# Table of Contents

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speaker:</th>
</tr>
</thead>
</table>
| Overview of Research in the School of Medicine                       | Jeremy M. Boss, Ph.D.  
Emory Chair in Basic Sciences Research  
Professor and Chair, Department of Microbiology & Immunology  
Associate Dean for Basic Science Research |
| Emory Integrated Core Facilities                                      | Jeremy M. Boss, Ph.D.                                                  |
| Lab Management                                                        | Jeremy M. Boss, Ph.D.                                                  |
| How the Office of Research can Help You                               | Kimberly Eck  
Associate Vice President for Research, Emory University             |
| Institutional Review Board (IRB)                                      | Rebecca Rousselle  
Director, IRB                                                           |
| Clinical Research Resources                                           | Sherry Coleman  
Associate Executive Director, Clinical Trials                         |
| The Grant Lifecycle                                                  | Teresa Sussman  
Director, Grants, OSP                                                   |
| -Working with Research Administration Services (RAS)                 | Becky Rogers  
Interim Executive Director, RAS                                         |
| -Office of Sponsored Programs (OSP)                                  | Jumionne Tiako  
Associate Director, RGC                                                  |
| -Research Grants and Contracts (RGC)                                 | Brian Miller  
Financial Manager, RGC                                                  |
| Getting involved with GDBBS                                           | Nicole Gerardo  
Interim Director, GDBBS                                                  |
| Resources for Postdoctoral Fellows                                    | Lou Ann Brown, PhD  
Director, Office of Postdoctoral Education                               |
| Institutional Animal Care and Use Committee (IACUC)                  | Esmeralda Meyer  
Interim Director, IACUC Office                                           |
RESEARCH IN EMORY UNIVERSITY SCHOOL OF MEDICINE

JEREMY M. BOSS, PH.D.
EMORY CHAIR IN BASIC SCIENCES RESEARCH
PROFESSOR AND CHAIR, DEPARTMENT OF MICROBIOLOGY & IMMUNOLOGY
ASSOCIATE DEAN OF BASIC RESEARCH
RESEARCH ADMINISTRATION: DEAN’S OFFICE

Deanlets

- Allen Levey, MD, PhD  
  *Interim Executive Associate Dean*
- Jeremy Boss, PhD  
  *Associate Dean for Basic Research*
- Haian Fu, PhD  
  *Associate Dean for Innovation & International Strategies*
- Jeff Lennox, MD  
  *Associate Dean for Clinical Research*
- Suresh Ramalingam, MD  
  *Associate Dean for Cancer Research*
- TBD  
  * Associate Dean for Novel Technology & Research Cores*

Support

- Lisa Carlson, MPH, MCHES  
  *Executive Administrator, Research Administration*
- Carlton White, MBA, CPA  
  *Associate Director, Research Finance and Operations*
- Krista Charen, MPH  
  *Associate Director, Research Projects*
- Darryl Barr  
  *Director, Strategic Data Analytics*
WHAT WE DO

• Facilitate development and implementation of research initiatives across core SOM missions

• Create and implement processes and tools to improve SOM endeavors
FUNCTIONS OF THE RESEARCH DEAN’S OFFICE

- Emory Integrated Core Facilities
  - Division of Animal Resources
- Clinical Trials and Translational Research Activities
- Bridge funding programs
- Research Recognition Awards
- Office of Postdoctoral Education
- VA Memorandum of Understanding
- Letters of Support
SCHOOL OF MEDICINE AWARD TRENDS

3362 proposals
2796 Awards
NIH FUNDING TO MEDICAL SCHOOL INVESTIGATORS (ALL LOCATIONS)
DATA SOURCES: NIH AND BRIMR.ORG

<table>
<thead>
<tr>
<th># of NIH funded PIs</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty</td>
<td>301</td>
<td>301</td>
<td>317</td>
<td>333</td>
<td>335</td>
</tr>
<tr>
<td>Fellowship Recipients</td>
<td>55</td>
<td>59</td>
<td>60</td>
<td>62</td>
<td>59</td>
</tr>
<tr>
<td>Total PI Count</td>
<td>356</td>
<td>360</td>
<td>377</td>
<td>395</td>
<td>394</td>
</tr>
</tbody>
</table>

NIH COVID-19 Response Funding to Medical Schools

Cumulative to date, Emory Medical School investigators have had the most NIH COVID-19 response projects funded (58).

Cumulative to date, Emory Medical School investigators have received 10.5% of all NIH COVID-19 response funds to medical schools (third highest $)

NIH COVID-19 Response Funding (Medical Schools)

<table>
<thead>
<tr>
<th>Medical School (Top 10)</th>
<th>NIH COVID Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNIVERSITY OF CALIFORNIA LOS ANGELES</td>
<td>$234,483,130</td>
</tr>
<tr>
<td>DUKE UNIVERSITY</td>
<td>$188,631,514</td>
</tr>
<tr>
<td>EMORY UNIVERSITY</td>
<td>$142,624,173</td>
</tr>
<tr>
<td>UNIV OF MASSACHUSETTS MED SCH WORCESTER</td>
<td>$128,769,857</td>
</tr>
<tr>
<td>NEW YORK UNIVERSITY SCHOOL OF MEDICINE</td>
<td>$55,026,977</td>
</tr>
<tr>
<td>JOHNS HOPKINS UNIVERSITY</td>
<td>$34,735,764</td>
</tr>
<tr>
<td>UNIVERSITY OF MARYLAND BALTIMORE</td>
<td>$32,740,207</td>
</tr>
<tr>
<td>UNIVERSITY OF CALIFORNIA, SAN FRANCISCO</td>
<td>$31,521,858</td>
</tr>
<tr>
<td>STANFORD UNIVERSITY</td>
<td>$31,352,120</td>
</tr>
<tr>
<td>SAINT LOUIS UNIVERSITY</td>
<td>$25,775,548</td>
</tr>
</tbody>
</table>
SCHOOL OF MEDICINE AWARD STATS / TOP TENS

# of faculty, postdocs, staff, and students paid on SOM sponsored projects in FY21: 3766

# of SOM research infrastructure team members (DAR, Core Labs, Research Admin/RAS) >250

# of Contact PIs with FY21 funding > $1M 136

Top 10 Sponsoring Agencies - FY2021

<table>
<thead>
<tr>
<th>Sponsor incl Flow Thru</th>
<th>Total Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>NATL INSTITUTES OF HEALTH</td>
<td>417.6M</td>
</tr>
<tr>
<td>CENTERS FOR DISEASE CONTROL</td>
<td>24.9M</td>
</tr>
<tr>
<td>US DEPARTMENT OF DEFENSE</td>
<td>9.8M</td>
</tr>
<tr>
<td>INTL AIDS VACCINE INITIATIVE</td>
<td>7.1M</td>
</tr>
<tr>
<td>PFIZER</td>
<td>5.7M</td>
</tr>
<tr>
<td>HEALTH RESOURCES AND SERVICES ADMIN</td>
<td>5.3M</td>
</tr>
<tr>
<td>ASST SECTY FOR PREPAR. &amp; RESPONSE BARDA</td>
<td>5.2M</td>
</tr>
<tr>
<td>US DEPT OF VETERANS AFFAIRS</td>
<td>5.2M</td>
</tr>
<tr>
<td>GEORGIA DEPT OF PUBLIC HEALTH</td>
<td>4.5M</td>
</tr>
<tr>
<td>HEMOPHILIA OF GEORGIA</td>
<td>4.4M</td>
</tr>
<tr>
<td>Top 10 Subtotal</td>
<td>489.7M</td>
</tr>
</tbody>
</table>

