Research in the 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
October 2020
RESEARCH DEAN’S OFFICE

Deanlets
• Allan Levey
• Jeremy Boss
• Haian Fu
• Jeff Lennox
• Suresh Ramalingam
• Michael Zwick

Support
• Lisa Carslon
• Darryl Barr
Functions of the Research Dean’s Office

- Research Core Facilities
  - Division of Animal Resources
- Clinical Trials and Translational Research Activities
- Bridge funding programs
- Research Recognition Awards
- International Alumni Network
- Office of Postdoctoral Education
- Human Embryonic Stem Cell Oversight
- VA Memorandum of Understanding
SCHOOL OF MEDICINE AWARDS FY 16 – FY 20

Total Awards (in Millions)

FY16: 348
FY17: 356
FY18: 456
FY19: 444
FY20: 565

Data: Office of Research Administration
TOP FUNDED PROGRAMS AND DEPARTMENTS

FY20 NIH AWARDS TO TARGETED AREAS
(data thru 9/21/2020)  

<table>
<thead>
<tr>
<th>Targeted Areas</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Health and Aging</td>
<td>81.7 M</td>
</tr>
<tr>
<td>Cancer</td>
<td>22.5 M</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>34.9 M</td>
</tr>
<tr>
<td>Child Health</td>
<td>77.9 M</td>
</tr>
<tr>
<td>Infectious Disease &amp; Immunology</td>
<td>103.5 M</td>
</tr>
</tbody>
</table>

FY20 – Principal Investigators

954 SOM PIs
127 PIs > $1M awards
# of SOM awards: 2634

<table>
<thead>
<tr>
<th>DEPARTMENT</th>
<th>FY20 Research Awards $</th>
<th>2019 National Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>135.6 M</td>
<td>23</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>108.6 M</td>
<td>3</td>
</tr>
<tr>
<td>Neurology</td>
<td>60.0 M</td>
<td>7</td>
</tr>
<tr>
<td>Hem/Onc</td>
<td>48.2 M</td>
<td>No ranking</td>
</tr>
<tr>
<td>Human Genetics</td>
<td>26.4 M</td>
<td>14</td>
</tr>
<tr>
<td>Surgery</td>
<td>24.8 M</td>
<td>6</td>
</tr>
<tr>
<td>Microbiology/Immun</td>
<td>20.0 M</td>
<td>16</td>
</tr>
<tr>
<td>Pathology</td>
<td>14.7 M</td>
<td>9</td>
</tr>
<tr>
<td>Pharmacology</td>
<td>14.0 M</td>
<td>24</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>12.5 M</td>
<td>24</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Funding Agency Type (including flowthru funding)</th>
<th>FY20 Research Awards $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>430.0 M</td>
</tr>
<tr>
<td>Industry</td>
<td>64.8 M</td>
</tr>
<tr>
<td>Private Foundations</td>
<td>49.4 M</td>
</tr>
<tr>
<td>State</td>
<td>11.6 M</td>
</tr>
<tr>
<td>Foreign</td>
<td>6.5 M</td>
</tr>
<tr>
<td>University</td>
<td>2.9 M</td>
</tr>
<tr>
<td>Total</td>
<td>565.2 M</td>
</tr>
</tbody>
</table>
SARS-CoV2 COVID-19

COVID-19 Research:  
Weekly review thru:  
9/20/2020

**SOM COVID-19 related Proposal Submissions**
- 121 # of PIs submitting
- 204 # of Submissions

**SOM COVID-19 related Sponsored Awards**
- 41 # of PIs funded
- 62 # of funded projects

**Publications: # of Emory University authored publications related to COVID-19**
- 375

**Funding Amounts (in USD)**
- Direct: 95.6M
- FAC: 33.5M
- Total: 129.1M
- Direct: 55.1M
- FAC Awarded: 16.8M
- Total Awarded: 71.9M

