A GUIDE TO GETTING YOUR CLINICAL TRIAL

GOING AT EMORY UNIVERSITY

Initial Steps and Important Contact Information

DEPARTMENT OF MEDICINE

2016

- **If you have a multi-center clinical trial, the confidential disclosure agreement (CDA) needs to be signed therefore 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

  Contract Tracking System (eCTS): provides the status of incoming agreements handled by the OSP Contracts Unit.

http://www.ogca.emory.edu/ra-systems/ects.html

- Once the CDA is signed by OSP and the sponsor reviews it, you should receive a protocol, contract template, budget (if already prepared, otherwise the Office of Clinical Research (OCR)) will assist. See below), and 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.

- Complete the clinical research readiness checklist including lab, nursing and radiology checklist. If the trial has radiology procedures, submit to radiology for review just prior to OCR submission by completing the Radiology Research Checklist. http://www.irb.emory.edu/forms/clinical.html

  For more information, contact Laura Dean at 404-778-7931

- If the research study will use one of the Clinical Research Network (CRN) sites, submit the initial application with the other documents to the CRN Or if you have CRC/ACTSI approval, provide their letter of support.
  http://actsi.org/what-we-do/index.html

- 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).

Next, send to the following:

1. Office of Clinical Research

How to Submit to OCR:

(Only necessary if your study has billables)

Email all appropriate document below to

- OCR at OCR@emory.edu

And

Research Administration Services (RAS team) at domraspreaward@emory.edu. The RAS unit will ensure that proposals are entered and routed in a timely manner and assist the PI in preparing and finalizing the budget justification for each proposal. **(see below for team contact information)**

Documents to be submitted:

- *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 current Emory template: http://www.irb.emory.edu/forms/consent_toolkit/index.html
- Drug/device Information
- Recruitment material

3. Office of Sponsored Programs (OSP) also gets the budget for review and negotiation. They have the final authority on all budgets being submitted.

This is often the rate limiting step!!!

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

- OCR
- RAS
- OSP
- IRB

There is often a bit of back and forth before these approvals are completed. Don't give up.
OSP will communicate award acceptance. Please note that award does not become official until an eNOA is issued.

RAS Post Award team will assist with the following:
domraspostaward@emory.edu
(see below for team contact information)

- Requesting sub-awards
- Reconciliation and projection of expenses
- Invoicing (for some award types)
- Effort pre-certification
- Facilitating award changes
- Financial close out of the award

Important Offices and Contact Information

Office of Clinical Research (OCR)

1599 Clifton Road
5th Floor, Northwest
Atlanta, GA 30322
Telephone: (404) 778-4960
Fax: (404) 778-4989
Email: **OCR@Emory.edu**
Website: http://www.ocr.emory.edu

ADMINISTRATIVE

Robin Ginn 404-778-2977
Executive Director
rginn@emory.edu

DATA INTEGRITY

Vickie Swafford 404-778-4521
Associate Director
vswaffo@emory.edu

Rekha Menon 404-778-2994
Research Services Consultant-clinical trials
Rekha.g.menon@emory.edu

Jennifer L. Prozonic,
Supervisor, Clinical Trials Compliance 404-778-3840
jprozon@emory.edu

Janis Phillip 404-712-0864
Data Information Specialist
janis.phillip@emory.edu

EDUCATION

Bridget Strong 404-778-2975
Director
bstrong@emory.edu

Wenona Favors 404-712-7117
Research Services Consultant
Wenona.favors@emory.edu

INVOICING

Michelle Robinson 404-712-7260
Associate Director
michelle.r.robinson@emory.edu

Stephani Britt 404-727-2949
Clinical Research Finance Manager
stephani.britt@emory.edu

Lavezza Zanders 404-778-3342
Clinical Research Finance Manager
lzander@emory.edu

PRE_AWARD

Sheila O'Neal 404-778-2606
CR Finance Supervisor
soneal@emory.edu

Sally Mountcastle 404-727-8328
CR Finance Manager
smountc@emory.edu

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

SUPPORT SERVICES

Sherry Coleman 404-727-4371
Associate Director
Sherry.coleman@emory.edu

Research Administration Service Team (RAS)

Woodruff Memorial Research Building (WMB)
1639 Pierce Drive NE
Atlanta, GA 30322
2nd floor
Rooms 2001 through 2009

Nancy Jenkins 404-727-4230
Director
nancy.c.jenkins@emory.edu

Pre-Award:

Jill Allen 404-712-2743
Pre-award Lead
jsalle3@emory.edu

Vaneita Adams 404-712-1429
Vadams2@emory.edu

Ashley Gorham 404-712-1034
adgorha@emory.edu

Chryssi Laguines 404-727-2142
claquin@emory.edu

Lawrence Rapier II 404-712-4054
lrapierii@emory.edu

Sandra Lea Justice 404 727-5771

sjustu2@emory.edu

Post-award

Mandi Blochberger 404-712-5963

Post-Award Lead

C. Tyler Bello 404-727-4561
tyler.bello@emory.edu

See website for additional contacts
http://medicine.emory.edu/research/internal-research-resources/administration/research-administration-service-team.html

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

Artis Hill 404-727-2508
artis.hill@emory.edu

OSP Contracts- handles industry and non-industry contracts

Shirley Vanier 404-727-2333
(Industry)
svanier2@emory.edu

Kanika Moss 404-727-1051
(non-industry)
Kanika.moss@emory.edu

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

Maria Davila 404-712-0724
Team Lead QA and Education Consultant

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

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

Investigational Drug Service (IDS)

http://ocr.emory.edu/ids/index.html

Monitor Visits: schedule Visits

http://www.ocr.emory.edu/ids/

(For monitors to schedule visit, click on link above, then click IDS Appointments for IDS Calendar)

Susan Rogers 404-712-7485
Registry Pharmacist

Jianguo Xu 404-712-2547

Esther Park 404-778-0674

VA Pharmacy

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

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

EUH Lab Support Services

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

Jean Nation 404-712-7791
Medical Technologist

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
(Clinic A)

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

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
- *Key concepts in Clinical Research for Investigators(every 2 years)* www.elmprod.emory.edu
- *Conflict of Interest(COI) (every year or when start a new contract)* 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

- **Kateisha Dowdell** *: CRN Scheduler :404-712-2901*
- **Guerline St***. Louis :CRN Coordinator : 404-712-7686*
- **Elizabeth Thompson***: 404-727-2579*

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

Frequently Asked Questions

For Study feasibility Questionnaire

- **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.