Top 10 Funded Depts - FY21 Awards

<table>
<thead>
<tr>
<th>Department</th>
<th>Total Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>181.2M</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>95.1M</td>
</tr>
<tr>
<td>Neurology</td>
<td>48.8M</td>
</tr>
<tr>
<td>Hematology Medical Oncology</td>
<td>45.1M</td>
</tr>
<tr>
<td>Human Genetics</td>
<td>30.9M</td>
</tr>
<tr>
<td>Pathology</td>
<td>28.4M</td>
</tr>
<tr>
<td>Microbiology/Immunology</td>
<td>23.0M</td>
</tr>
<tr>
<td>Surgery</td>
<td>21.2M</td>
</tr>
<tr>
<td>Biomedical Engineering</td>
<td>21.1M</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>13.8M</td>
</tr>
<tr>
<td>Top 10 Subtotal</td>
<td>506.7M</td>
</tr>
</tbody>
</table>

Top 10 Award PIs - FY2021

<table>
<thead>
<tr>
<th>Contact PI</th>
<th>Total Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanz,Ignacio</td>
<td>43.6M</td>
</tr>
<tr>
<td>Lam,Wilbur A</td>
<td>21.7M</td>
</tr>
<tr>
<td>Rouphael,Nadine</td>
<td>20.9M</td>
</tr>
<tr>
<td>Levey,Allan</td>
<td>15.0M</td>
</tr>
<tr>
<td>Stephens,David Samuel</td>
<td>12.9M</td>
</tr>
<tr>
<td>Lah,James J</td>
<td>12.7M</td>
</tr>
<tr>
<td>Ahmed,Rafi</td>
<td>12.6M</td>
</tr>
<tr>
<td>Taylor,William Robert</td>
<td>11.8M</td>
</tr>
<tr>
<td>Sekaly,Rafick-Pierre</td>
<td>10.6M</td>
</tr>
<tr>
<td>Allen,Susan</td>
<td>9.6M</td>
</tr>
<tr>
<td>Top 10 Subtotal</td>
<td>171.5M</td>
</tr>
</tbody>
</table>
RECOGNIZE DISCOVERY AND ACHIEVEMENTS

**GameChangers** Membership to date: 10

**MilliPub Club**: recognizes faculty who have published individual papers that have garnered >1000 citations. University-wide membership to date: 268

**The Emory 1%**: recognizes current faculty who have scored in the top 1% in their study section. University-wide membership to date: 112
GAMECHANGERS

- Andreas Gruentzig: Developed Angioplasty
- Doug Wallace: opened the field of human mitochondrial genetics
- Don Stein: Progesterone for TBI
- Chris Larsen and Tom Pearson: Belatacept for transplants
- Emie Garcia: Emory Cardiac Toolbox
- Steve Warren: Fragile X discovery and trinucleotide repeat disorder mechanisms
- Ray Schinazi and Dennis Liotta: Lamivudine (3TC) and emtricitabine (FTC) for HIV
- Mahlon DeLong: Surgery for Parkinson’s Disease
- Helen Mayberg: Deep brain stimulation for major depression
- Rafi Ahmed: PD-1 immunomodulator pathway
THE DEAN'S IMAGINE, INNOVATE, AND IMPACT AWARDS (I³)

<table>
<thead>
<tr>
<th>Awards Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I³ Wow! Research Awards</strong></td>
<td>Transformational impact in either fundamental biomedical knowledge or translational impact.</td>
</tr>
<tr>
<td><strong>COVID-Catalyst-I³ Awards</strong></td>
<td>To accelerate the development and availability of proof-of-concept and preliminary results regarding novel COVID-19 research.</td>
</tr>
<tr>
<td><strong>I³ Collaborations</strong></td>
<td>Synergy II/Nexus Awards, I³/Synergy/Kaiser Permanente Georgia Research Awards, Emory SOM/Georgia Tech Research Awards.</td>
</tr>
<tr>
<td><strong>I³ Venture Research Awards</strong></td>
<td>To cultivate inventors, innovators, and entrepreneurs driven to solve medicine’s challenges and create patient impact.</td>
</tr>
<tr>
<td><strong>I³ Nexus Awards</strong></td>
<td>Require interdisciplinary team collaboration to obtain sufficient data to ultimately develop external collaborative funding applications.</td>
</tr>
<tr>
<td><strong>I³ Teams Awards</strong></td>
<td>Support the infrastructure of building interdisciplinary collaboration with the ultimate goal of submitting a center or program project grant to target significant problem with an impact at a clinical or basic science level.</td>
</tr>
<tr>
<td><strong>I³ Education Awards</strong></td>
<td>Novel approaches to enhance the curriculum, assessment, learning support, wellness activities, simulation technology, and other aspects of the undergraduate and graduate medical education experience.</td>
</tr>
</tbody>
</table>
BRIDGE FUNDING

Goal
- To assist investigators who have temporarily lost significant federal research funding, and to facilitate carefully planned changes in research direction.

Potential
- The competitive renewal should have been discussed and scored.
- Proposals that have been triaged are not eligible.
- Applications that have not undergone another round of extramural review by the sponsor will not be accepted.

How it works
Bridge funding up to $100,000 (including Department support/matching funds) will be available to investigators based on:
- merit
- potential for renewal of external funding
- availability of SOM funds

*Bridge funds cannot be used for faculty salary support of the PI(s)*

Return on investment
- SOM & Department Supported Bridge Funds: $4.1M
- Generated new NIH funding (over 5 years): >59M
- ROI: 1461%
School of Medicine Postdocs

- ~500 Postdocs in Emory (SOM + Yerkes)
- Basic Departments ~200+
- Clinical ~300+
- Dr. Lou Ann Brown
POSTDOCTORAL TRAINING PROGRAMS

- Emory University has a variety of funded training opportunities as well as career development awards available for eligible postdoctoral fellows.