Source: PubMed
<table>
<thead>
<tr>
<th>Emory Integrated Cores</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BIOSTATISTICS &amp; COLLABORATION CORE (BCC)</strong></td>
</tr>
<tr>
<td><strong>CENTER FOR SYSTEMS IMAGING CORE (CSIC)</strong></td>
</tr>
<tr>
<td><strong>DIVISION OF ANIMAL RESOURCES (DAR)</strong></td>
</tr>
<tr>
<td><strong>EMORY COMPREHENSIVE GLYCOMICS CORE (ECGC)</strong></td>
</tr>
<tr>
<td><strong>EMORY FLOW CYTOMETRY CORE (EFCC)</strong></td>
</tr>
<tr>
<td><strong>EMORY GNOTOBIOТИС ANIMAL CORE (EGAC)</strong></td>
</tr>
<tr>
<td><strong>EMORY INTEGRATED COMPUTATIONAL CORE (EICC)</strong></td>
</tr>
<tr>
<td><strong>EMORY INTEGRATED GENOMICS CORE (EIGC)</strong></td>
</tr>
<tr>
<td><strong>EMORY INTEGRATED METABOLOMICS &amp; LIPIDOMICS CORE (EIMLC)</strong></td>
</tr>
<tr>
<td><strong>EMORY INTEGRATED PROTEOMICS CORE (EIPC)</strong></td>
</tr>
<tr>
<td><strong>EMORY MULTIPLEXED IMMUNOASSAY CORE (EMIC)</strong></td>
</tr>
<tr>
<td><strong>EMORY CELLULAR AND IMMUNOTHERAPY CORE (EXCITE)</strong></td>
</tr>
<tr>
<td><strong>EMORY STEM CELL CORE (ESCC)</strong></td>
</tr>
<tr>
<td><strong>INTEGRATED CELLULAR IMAGING CORE (ICI)</strong></td>
</tr>
<tr>
<td><strong>INVESTIGATIONAL DRUG SERVICE (IDS)</strong></td>
</tr>
<tr>
<td><strong>MOUSE TRANSGENIC &amp; GENE TARGETING CORE (TMF)</strong></td>
</tr>
<tr>
<td><strong>ROBERT P. APKARIAN INTEGRATED ELECTRON MICROSCOPY CORE (IEMC)</strong></td>
</tr>
<tr>
<td><strong>RODENT BEHAVIORAL CORE (RBC)</strong></td>
</tr>
</tbody>
</table>
$7.1 Million investment in Cryo EM

Solving protein structures at near-atomic resolutions
GEORGIA CLINICAL & TRANSLATIONAL SCIENCE ALLIANCE (GaCTSA)

HTTP://GEORGIACTSA.ORG/WHAT-WE-DO/INDEX.HTML

- Create an Atlanta-wide home for clinical and translational investigators
- Develop an Atlanta-wide integrated clinical research network for conducting clinical and translational science
- Integrate, improve, and innovate the quality of education and training programs for the next generation of clinical and translational researchers
- Leverage pilot grant programs to promote new and interdisciplinary clinical and translational science
- Develop a clinical and translational research program for children in Georgia
- Enhance, through a focus on health disparities, community engagement in clinical and translational research
Recognize Discovery & Achievement

- **GameChangers**  Membership to date: 10

- **MilliPub Club:** recognizes faculty who have published individual papers that have garnered >1000 citations. Membership to date: 217

- **The Emory 1%:** recognizes current faculty who have scored in the top 1% in their study section. Membership to date: 90
Other Research Programs and Support

School of Medicine Postdocs

- ~500 Postdocs in Emory (SOM + Yerkes)
  - Basic Departments ~200+
  - Clinical ~300+

- Dr. Lou Ann Brown

School of Medicine Bridge Funding Program

SOM & Department Supported Bridge Funds $4.1M

Generated new NIH funding (over 5 years) $59M
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
Ernie 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
COLLABORATE – ITS FUN!
# NIH FYTD Awards to Emory University (Grants only)

## Cumulative NIH Awards FYTD Periods (Oct-Sep)

<table>
<thead>
<tr>
<th>Year</th>
<th>Awards (M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH FY 2018</td>
<td>330.6M</td>
</tr>
<tr>
<td>NIH FY 2019</td>
<td>364.4M</td>
</tr>
<tr>
<td>NIH FYTD 2020</td>
<td>439.5M</td>
</tr>
</tbody>
</table>

