A GUIDE TO GETTING YOUR CLINICAL TRIAL

GOING AT EMORY UNIVERSITY

DEPARTMENT OF MEDICINE

Digestive Diseases

2014
If you have a multi-center clinical trial, the confidential disclosure agreement (CDA) needs to be signed, submit the CDA to the Office of Sponsored Programs (OSP) at email below for review before the sponsor sends protocol to you. **OSP-CONTRACTS@LISTSERV.CC.EMORY.EDU**

Once the CDA is signed by OSP and the sponsor, review protocol, contract template, budget (if already prepared, otherwise the Office of Clinical Research (OCR) will assist. See below), IDE or IND number (*if applicable*) from the sponsor.

Determine how the trial will be operationalized. Identify where procedures will take place since this can have a significant impact on how the prospective reimbursement analysis PRA and budget are developed.

If the trial has radiology procedures, submit to radiology for review just prior to OCR submission by completing the Radiology Research Checklist.

If the research study will use one of the Clinical Research Network (CRN) sites, submit the initial application with the other documents. Or if you have CRC/ACTSI approval, provide their letter of support.

Additionally, it may be helpful to contact affiliated sites if subjects are enrolled at any
of the following sites to obtain additional guidance on what is required:

- Atlanta Veteran’s Administration Medical Center (AVAMC);
- Children’s Healthcare of Atlanta (CHOA);
- Clinical Research Network (CRN);
- Grady Memorial Hospital (GMH).

1. **If your study has billables, submit your study to the DOM RAS Pre-Award Specialist, Lisa Warren. She will create the OCR submission form and submit to the Office of Clinical Research (OCR) for budget creation**

How to Submit to OCR:

Ms. Warren will submit the following documents in **EPEX**. Ensure a “complete” submission which consists of the following:

The Pre-award unit of OCR will assist with this:

- **OCR Submission Form**-All items must be filled out completely for both initial and amendment submissions
- Protocol-final version, draft protocols cannot be accepted
- Draft Inform Consent (Emory draft required)
- Draft Clinical Trial Agreement (CTA) or contract/Award (if Federal funding)
- Draft Budget Template
- **Investigator Effort calculation**
• Most recent FDA communications, e.g., IND letter that includes IND number, IDE letter that includes IDE number and category assignment

• If using any CHOA services, submit the budget grid from CHOA’s CTO which accompanies the BAF (Budget Approval Form).

2. Also submit your proposal to the IRB with:

• Written Protocol
• Draft informed consent using Emory template
• Drug/device Information
• Recruitment material

3. You or Ms. Lisa Warren will send Study Contract that includes the finalized budget to the Office of Sponsored Program (OSP) via EPEX system

• OSP gets the contract for review and negotiation. They are our lawyers!!!

This is often the rate limiting step!!!

4. Follow up on approvals and completed contracts/budgets from:

• OCR
• OSP
• IRB

You will sign these and be ready to execute on your study.

There is often a bit of back and forth before these approvals are completed. Don’t give up.
Important Offices and Contact Information

Office of Clinical Research (OCR)
OCR review is required for studies with billable items and services: OCR@emory.edu

Margaret Douglas 404-778-3888
Associate Executive Director
Post-Award

Sheila O’Neal 404-778-2606
CR Finance Supervisor  soneal@emory.edu
Pre-Award

Judith Robinson 404-712-9751
CRFM, Lead  jmrobi3@emory.edu
Pre-Award

Vickie Swafford 404-778-4521
CR Finance Supervisor  vswaffo@emory.edu

Michelle Robinson 404-712-7260
Invoicing  mrrobi4@emory.edu

Bridget Strong 404-778-2967
Director, Education/Outreach  bstrong@emory.edu

Wenona Favors 404-712-7117
Education & Outreach  wenona.favors@emory.edu
Research Services Consultant
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Office of Sponsored Programs (OSP)

1599 Clifton Road, 4th Floor, Atlanta, GA 30322
Phone (404) 727-2503
Fax (404) 727-2509 or (404) 712-3026
Email: osp@emory.edu
Payment Correspondence: ogcacmt@emory.edu

OSP is divided into two teams:

OSP Grants – handles proposals and awards

Holly Sommers 404-727-2507
Director Pre-Award Grants

OSP Contracts- handles industry and non-industry contracts

Nikki Simmons 404-727-7334
Director Pre-Award Contracts

Institutional Review Board (IRB)

1599 Clifton Road NE, 5th Floor
Atlanta, GA 30322
Phone: (404) 712-0720
Fax: (404) 727-1358
Website: http://www.irb.emory.edu

Rebecca Rousselle 404-712-0785
Interim Director

Sam Roberts 404-712-0761
Sr. Research Protocol Analyst
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VA Research and Development Committee (R&D)
All studies using the Atlanta VA Medical Center as a site must seek VA R&D approval after IRB approval has been obtained.