- Institutional T32 Training Grants
  - Advanced Research Training in Transplantation Science
  - The Emory Training Program in Lung Health
  - Critical Care Training Program
  - Training in Interventions to Improve Outcomes in Chronic Conditions
  - Multidisciplinary Training in Vision and Research
  - Nephrology Institutional Training Grant
  - Research Training in Academic Cardiology
  - Translational Physician-Scientist Training Program in Oncology

- Institutional Research and Academic Career Development Award (K12)
  - Training Grant In Transfusion Medicine
  - Training In Translational Research In Neurology
  - Training A New Generation of Vaccinologists
  - Research Training in Pediatric Non-Malignant Hematology
  - Research Training in Translational Gastroenterology and Hepatology
  - Postdoctoral Residency Program in Health Service Psychology

- Fellowships in Research and Science Teaching (FIRST)
The GDBBS has around 400 graduate students in eight interdisciplinary PhD programs:

- Biochemistry, Cell and Developmental Biology
- Cancer Biology
- Genetics and Molecular Biology
- Immunology and Molecular Pathogenesis
- Microbiology and Molecular Genetics
- Molecular and Systems Pharmacology
- Neuroscience
- Population Biology, Ecology, and Evolution

Training opportunity with faculty at:

- Atlanta VA Medical Center
- U.S. Centers for Disease Control and Prevention (CDC)
- Emory College of Arts and Sciences
- The Robert W. Woodruff Health Sciences Center
- The Rollins School of Public Health
- The Winship Cancer Institute
- The Yerkes National Primate Research Center
Our Integrated Core Facilities provide researchers with advanced tools and equipment paired with specialized expertise to advance multidisciplinary research excellence. Our services span from bench to publication.
OUR CORES PROVIDE

- Specialized services and platforms
- Access to expensive equipment and its maintenance
- Services at reduce costs to investigators
- Expertise for a grant application
  - On-line descriptors of activities, methods, assays, facilities, and equipment
  - Letters of support
- Help in recruiting new faculty
- Help in retaining faculty
**Purpose:** To provide state-of-the-art high-speed Fluorescence Activated Cell Sorting (FACS), sample analysis and analyzer training facilities.

The SOM Sorting core is available on a daily basis with easy sign up to support both clinical and basic research efforts on the campus and the surrounding area. Sorters are fully supported with full time very experienced operators.

This Flow Cytometry Core Facility provides quantitative flow cytometric analyses on samples from a wide variety of biological samples.

One-on-one training sessions are offered to help the uninitiated learn how to use a flow cytometer analyzer.

**Investigators Supported in 2021:** 36

**Sorter Cytometers**
- FACS Aria II high-speed multi-parameter cell sorter, each capable of 17-colors from 5 lasers (including UV) and 4-way sorting
- Sorts into cell culture plates of varying sizes

**Analyzer Cytometers**
- FACS Symphony A3s
- Each capable of 24-color analysis
**Purpose:** To provide investigators the latest proteomics technologies to identify and characterize proteins in support of their fundamental and clinical research.

The EIPC’s proteomics platform relies on LC-MS/MS to analyze peptide mixtures of single proteins and more complex proteomes captured from cells and tissues. The sensitivity and high throughput of the LC-MS/MS system is pivotal to proteomic analyses.

The EIPC provides qualitative and quantitative proteomic services using the LC-MS/MS system and its associated bioinformatics pipelines.

**Investigators Supported in 2021:** 37

---

**Nicholas T. Seyfried, PhD**
EIPC Scientific Director

**Duc Duong, BS**
EIPC Core Director
(Quantitative service)

**Pritha Bagchi, PhD**
EIPC Core Director
(Antalytical service)
EMORY INTEGRATED PROTEOMICS CORE (EIPC)

Major services

- Protein identification (in-gel or in-solution digestion)
- Interactome analysis (on-bead digestion)
- Analysis of post-translational modifications (PTM)
- Quantitative comparative proteomics

Mass Spectrometers

- The proteomic platform of EIPC relies on LC-MS/MS to analyze peptide mixtures of single proteins as well as more complex proteomes captured from cells and tissues.
- The sensitivity and high throughput of the LC-MS/MS system is pivotal to proteomic analyses.
- Instruments currently available include Q-Exactive (QE) Plus, Q-Exactive (QE) HF-X, and Orbitrap Fusion.
**Purpose:** To provide investigators access to the latest genomics platforms to pursue their research goals.

- The EIGC maintains CLIA certification offering assay validation and nucleic acid extraction services from various biological sources to support fundamental and clinical research.
- Sample types include blood cells, serum, plasma, solid tissues, and cell extracts.
- The EIGC also characterizes and confirms the identity of cell lines in support of scientific rigor and reproducibility and provides next-generation sequencing, single-cell sequencing, epigenetics, and genome engineering services for researchers.

**Investigators Supported in 2021:** 116
EMORY INTEGRATED GENOMICS CORE (EIGC)

Major Services

- CLIA
  - DNA and RNA extractions

- Genomics
  - Library Sequencing, Whole Genome Sequencing, Whole Exome Sequencing, Targeted sequencing, RNA-sequencing, single cell sequencing (10X Genomics)

- Epigenetics
  - ATAC-Seq, ChIP-Seq, RRBS, RNA-seq

- Genome Engineering
  - Cloning and Genome Editing
EMORY INTEGRATED GENOMICS CORE (EIGC)

Instrumentation Includes:

- Illumina Miseq
- Illumina Nextseq 550
- Covaris E220
- 10X Genomics Chromium Controller
- Applied Biosystems 7900HT qPCR Applied Biosystems 3130 capillary electrophoresis instrument
- Agilent Bioanalyzer
- Agilent Fragment Analyzer
- Fluidigm AccessArray
- BioRad QX200 Droplet Digital PCR System
- Bionano Saphyr
- Nanostring nCounter FLEX.
MAJOR RESEARCH CORE INVESTMENT: ROBERT P. APKARIAN INTEGRATED ELECTRON MICROSCOPY CORE

Solving protein structures at near-atomic resolutions

- **Cryo-Transmission Electron Microscopy**
  - Four of our TEMs are equipped with cryo-capabilities using Gatan 626 or 714 cryo-holders for single-tilt and high-tilt imaging of biological specimens or materials.
  - Our Talos 200kEV Arctica comes with an autoloader system which allows loading of 12 cryo-EM samples for fast grid mapping and high-throughput image acquisition of high resolution, single particle data.
  - Image acquisition is done on a Gatan K3 direct electron detector (Talos Arctica), or a Direct Electron DE20 detector.
GEORGIA CORE FACILITY PARTNERSHIP

Through the Georgia Research Alliance’s Georgia Core Exchange website and database, investigators can access core facilities at Georgia’s eight largest research universities (>95 core facilities):

- Augusta University
- Clark Atlanta University
- Emory University
- Georgia Institute of Technology

- Georgia State University
- Mercer University
- Morehouse School of Medicine
- University of Georgia
10 of 18 integrated cores will expand to support investigators in HSRB-11:

- Emory Integrated Computational Core
- Emory Integrated Metabolomics and Lipidomics Core
- Center for Systems Imagine Core
- Emory Flow Cytometry Core
- Emory Integrated Genomics Core
- Rodent Behavioral Core
- Integrated Cellular Imagine Core
- Mouse Transgenic and Gene Targeting Core
- Emory Gnotobiotic Animal Core
- Division of Animal Resources

Emory’s first research building with core facilities integrated into the building design.
Thank you!
LAB MANAGEMENT

SOM New Faculty Orientation - 2021

Jeremy M. Boss, Ph.D.