## NIH FYTD 20 Funding Breakdown

- FYTD20 Non-COVID: 372.4M
- FYTD20 COVID-19: 67.1M

## NIH $ Awarded thru 9/19/2020

<table>
<thead>
<tr>
<th>Award Month</th>
<th>Award $</th>
<th># of Projects</th>
<th>Award $</th>
<th># of Projects</th>
<th>Award $</th>
<th># of Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>0.4M</td>
<td>1</td>
<td>1.5M</td>
<td>4</td>
<td>13.1M</td>
<td>26</td>
</tr>
<tr>
<td>November</td>
<td>9.0M</td>
<td>26</td>
<td>13.7M</td>
<td>23</td>
<td>14.5M</td>
<td>37</td>
</tr>
<tr>
<td>December</td>
<td>17.3M</td>
<td>28</td>
<td>16.1M</td>
<td>40</td>
<td>19.5M</td>
<td>55</td>
</tr>
<tr>
<td>January</td>
<td>20.9M</td>
<td>50</td>
<td>22.9M</td>
<td>50</td>
<td>22.3M</td>
<td>43</td>
</tr>
<tr>
<td>February</td>
<td>17.1M</td>
<td>44</td>
<td>19.3M</td>
<td>38</td>
<td>19.5M</td>
<td>55</td>
</tr>
<tr>
<td>March</td>
<td>23.7M</td>
<td>53</td>
<td>27.8M</td>
<td>73</td>
<td>32.7M</td>
<td>74</td>
</tr>
<tr>
<td>April</td>
<td>34.1M</td>
<td>66</td>
<td>38.4M</td>
<td>56</td>
<td>33.6M</td>
<td>68</td>
</tr>
<tr>
<td>May</td>
<td>32.0M</td>
<td>69</td>
<td>30.4M</td>
<td>66</td>
<td>74.9M</td>
<td>72</td>
</tr>
<tr>
<td>June</td>
<td>54.6M</td>
<td>93</td>
<td>41.8M</td>
<td>74</td>
<td>62.6M</td>
<td>106</td>
</tr>
<tr>
<td>July</td>
<td>45.8M</td>
<td>98</td>
<td>54.9M</td>
<td>112</td>
<td>80.2M</td>
<td>129</td>
</tr>
<tr>
<td>August</td>
<td>47.6M</td>
<td>99</td>
<td>61.0M</td>
<td>116</td>
<td>60.6M</td>
<td>113</td>
</tr>
<tr>
<td>September</td>
<td>28.2M</td>
<td>66</td>
<td>36.5M</td>
<td>66</td>
<td>25.6M</td>
<td>48</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>330.6M</strong></td>
<td><strong>657</strong></td>
<td><strong>364.4M</strong></td>
<td><strong>693</strong></td>
<td><strong>439.5M</strong></td>
<td><strong>712</strong></td>
</tr>
</tbody>
</table>

## Tracking COVID-19 Impact: Monthly NIH Funding

### NIH Award $ (2018 - 2020)

- February: 0M
- March: 40M
- April: 60M
- May: 80M
- June: 100M
- July: 120M
- August: 140M
- September: 160M

### Award Month

- February
- March
- April
- May
- June
- July
- August
- September

Source: NIH RePORTER thru 9/19/2020
LAB MANAGEMENT

SOM New Faculty Orientation - 2020
Jeremy M. Boss, Ph.D.
Emory Chair in Basic Sciences Research
Professor and Chair – Microbiology & Immunology
Associate Dean for Basic Research

jmboss@emory.edu
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
LAB PERSONNEL

• The most important person in your lab is...

• Do not underestimate the fact that you need to be...

• Set up your workspace...

• Plan your 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 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
MENTORS

• 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!
IRB Overview

New Faculty Orientation
Emory University School of Medicine
October 1, 2020
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
Institutional Review Board

Activities:

- Review research proposals, of course, and...
  - Conduct continuing review
  - Handle complaints/concerns from participants
  - Education and outreach
  - Site inspections
- Sit as HIPAA Privacy Board for waivers of HIPAA authorization
Who is the Emory IRB?

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

- Weekly!
  - Though Sociobehavioral Committee rarely meetings – almost all expedited or exempt review

- Rolling submissions!
Not everything needs IRB review!

- Is it “research”? 
- Are there “human subjects”? 
- Is it “exempt from review”? 
- Is it eligible for “expedited review”? 

Email irb@emory.edu for an early determination when you have developed an idea for a project.
http://irb.emory.edu/forms/review/request.html

Access the Non-Human Subject Research Determination Form

As described in the preceding page, the IRB is responsible for reviewing all human subjects research activities. If you are relatively sure that your upcoming project meets the definition of "human subjects research," you may go ahead and submit the study in the eIRB system. If, however, you are unsure whether your project needs IRB review, you should use our Non-Human Subjects Research Determination Electronic Form by clicking the button below. This form will indicate if the study needs IRB submission or not. If not, the study team is expected to keep a copy of the form responses as an attestation of the researchers' intent for the project. For more information, refer to this memo. The responses from the form and this memo can be provided to others as needed.

This form is solely for use by Emory faculty, staff, and students. You may first need to log in to your Office365 account (email.emory.edu) in your internet browser before clicking the below link in order to view the form.

Form to Determine if IRB Review is Needed
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.
Factors impacting the overall timeline:

- The quality of the submission...
  - Use our ICF/HIPAA templates
  - See our guidance information for new studies, and...
  - REQUIRED: Protocol templates
  - See our Page Level Help for eIRB submissions
- Whether grant/contract negotiations and any ancillary reviews are still outstanding
  - Submit to other departments in parallel whenever possible
- How quickly the study team replies to requests for clarification or changes
- Departmental review (or faculty advisor review) issues
  - Please review the "Departmental Approval - What should I select in the smartform?" FAQ here - it could save you weeks!
- Spikes in submissions to the IRB
Getting started

- CITI 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...