Daniel Roysden 404-712-9749
Sr. Research Protocol Analyst

David Knight 404-321-6111 ext 4827
Science Information Officer

Jane Guidot 404-321-6111 ext 6933
Clinical Studies Center Manager

Nakela Jackson 404-321-6111 ext 6177
Research Credentialing and Training Officer

Priscilla Miller 404-321-6111 ext 2512

David Worley 404-3327-4943
Clinical Studies Center

Office of Research Compliance (ORC)
ORC offers counseling to all Emory investigators acting both as sponsor and investigator

Margaret Huber 404-727-2233
mhuber@emory.edu
Research Billing Compliance
Phone: 404778-4960 or OCR@Emory.edu

Tiffani Pierce 404-727-3471
Clinical Research Billing Supervisor
tiffani.pierce@emoryhealthcare.org

Janice Newman 404-778-5915
Manager, Business/Patients Accounts

Chaunda Mitchell 404-778-2676
Clinical Research Billing Specialist
Chaunda.mitchell@emoryhealthcare.org

Renee Osborne 404-778-2312
Clinical Research Grant Coordinator
Renee.osborne@emoryhealthcare.org

Participant Stipend Fund (PSF)
Building 1599 front desk (check pickup)
404-727-2859

Damian Alston 404-727-5400
Payment Services

Monique Day 404-727-2859
Officer of Controller

Reginald Boozer 404-727-6331
Administrative Assistant
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**Investigational Drug Service (IDS)**

Monitor Visits: schedule visits by e-mailing  
Ehc.idsvsvisit@emoryhealthcare.org

Susan Rogers  
Registry Pharmacist  
404-712-7485

Jianguo Xu  
404-712-2547

Esther Park  
404-778-0674

**VA Pharmacy**

Mehran Salles  
Program Manager  
Khadijeh.SallesShahid@va.gov  
404-321-4214

Linda Skinner  
Pharmacist  
linda.skinner1@va.gov  
404-321-6111

**EUH Lab Support Services**

Mary-Jo Ploessl  
Technical Coordinator  
(EUH lab support services/  
blood processing/dry ice)  
404-712-5059

Lynn Mcclure  
Lab Technical Coordinator (EUH)  
404-712-7373

Jean Nation  
Medical Technologist  
404-712-7791
Marsha Twitty 404-712-7312
Technical Coordinator (EUH Microbiology)

Colleen Kraft, MD 404-712-8889
Medical Director
Microbiology department/infectious disease

Nancy Arroyo 404-712-7287
Lab Supervisor

Department Access Coordinator/Medical Record Access

Wanda Barlow 404-778-3055
Administrative Assistant/GI

Don Carpenter 404-712-1947
Access Control/Medical Records

Brittany Tharp 404-778-3808
Supervisor of Health Information
Department of Medicine Research Administration
Service (RAS) Team

**RAS Team website:**
http://medicine.emory.edu/research/administration

**Pre-award team:** domraspreaward@emory.edu
**Post-award team:** domraspostaward@emory.edu

**Director**
404-727-4230
Nancy Jenkins

**Training/Certificates**

**Myra Kitchin**
404-712-0510
Credentialing Specialist
Myra.Kitchin@emoryhealthcare.org

**Brenda Seiton**
404-727-4406
Assistant VP/Research Administrator

- **Collaborative Institutional Training Initiative (CITI)** (every 2 years) [www.citiprograms.org](http://www.citiprograms.org)

- **Key concepts in Clinical Research for Investigators** (every 2 years) [www.elmprod.emory.edu](http://www.elmprod.emory.edu)

- **Conflict of Interest (COI)** (every year or when start a new contract) [www.ecoi.emory.edu](http://www.ecoi.emory.edu) or contact
Atlanta Clinical and Translational Science Institute (ACTSI)

http://www.atlantactsi.org/areas/crn/index.html

- Inpatient and/or outpatient nursing units and/or use of resources provided by the Core Laboratory and Bionutrition services
  - **Debora Clem** 404-712-1993
    
    *Administrative Director*

- **REDCap**: CRN Support for Research Electronic Data Capture: redcap.help@emory.edu.

- **ResearchMatch**: A secure place for volunteers and researchers to get connected
  
  - **Khushbu Amin**: 404-712-4779
  - **Elizabeth Thompson**: 404-727-2579
  - **Rebecca Rousselle**: 404-712-0785

Biostatistics, Epidemiology & Research Design:
actsi@emory.edu or (404) 727-9296.

Frequently Asked Questions
(Study feasibility Questionnaire)
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- **What is the OHRP (Office for Human Research Protections) registration number of Emory’s IRB?** IORG # 0000267

- **How much time is required in advance to submit to the IRB?** There is no “submission deadline” per se, rather a completed study submission will be sent to the next available meeting.

- **How often does the IRB committee meet?** Biomedical meets 6x/month: every Wednesday, 2nd Thursday & 4th Tuesday. Sociobehavioral meets 1x/month: 1st Friday

- **Are any local, national, or internal committee reviews required prior to IRB/IEC submission or approval?** Yes, Departmental Review

- **What is the general turnaround time from meeting date to written approval?** 1-2 months however, it varies depending on the contract negotiation. *(Most pending issues can be resolved within a few days. But IRB can’t issue final approval until the “in case of injury” and “costs to subjects” consent sections are finalized, which depends on the contract being finalized for those terms)*

- **Can our site use a Central IRB/EC?** Emory is selective about using central IRB’s, but we do rely on WIRB for all Phase III industry-sponsored drug and device trials. We also rely on NCI’s CIRB for NCI-funded studies. Other studies are looked at on a case-by-case basis but generally Emory IRB will review.
Is a final contract and budget required before submission to IRB? – Not at all. IRB submission is encouraged as early on in the process as possible. As mentioned above, though, final IRB approval depends on the subject injury terms being finalized in the contract (though the rest of the contract doesn’t need to be finalized) and the PRA (*Prospective Reimbursement Analysis*) being completed at OCR.