Emory Chair in Basic Sciences Research
Professor and Chair – Microbiology & Immunology
Associate Dean for Basic Research

jmboss@emory.edu

October 2020
LAB MANAGEMENT

1. Hiring - Firing
2. What standards do I need to set?
3. How do I organize my Staff
4. How do I monitor my staff?
5. How do I motivate my staff?
6. Mentoring
• The most important person in your lab is…
• Do not underestimate the fact that you need to be…
• Set up your workspace…
• Plan your own experiments…
• Who should you hire first?

• How should you go about the process?

• How big should you lab get?
INTERVIEWING - YOU WANT TO KNOW!!!!

• Did they understand the science that they did in the last job?
  • What were the goals of your last set of experiments?
• What can they really do?
  • What technologies can you do without supervision?
• What is their overall motivation
  • Where do you see yourself in 5 years?
• Is this a viable hire?
  • Do you object to working with mice, radioactivity, Ebola?
• Can they enumerate their qualifications?
  • What do you think makes you the best fit for this position?
• What do they expect from me?
  • What do you expect from a supervisor?
• Are they interested in what I do?
  • Do you have any questions about my science?
  • Do you have any questions about the job?
AVOID YES / NO QUESTIONS. THEY NEED TO TALK, NOT YOU.
CALL THEIR REFERENCES!
UNHIRING

- It is your fiduciary responsibility to use your funds wisely
- Be fair! Be professional!
- Can sometimes – simply set a date that you are willing to support them (postdocs, etc.)
- Need to go through channels – seek help from administrator and HR – they are good at this!
- Sooner than later....
TEAM MEETINGS

- Meetings - Weekly
  - Group
  - 1-on-1 meetings - Weekly
  - Mini groups

- You must see the raw data!

- Journal articles?
WHAT EVERYONE NEEDS

• Clear directive and goals
• Clear overview of project
• How they fit in
• How they get to be an author
• Accurate Feedback and Praise
TREATING YOUR TEAM RIGHT

• Be FAIR to ALL
• Reward good work
  • Stars
  • Figure of the Month
• Have the Team over to the house
• Celebrate LAB achievements
  • New Grant
  • Paper submission/acceptance
• Celebrate People
  • Graduation
  • Leaving the lab
  • Birthdays
• Determine what your department does
• Keep your ears open for who would be a good mentor
• Multiple Mentors
  • Someone for everything....
• Network with your peers
  • Go to lunch (but not too long and not everyday)
  • Organize a small research/social group with peers or others in field (Zoom Social hour)
• Find colleagues who are editors, study section members who are gracious with their time.
  • Listen to what they say!
GOOD LUCK & DO GREAT THINGS!
Research Compliance and Regulatory Affairs

Kimberly Eck, MPH, PhD
Associate Vice President for Research
September 29, 2021
Research Compliance and Regulatory Affairs

- RCRA
  - Office of Conflict of Interest
  - Export Control Office
  - Office of Research Integrity
- International Collaborations
Office of Conflict of Interest

- Institutional steward for Emory’s conflict of interest in research policies
- Supports the work of the COI Committee, a faculty committee
- Monitors conflict management plans
- Transition to new electronic disclosure system launch in 2022
Office of Conflict of Interest

What you need to know:

• Generally speaking, a conflict of interest arises when an Investigator’s financial interests could directly or significantly affect the design, conduct, or reporting of a particular research project.

• Emory policy says:
  
  • Investigators must disclose Significant Financial Interests (generally, remuneration received totaling $5,000+, ownership, or management role) that could affect or be affected by their research at Emory within 30 days and annually.
  
  • PHS Investigators must disclose all Significant Financial Interests that are related to their institutional responsibilities.
  
  • Some agencies are expanding the definition for investigator to include anyone who could be an author on a peer reviewed article (meaning, more individuals may need to make COI disclosures than currently required) – stay tuned for updates as the regulations change.
  
• Make disclosures through the eCOI system – soon to be eDisclose.
Export Control Office

- ECO was established in July 2020
- Internal oversight for compliance with laws and regulations governing export controls
- These regulations are very complicated and can change suddenly
- Provides guidance to research teams and operational units
Export Control Office

What you need to know:

• Contact us if you want to do anything with an embargoed country:
  • Cuba, Iran, North Korea, Syria, and the Crimea Region of Ukraine
• Contact us if you want to ship something out of the U.S.
• Contact us if you would like confirmation that an international collaborator, visitor, scholar, host institution is not a “restricted party”
• exportcontrol@emory.edu
Office of Research Integrity and Compliance

• Established in 2021
• Leads research misconduct
• Assist in the review of research non-compliance investigations
• Facilitates compliance with regulations governing access and use of controlled substances and other dangerous drugs in research
• Facilitates compliance with FDA and DEA regulations as it relates to research
Office of Research Integrity and Compliance

What you need to know:

• Contact us with research regulatory questions
• Contact us if you use of controlled substances and other dangerous drugs in your research
• Contact us if you are considering a sponsor-investigator investigational new drug or device trial
• Reach out if you have questions about research misconduct or to request a training for your group
• oric@emory.edu
International Collaborations

- International collaborations are foundational to Emory’s research profile
- Complex international collaborations can generate complex compliance issues
- Can span many administrative offices
- We want to help you navigate those
- Request a tailored guidance session
- InternationalCollaborations@emory.edu
Overview

- About the Emory IRB
- What does (and what does not) need IRB approval?
- Tips for getting started
- Questions
Our Mission

- To facilitate ethical human subjects research
About the Emory IRB

- **Institutional Review Board**
- **Activities:**
  - Review research proposals...
  - Conduct continuing review
  - Handle complaints/concerns from participants
  - Education and outreach
  - Site inspections
Who is the Emory IRB?

- 6 biomedical panels, 1 sociobehavioral committee
  - 1 panel is for noncompliance and adverse events
- WCG or Advarra IRB for multicenter industry trials
  - More and more external IRB’s as well
- ~21 full time professional staff
- ~ 90 Committee members
How often does the IRB meet?

- Weekly
  - Except Sociobehavioral Committee - almost all expedited or exempt reviews

- Rolling submissions!
Not everything needs full IRB review!

