on submitting to the IRB can be found here: https://www.choa.org/-/media/Files/Childrens/research/irb/eirb_newstudy_modificationtipsheet.pdf?la=en&hash=7250C0CC738C8A97370B8E82F8227ECE460A2218

Unfunded Studies routing to Children's

- **Submit to the IRB, if applicable**: https://eirbchoa.huronresearchsuite.com/
        - New users - Emory IRB uses single sign on (SSO), so you should use your Emory NetID to log in. Once you log in, your account will be created automatically.
        - Guidance on submitting to the IRB can be found here: https://www.choa.org/-/media/Files/Childrens/research/irb/eirb_newstudy_modificationtipsheet.pdf?la=en&hash=7250C0CC738C8A97370B8E82F8227ECE460A2218

- **Be aware of contracting requirements.** Upon IRB submission, Children's will automatically start the process for the appropriate agreement.

Research at Hughes Spalding: If you plan to conduct research at Hughes Spalding, reach out to Marco Benoit.

Research at Grady: If you plan to conduct research at Grady, you will need to submit to the Grady Research Oversight Committee (ROC) after Emory or Children's IRB approval has been obtained. More information can be found here: https://www.gradyhealth.org/office-of-research-administration/

Managing a Study

It is important to maintain IRB approval and reconcile financial accounts on a regular basis.

Ensure IRB approval and eNOA are received from Emory and Children's (if applicable) before starting the project.

If you are conducting a Clinical Trial, review the Clinical Trials Guidebook.

- **IRB**
  - Review the protocol and consent documents to ensure no changes are needed.
  - Train staff on protocol.
  - Set up study binders that include essential documents.
  - Create a Delegation of Duties log, if applicable.
  - Create an Enrollment Log, if applicable.
  - Other Organizational Log templates (Adverse Events, Specimens, Protocol Deviations) can be found here: https://ctac.emory.edu/guidebook/organizational-logs.html
  - Changes: Any revisions to approved study documents, must be submitted to and approved by the IRB in advance of the change. How to Submit an Amendment in eIRB
  - Reportable Events: How to Submit a Reportable Event in eIRB
  - Continuing Reviews: How to Submit a Continuing Review in eIRB

    Amendment/Modification, Reportable Events and Continuing Review guidance can be found here: https://irb.emory.edu/guidance/faqs/eirb-saas.html (scroll to relevant section)

- **Post-Award**
  - Attend regular meetings (at least quarterly) with your Post-Award team.
  - Review Emory Purchasing Guidelines and request Emory Express training, if needed. Review allowable expenditures in the grant budget before making purchases.
  - Review Emory Effort Reporting requirements. Federal awards represent the majority of Emory's sponsored project grant and contract award activity. Salary expense represents the largest direct cost component included in the budgets of sponsored projects. Paying salaries with federal funds requires an institution to have a system that provides records on how individuals participating in federally funded sponsored agreements actually spend their time. It is incumbent upon institutions receiving federal funding to maintain accurate and auditable systems and records.
  - Track progress towards pending of project funds in accordance with approved grant budget.
- **Contracts**
  - Carefully re-read the grant proposal, review the award notification and read any other guidance provided by funder on managing the award.
  - Review the funder's policy on publicity. The funder may have included specific language or restrictions in the contract that must be followed when issuing press announcements or creating project-related materials.
  - Make note of important deadlines and set up a process to track deliverables, including:
    - Interim and final progress/narrative reports
    - Interim and final financial reports
    - Deadlines for requesting Scope of Work or budget modifications
    - Deadline for requesting no-cost extensions

Closing a Study (start this process approx. two months prior to award end date)

The closeout is a critical piece in the life cycle of a grant. All awards have different reporting requirements and end dates that require a variety of closeout procedures. Please read your award carefully to determine the requirements of your award.

- **Notify HR of the end date for grant-funded positions.**
- **Closing a Study with RAS**
    - Complete all proposed project activities and services by the study end date.
    - Work with your post-award analyst to be sure you are on track to spend down all funds by the award end date. *If you anticipate issues with completing the project on time, determine if a no-cost extension is appropriate and allowed. Contact your post-award analyst, if you plan to request a no-cost extension.*
    - Ensure all costs are appropriate and transactions have been properly recorded (i.e., verifying restricted categories are spent account to award notice, verifying F&A charges are correctly posted, verifying cost sharing requirements are identified and recorded, verifying that any program income is properly recorded.
    - Work with RAS to schedule, prepare and complete the final narrative and financial reports (i.e., fiscal closeout, intellectual property certification, final progress report)
- **Closing a Study with the IRB**
    - A study cannot be closed if:
        - You are still collecting follow-up data;
        - The sponsor is still reviewing collected data (i.e., asking study teams to verify data);
        - The study is submitted for publication and it is likely the publisher will ask for additional data;
        - Data analysis with identified data with PHI is ongoing;
        - The study is under an Emory sponsor and the final IND or IDE reports need to be submitted to the FDA.
    - When you are ready to close your study, submit a close-out request before study approval expiration. Don't let your IRB approval lapse, even if your study is about to close.

**Don't sign any legal documents without routing through Research Administration.*
**Don't accept checks/payments directly from the funder.*
**Don't overspend on the project budget.*
**Make commitments on behalf of Emory without prior authorization*