- Is it “research”?
- Are there “human subjects”?
- Is it exempt?
- Is it expeditable?

Emory University IRB
Guidance for Investigators of Biomedical Projects

Questions? Contact the IRB staff at (404) 712-0720 or irb@emory.edu

Full Board
All other studies must be reviewed at a convened meeting of the IRB where quorum is present

Expedited
Only if IRB determines that study poses no more than minimal risk AND all study procedures fit one or more categories in a special list published in the Federal Register
- E.g., surveys, questionnaires, focus groups; noninvasive biological samples

Exempt
- PI must submit study proposal via eIRB for this determination
- Informed Consent usually must be obtained; HIPAA may still apply
- Many surveys and interviews of adults, educational program evaluations and secondary analysis of de-identified pre-existing data or samples
- The IRB is the only unit authorized to make this determination
- Exempt determination is valid indefinitely unless changes in project affect the analysis. PI must request clarification from IRB (submit an “amendment” in eIRB)

Not “Research” with “Human Subjects”

1. PI can make this determination without the IRB.
2. PI is encouraged to consult IRB in making this decision (email request to irb@emory.edu).
3. PI can submit study proposal in eIRB to get an official letter.
   - Is it “research”? Term of art defined at 45 CFR Section 46.102(d): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
   - Does it involve “human subjects”? Term of art defined at 45 CFR Section 46.102(f): a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

General examples: case studies (descriptive without drawing generalizing conclusions); public domain literature review; local-only QI project.
Not Human Subjects Research?

http://irb.emory.edu/forms/review/request.html
Exempt research

- Submission in eIRB required
  - Informed consent (if not waived) must be appropriate
  - HIPAA Privacy Rule may still apply (may need patient authorization or waiver)
- Exempt determinations can be made by qualified IRB staff and members
  - PI cannot make determination
- Determination cannot be made retroactively.
How long will review take?

http://irb.emory.edu/about/IRB%20Target%20Turnaround%20Times.html

Factors impacting the overall timeline:

- Quality of the submission...
  - See our guidance information for new studies
  - REQUIRED: Protocol templates and consent templates
  - Use our Page-Level Help for eIRB
- Funding negotiations and outstanding ancillary reviews
  - Submit to other departments in parallel whenever possible
- Study team response time
- Holidays (e.g. winter break)
Getting started

- CITI Training, clinical trial training
- VA affiliates: special VA training
- Use our website: IRB.emory.edu
- HIPAA Privacy Rule and Security Rule training
- Access eIRB and review instructional tools

Click me!
Our website resources...

Does My Project Need IRB Review?

The IRB is responsible for reviewing human subjects investigations, and ensuring that they are conducted and institutional policies. This page will help you determine if your project falls into one of the following categories:

1. Systematic investigation - An activity that involves data collection, either quantitative or qualitative, often includes surveys, interviews, data analysis, or reviews.
2. Generalizable Knowledge - Knowledge that can be applied to populations outside of the specific study. More of the following concepts: knowledge of an established body of knowledge; the need for researchers, scholars, and practitioners to find the field of study; the field constitute research designed to contribute expected to be generalized to a larger population of interest.

The FDA regulations, meanwhile, use the term "applicable regulations" to apply to studies. (For the purposes of research, clinical study, study, and clinical investigation.)
Our website resources...

Guidance to Connect Grants and IRB Approved Protocols

Use this when thinking that a new grant might be squeezed into an ongoing IRB-approved study
Collaborative Research

Continuing a study with your former institution?
New collaborative study?
Want to use a single IRB?
Stop and talk to us...
Questions
Clinical Research Resources

SOM New Faculty Orientation
September 2021

Sherry D. Coleman, DNP, RN, CHC, CHRC
Associate Executive Director, Clinical Trials
Office for Clinical Research
Office for Clinical Research

Develop strong relationships that make a difference by working together across boundaries to meet the needs of our customers through service excellence and empowering our research community to conduct high quality research, thereby providing life-changing research opportunities for our patients and research participants.

Services include:

• **Prospective Reimbursement Analysis (PRA) and Budget Development**
  • Develops PRA for all studies with EHC or Grady billables per Medicare/Medicaid guidelines for research billing compliance
  • Develops & negotiates budgets to cover costs for non-federal studies
  • Develops Letters of Intent (LOI) for industry studies

• **Research Documentation in EeMR**
  • Enters studies, study documents & subjects in EeMR
    • Clinical Research Key Points
    • Investigational Drug Data Sheet
    • Informed consent document signed by subject
    • PRA
  • Flags research subjects for 100% bill hold & review by EHC

• **ClinicalTrials.gov Management**
  • Facilitates ClinicalTrials.gov for Emory sponsored trials
    • Registers studies
    • Uploads clinical trial number (NCT#) required for Medicare claims
    • Updates records within required federal timeframes
    • Updates amendments
    • Reports results at closeout
Office for Clinical Research (cont’d)

• Industry Sponsors: Invoices & Payments
  • Invoices industry sponsors per PRA & tracks non-invoiceable visits
  • Study accounts receivable
  • Study accounts payable
  • Reconciles clinic & hospital charges to grant account per PRA
  • Processes subject reimbursement & travel stipends
  • Monthly reports to investigator and study team

• Clinical Research Training
  • Mandatory clinical research training
  • BLS/CPR training
  • Internal quality assurance
  • User support & triage
  • OCR website

• Clinical Research Support Services
  • Facilitates pre-award approvals across ORA departments for industry studies
    • Clinical Trial Automated System (CTAS) – a web-based application developed to assist the Clinical Research Navigator with improving the pre-award approval process
  • Fosters partnerships with industry sponsors & CROs (Contract Research Organizations)
  • Quarterly performance metrics by department
Emory is currently accepting participants for 682 clinical trials

Enter keywords, such as condition, treatment, physician:

Only show trials currently accepting participants

Volunteers needed for research studies

Cancer Trials
- Multiple Myeloma
- Prostate Cancer
- Breast Cancer

Cardiovascular Trials
- Coronary Artery Disease
- Atherosclerosis
- Heart Failure

Infectious Disease & Immunology Trials
- HIV Infections
- HIV-1 Infections
- Hepatitis C Virus Infection

All Cancer Trials
All Cardiovascular Trials
All Infectious Disease & Immunology Trials
Tableau: Clinical Trials Dashboard

<table>
<thead>
<tr>
<th>Department</th>
<th>Active Studies</th>
<th>Total Studies to Date</th>
<th>On Study</th>
<th>Total Enrolments to Date</th>
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<td>Urology</td>
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<td>81</td>
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<td>Family and Reproductive Medicine</td>
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<td>Medicine Surgery</td>
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<td>Neurology</td>
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<tr>
<td>Neurology &amp; Neurosurgery</td>
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<td>Pediatrics &amp; Laboratory Medicine</td>
<td>23</td>
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<td>24</td>
<td>2,270</td>
</tr>
</tbody>
</table>

**Emory CT Dashboard Accrual Volume & Trends FY13 - FY14**

**Total Accrual by Location**

**Monthly Accrual by Location**

**Total Accrual by Fiscal Year**

- **Unit/Department:**
  - Anesthesiology
  - Critical Care Medicine
  - Emergency Medicine
  - Internal Medicine
  - Neurology
  - Neurosurgery
  - Pediatrics
  - Pediatrics & Laboratory Medicine
  - Pediatrics & Laboratory Medicine
  - Pediatrics & Laboratory Medicine
  - Pediatrics & Laboratory Medicine
  - Pediatrics & Laboratory Medicine
  - Pediatrics & Laboratory Medicine

- **Principal Investigator:**
  - BANISTER, CAROLYN F
  - CARLSON, KAREN TRULSON
  - CURTIS, DOUGLE
  - DUGGAN, JOHN
  - GUGGETTA, NINA
  - HAMPTON, RONALD
  - HYDE, DAVID
  - JONES, JACOB
  - KIRKLAND, JOHN
  - KIRKLAND, JOHN
  - KIRKLAND, JOHN
  - KIRKLAND, JOHN

- **Study Status:**
  - Active
  - Closed
  - Not Started

- **Compassionate Use:**
  - Not applicable

- **IND / IDE:**
  - Not applicable
Investigator Dashboard

• A self-service tool developed for Emory Research Community with just in time metrics in one view for RAS/OCR/OSP/OTT/IRB, Winship & EHC

<table>
<thead>
<tr>
<th>Information you will see:</th>
<th>Information you will not see:</th>
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<tbody>
<tr>
<td>New studies submitted to OCR</td>
<td>• Studies not routed to OCR</td>
</tr>
<tr>
<td>• Federal/Non-Federal</td>
<td>• Amendments</td>
</tr>
<tr>
<td>• EHC billable items/services</td>
<td>• Pediatric studies</td>
</tr>
<tr>
<td>• If not consented or enrolled 1st subject</td>
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</table>
## Office for Clinical Research Invoicing
### Dermatology Clinical Trials Financial Report

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<tr>
<th></th>
<th>Through FY2016</th>
<th>FY2017</th>
<th>FY2018</th>
<th>FY2019</th>
<th>FY2020</th>
<th>FY2021 Q1</th>
<th>FY2021 Q2</th>
<th>FY2021 Q3</th>
<th>FY2021 Q4</th>
<th>Total</th>
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<td>$125,678.73</td>
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<td><strong>Encumbrances</strong></td>
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<tr>
<td>Outstanding Unpaid Invoices</td>
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<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
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<tr>
<td>Amount Withheld (per CTA)</td>
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<td>$0.00</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$846.75</td>
<td>$1,758.95</td>
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### Study Expenses Paid by OCR

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<tr>
<th></th>
<th>Through FY2016</th>
<th>FY2017</th>
<th>FY2018</th>
<th>FY2019</th>
<th>FY2020</th>
<th>FY2021 Q1</th>
<th>FY2021 Q2</th>
<th>FY2021 Q3</th>
<th>FY2021 Q4</th>
<th>Total</th>
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<tbody>
<tr>
<td>Study Expenses Paid by OCR</td>
<td>$0.00</td>
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<td>Sponsor Refunds</td>
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<td>$0.00</td>
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<tr>
<td><strong>Total</strong></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
<td>$8,284.00</td>
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<td>$0.00</td>
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<td>$8,699.00</td>
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### Studies

<p>| | |</p>
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<tr>
<td>Active</td>
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<tr>
<td>OCR Financials Completed</td>
<td>5</td>
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<tr>
<td><strong>Total</strong></td>
<td>9</td>
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</tbody>
</table>

**Uncollectible Debt:** Total outstanding monies identified as uncollectible; indicating that the sponsor is unable to fulfill the payment terms per the CTA.

**Non-Invoiceable:** Internal worksheet created by the assigned CRF; assists in organizing all non-invoiceable activities tracked by the CRC in which payment is dependent upon contractual obligations as determined by the sponsor (e.g., CRF completion, responses to queries, responses to monitoring reports, sponsor reconciliation, and verification).
The Georgia CTSA now offers studio consultations and resources that support investigators with the development of a Data and Safety Monitoring Plan (DSMP) and/or Board (DSMB) that includes:

- Studio consultation
- NIH guided charter template
- DSMB registry of participating members
- Emory IRB guidance document
Clinical Trial Feasibility Review Tools

• Self-service tools developed to:
  – Communicate and educate the impact of clinical trials with no/low enrollment prior to IRB review
  – Assist departments with assessment of internal and environmental capacity from a logistical standpoint

• Online Tools and Templates
  – Draft Standard of Operations Procedure (SOP)
  – Draft Protocol Feasibility Review Forms
  – Draft Clinical Trial Feasibility Review Forms
  – Listing of resources and websites for consultation
  – Quarterly report (tabulation of low to no enrollment vs. study duration in Tableau)
Questions?
Sponsored Award Lifecycle

**Pre-Award**
- Develop an Idea & Identify Funding (PI)
- Develop Proposal (Pre-Award RAS)
- Review & Submit Proposal (OSP)
- Sponsor Notice of Award (PI, OSP)
- Award Set up in Compass / Issue eNOA (RGC)

**Post-Award**
- Establish & Execute Sub-awards (OSP)
- Post-Award Management (RAS, PI, RGC, AR)
- Reporting (RAS, PI, RGC, FSR)
- Close-outs (RAS, RGC)

**Award Set-up**
- Close in COMPASS (RGC)
- PACT submission to RGC (RAS)
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Ongoing activities**
- Compile (RAS) and submit (OSP) Just-in-Time materials
- Ensure all components of awards are complete, e.g., IRB, IACUC, etc. If not, gather as needed from RAS, Sponsor, etc. (OSP)
- Ensure the terms of the award are acceptable and the award is ready for setup (OSP)
- Initiate award set-up request in Compass (OSP)

**During setup**
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Pre-Award**
- Develop an Idea & Identify Funding (PI)
- Develop Proposal (Pre-Award RAS)
- Review & Submit Proposal (OSP)

**Post-Award**
- Establish & Execute Sub-awards (OSP)
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**During setup**
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- PACT submission to RGC (RAS)

**Pre-Award**
- Develop an Idea & Identify Funding (PI)
- Develop Proposal (Pre-Award RAS)
- Review & Submit Proposal (OSP)

**Post-Award**
- Establish & Execute Sub-awards (OSP)
- Post-Award Management (RAS, PI, RGC, AR)
- Reporting (RAS, PI, RGC, FSR)
- Close-outs (RAS, RGC)

**Award Set-up**
- Close in COMPASS (RGC)
- PACT submission to RGC (RAS)
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Ongoing activities**
- Compile (RAS) and submit (OSP) Just-in-Time materials
- Ensure all components of awards are complete, e.g., IRB, IACUC, etc. If not, gather as needed from RAS, Sponsor, etc. (OSP)
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**During setup**
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Pre-Award**
- Develop an Idea & Identify Funding (PI)
- Develop Proposal (Pre-Award RAS)
- Review & Submit Proposal (OSP)

**Post-Award**
- Establish & Execute Sub-awards (OSP)
- Post-Award Management (RAS, PI, RGC, AR)
- Reporting (RAS, PI, RGC, FSR)
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**Award Set-up**
- Close in COMPASS (RGC)
- PACT submission to RGC (RAS)
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Ongoing activities**
- Compile (RAS) and submit (OSP) Just-in-Time materials
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- PACT submission to RGC (RAS)

**Pre-Award**
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- Close-outs (RAS, RGC)

**Award Set-up**
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- PACT preparation (RAS)
- PACT submission to RGC (RAS)

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**During setup**
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Pre-Award**
- Develop an Idea & Identify Funding (PI)
- Develop Proposal (Pre-Award RAS)
- Review & Submit Proposal (OSP)

**Post-Award**
- Establish & Execute Sub-awards (OSP)
- Post-Award Management (RAS, PI, RGC, AR)
- Reporting (RAS, PI, RGC, FSR)
- Close-outs (RAS, RGC)

**Award Set-up**
- Close in COMPASS (RGC)
- PACT submission to RGC (RAS)
- PACT preparation (RAS)
- PACT submission to RGC (RAS)

**Ongoing activities**
- Compile (RAS) and submit (OSP) Just-in-Time materials
- Ensure all components of awards are complete, e.g., IRB, IACUC, etc. If not, gather as needed from RAS, Sponsor, etc. (OSP)
- Ensure the terms of the award are acceptable and the award is ready for setup (OSP)
- Initiate award set-up request in Compass (OSP)

**During setup**
- PACT preparation (RAS)
- PACT submission to RGC (RAS)
Graduate Division of Biological and Biomedical Sciences (GDBBS)

New Faculty Information Packet

Welcome!
The Graduate Division of the Biological and Biomedical Sciences (GDBBS) is composed of eight graduate training programs, which are listed above. Training faculty apply to be affiliated with a program or programs that overlap with their research. The Division facilitates interdisciplinary, innovative training, student recruitment and student support. The Division is, in turn, supported by the Laney Graduate School, which oversees graduate training in 40 programs across the University.
Unlike a traditional model where graduate programs are affiliated with particular departments, all eight of our programs are composed of faculty from across the University, providing a unique opportunity for faculty and students to connect with potential collaborators and mentors.
Students

GDBBS programs admitted 72 students for academic year 2020-2021.

Not pictured are students that are non-US or unidentified home state.

Students are recruited from across the country. Twenty-six percent of the recent entering class is from abroad.
Students enter a variety of professions after obtaining a PhD.
Training

Year 1: Course Work and Rotations
Join Lab

Year 2: Course Work, Teaching Training, Qualifying Exam

Years 3-5: Research, Grant Writing, Presentations, Professional Development, Teaching Training, Internships

Years 5-6: Complete Degree Requirements, Professional Development, Defend PhD

• Each program has its own core curriculum tailored to their discipline(s).
• Grant Writing Courses and Statistics are some of the training that is shared between programs.
• All programs have seminar series and opportunities for students to present their work.
How to Become A GDBBS Faculty Member:

1. Look at the programs and decide where you fit. http://www.biomed.emory.edu/
2. Contact the Program Director(s) for the Program(s) to which you want to apply. Program Directors are listed at https://biomed.emory.edu/about-us/leadership.html
3. Each program has a slightly different application process, but you may need to give a seminar.
4. Your appointment will be approved by the program faculty, the GDBBS Director and the LGS Dean.

Your Commitment Once You Join

1. Take Mentor Training through the Atlanta Society of Mentors (ASOM).
2. Participate in Program Activities, Course Instruction and Leadership.
3. Fund Students that Join your Lab (after 21 months).
4. Foster a Supportive Environment for All Students.
<table>
<thead>
<tr>
<th>The GDBBS Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Nicole Gerardo</td>
</tr>
<tr>
<td>Division Director</td>
</tr>
<tr>
<td>Emily Neutens</td>
</tr>
<tr>
<td>Assistant Director of Student Affairs</td>
</tr>
<tr>
<td>K’La Albers</td>
</tr>
<tr>
<td>Business Manager</td>
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<tr>
<td>Sean Porter</td>
</tr>
<tr>
<td>Business Analyst</td>
</tr>
<tr>
<td>Kathy Smith</td>
</tr>
<tr>
<td>Director, Recruitment and Admissions</td>
</tr>
<tr>
<td>Maureen Thomas</td>
</tr>
<tr>
<td>Administrative Assistant</td>
</tr>
</tbody>
</table>
**Program Directors**

- Christine Dunham
  - BCDB
- Levi Morrán
  - PBEE
- John Altman
  - IMP
- Robert Liu
  - NS
- Anice Lowen
  - MMG
- Danny Reines
  - GMB
- Carlos Moreno
  - CB
- Eric Ortlund
  - MSP

**Program Administrators**

- Rathan Kersey
  - IMP & MMG
- Roberta Lynn
  - CB & GMB
- Chanell Loiseau
  - NS & PBEE
- Tracey Wright
  - BCDB & MSP
THE OFFICE OF POSTDOCTORAL EDUCATION

Lou Ann S. Brown, Ph.D.
Director of Postdoctoral Education

September 29, 2021

http://www.med.emory.edu/POSTDOC/

Room 301 & 303 1462 Clifton Building
School of Medicine Postdocs

- ~450 Postdocs in Emory (SOM + Yerkes)
  - Basic Departments ~100+
  - Clinical ~350+

- Citizenship-
  - ~50% international postdocs
  - 30+ countries represented
  - 50% men and 50% women
  - 3.4 years average stay at Emory
# Rules of the Road for Postdoctoral Fellows

- Stipends required to follow NRSA tables

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Stipend for FY 2021</th>
<th>Monthly Stipend</th>
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<tbody>
<tr>
<td>2016 - 2017</td>
<td>0</td>
<td>$53,760</td>
<td>$4,480</td>
</tr>
<tr>
<td>2017 - 2018</td>
<td>1</td>
<td>$54,144</td>
<td>$4,512</td>
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<tr>
<td>2018 - 2019</td>
<td>2</td>
<td>$54,540</td>
<td>$4,545</td>
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<tr>
<td>2019 - 2020</td>
<td>3</td>
<td>$56,712</td>
<td>$4,726</td>
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<tr>
<td>2020 - 2021</td>
<td>4</td>
<td>$58,608</td>
<td>$4,884</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>$60,780</td>
<td>$5,065</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$63,036</td>
<td>$5,253</td>
</tr>
<tr>
<td></td>
<td>7 or More</td>
<td>$65,292</td>
<td>$5,441</td>
</tr>
</tbody>
</table>

*All professional experiences count to minimum stipend*
One-year appointments with annual renewals

90 Day notice of termination ~ non-renewal, insufficient funds, or poor performance

Review of Individual Development Plan completed by Postdoctoral Fellow

Sign off on completed Annual Review of Performance – tied to annual renewal of position (Years 2-5)

Vacation – 21 calendar days/yr

Sick leave – 12 calendar days/yr

5 Year limit as Postdoctoral Fellow

All professional experiences count
Required: First 6 months
Individual Career Development Plan (IDP)

Plans for Research → Set Goals
- Research Plan(s) agreed to by Postdoc and Mentor
- Plan for published papers
- Plan for attendance at national/international meetings
- Plan for applications for fellowships and grants

Plans for Career Path → Set Goals
- Career path/direction explored and chosen
- Plan extra training for skills needed for career goal(s)
JOBS: Private Sector >> Academia

Employment sector

- Private sector
- Educational institution, other
- Educational institution, tenured and tenure track
- Public sector
- Other

Data points from 1997 to 2017 show changes in employment sectors.
Office of Postdoctoral Education - Services Offered

• **Responsible Conduct of Research Ethics Course** (Spring and Fall Courses)
  Meets all of the NIH mandates
  8 hours
  Faculty-led
  Participants: Postdocs; Medical Fellows; Junior Faculty (K series)

• **Lab Management Course** (Spring)
  Meets all of the NIH mandates for K trainees

• **T32 Tables** relevant to Postdoctoral Fellows
• **F32 Boot Camp**
  Develop mature F32 application
  Also applicable to other fellow training applications
  Provide background information on all of the grant components
  Editing and guidance services of grant applications

• **K workshops** -- Editing and guidance services

• **Workshops**
  o Resume lab
  o How to write a research statement
  o How to write a teaching statement
  o Professional LinkedIn profile
  o Preparing for a faculty job search
  o Work-life balance
Proposed Trainee Focused Objectives
Professional Skills

Alison Gammie, PhD
National Institute of General Medical Sciences
OPE Certificate Program in Leadership and Management
(Emory Goizueta Business School Faculty)

- Strategic Thinking and Alignment
- Developing Social-Emotional Intelligence
- Conflict Management
- Gaining Self-Awareness
- Motivation and performance
- Finance for Non-Finance Managers
- Managing High-Performing Teams
- Professional Communications
- Influencing without Authority
Communication is Key
REACH OUT TO US
QUESTIONS?
Institutional Animal Care and Use Committee (IACUC)

Esmeralda Meyer
Interim Director - IACUC Office
IACUC Responsibilities and Oversight

**Oversight and continuing review of the University Animal Care Program including the following:**

- Review and approval of animal care and use protocols and subsequent revisions
- Semiannual Site inspection of animal housing and use areas
- Semiannual Review of Animal Program(s)
- Investigation and review of potential noncompliance
- Regulatory reporting to institutional and federal agencies
Resources to Assist new PI’s/labs

• **IACUC Website**: [http://www.iacuc.emory.edu/](http://www.iacuc.emory.edu/)
  - Guidance Documents for review expectation
  - Protocol Submission Checklists
  - Use of Standard and Team procedures
  - Substance Administration Worksheet

• **IACUC Office Staff**
  - Facilitation Program (pre-submission assistance)
  - IACUC office staff: RPA assigned by PI last name

• **eIACUC Software Solution**
  - Bubble Map: real time indication of protocol status
  - Question-level help: Point of contact help and instruction
  - Extensible help: Link Protocol Submission Guide and other help
To return to this clickable Table of Contents anytime, click “NAVIGATION HOME” in the Left-dark-blue menu.
Scientific Aims

1. **Specific aims - Provide a description of the scientific goals and objectives of the study:**
   - Specific Aim 3. Determine the effective dose, safety and efficacy for selected lysine specific demethylase 1 (LSD1) inhibitors that promote hemoglobin F (HbF) induction, using the Towner's sickle cell mouse model. To evaluate safety, compounds will be administered for 2 weeks via IP injection in incremental doses using Towner's SS mice and normal control mice. Doses will typically be between 3mg/kg (minimum) and 20 mg/kg (maximum), but may be adjusted (within this range) based on data from cell-based assays (studies). Toxicity will be evaluated through pre- and post-treatment determination of complete blood count (CBC), renal function (GFR, BUN, Creatinine) and hepatic toxicity (serum bilirubin, liver enzymes, and albumin). The dose-concentration response curve of the target compound(s) will be determined.

2. **Significance and benefits of the research:**
   - Despite the fact that sickle cell disease was described over 100 years ago, there is still no one drug available for managing the disease in the form of hydroxyurea (HU), which is an inducer of gamma-globin. Given the health benefit if increased gamma globin re-expression to the clinical course of sickle cell disease, there is an increased need for the development of better and more predictable inducers because the efficacy of HU for gamma-globin induction is not consistent from patient-to-patient. Furthermore, the exact mechanism of action of HU is unknown and as such, it is difficult to optimize its clinical benefit since its drug target is unknown.

For more information regarding this section including examples: Refer to the Study Submission Guide by clicking the "? Help" menu at the top right of this screen.
Other Stakeholders to consider

• Division of Animal Resources (DAR)
  - http://www.dar.emory.edu/pi/index.php

• Environmental Health and Safety
  - https://ehso.emory.edu
  - Registration of biologicals, chemicals and radioactive materials used in vivo and in vitro
  - Biosafety approval for use of biologicals and chemicals in laboratory animals

• Occupational Health and Safety:
  - http://www.iacuc.emory.edu/
  - OHS questionnaire needs to be completed
  - Employee Health provides clearance for work with laboratory animals

• Office of Research Compliance and Integrity
  - http://or.emory.edu/research-compliance/oric/index.html
Final Take-Home: We’re here to help

**IACUC Director**
W. David Martin PhD, CPIA  
Director, Institutional Animal Care and Use Committee (IACUC)  
Phone: 404-727-9510  
Email: dwmarti@emory.edu  
Internet: [http://www.iacuc.emory.edu/](http://www.iacuc.emory.edu/)

**IACUC Interim Director**
Esmeralda Meyer MD, JM  
Interim Director, IACUC  
Phone: O: 404-727-8083 | M: 470-249-1158  
Email: evargas@emory.edu

**IACUC Chair**
Jeffrey H. Boatright, PhD, FARVO  
Professor of Ophthalmology  
Emory University School of Medicine  
Research Biologist & Core Director  
Atlanta VA Center for Visual & Neurocognitive Rehabilitation