---

**eIRB**

Submit Studies for Review

---

**Important Information and Resources**

- Do I need IRB Review?
- Revised Common Rule
- Emergency/Compassionate Use of Drugs/Devices
- Staff Change Request Tool
- eIRB Guides and FAQ
- Researcher FAQ
- IRB Turnaround Times
- New to Emory? We want to help!

---

**Does My Project Need IRB Review?**

- Access the Non-Human Subject Research Determination Form
- Case Studies/Series
- Classroom Activities
- Public Health Practice
- Program Evaluations
- Quality Improvement

---

**Revised Common Rule at Emory**

- Treating a Patient with an FDA Unapproved Drug or Device
- Study Submission Guidance
- Consent Toolkit
- Waivers
- Certificates of Confidentiality
- Clinical Study Initiation and Tools
- Data Sharing Certifications (NIH)
- Collaborative Research and External IRBs
- Frequently Asked Questions
- Reportable New Information
- Socio-behavioral Research/Minimal Risk Studies

---

**Does My Project Need IRB**

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

- **Note:** There are situations in which Emory is no longer collaborating with other institutions, in which case Emory is only analyzing completely de-identified data, not enrolling. Emory personnel are performing for research purposes, and others. Please engage. (Funding flow may affect this determination.)

First we consider, what is "research?"

The "Common Rule," generally used by the Emory IRB, defines "research" as a systematic investigation, designed to develop or contribute to generalizable knowledge. This leads to two further explanations:

1. **Systematic Investigation** - An activity that involves collection, either quantitative or qualitative, of data often includes surveys, interviews, data reviews.

2. **Generalizable Knowledge** - Knowledge that is applied to populations outside of the specific context, more of the following concepts: Knowledge that is generalizable to a larger population, or results are intended to be replicated in other settings.

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

Covid-19 and Human Subjects Research

Emory IRB Guidance: Resuming In-Person Research Activities

Whether your study was temporarily on hold, or is newly starting up, the below guidance outlines the safety measures required for different kinds of in-person study activities, and if and when IRB modifications are required to resume these activities.

Emory IRB COVID-19 Ramp-Up Guidance

Addressed in the above Guidance:

- What PPE and other safety measures are needed to resume non-essential in-person research activities?
- How can I request an exception to the guidelines?

Emory IRB Guidance: Managing Research during Covid Pandemic

In this unusual circumstance of a pandemic illness, it may be necessary to urgently modify research study procedures. New protocols may also need prioritized IRB review.

Emory IRB Guidance for Managing Research during Covid-19

Addressed in the above Guidance:

- When and how must the Emory IRB be notified of changes to approved research?
- When may prior Emory IRB approval not be needed?
- How quickly can the IRB review new COVID-19 protocols?
- Will Emory IRB’s review capacity be impacted due to Emory’s closures?
- What are my Informed Consent options (electronic and other)?
- What if we experience a decrease in the workforce?
- What if I need to request an expanded access use for patient treatment?
- Links to additional resources
- Example of a Screening Log
Our website resources...

Guidance to Connect Grants and IRB Approved Protocols - NEW

Use this when thinking that a new grant might be squeezed into an ongoing IRB-approved study
Continuing a study with your former institution? New federal multisite study? **Always** use the process on our website...
Questions
Clinical Research Resources

SOM New Faculty Orientation
October 2020

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

- Georgia CTSA—Georgia Clinical & Translational Science Alliance
  - GCRN—Clinical Research Center
  - ResearchMatch
- Clinical Trials Audit & Compliance
- Library & Information Technology Services
Departmental Resources

• Department Chair/Division Director
• Vice Chair for Research
• Research Administrator
• Senior Mentor
• DOM Hitchhiker’s Guide to navigating mandatory research compliance & approvals (medicine.emory.edu/research/internal-research-resources/hitchhikers-guide/)
Office of Research Administration Resources

• Conflict of Interest
• Environmental Health & Safety
• Institutional Animal Care & Use Committee
• Institutional Review Board
• Investigational Drug Service
• **Office for Clinical Research**
• Office of Sponsored Programs
• Office of Technology Transfer
• Research Administration Services
Office for Clinical Research

Our mission is to facilitate and support the efforts of the clinical research team in the timely initiation, management and completion of clinical trials at Emory.

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
    o Clinical Research Key Points
    o Investigational Drug Data Sheet
    o Informed consent document signed by subject
    o PRA
  • Flags research subjects for 100% bill hold & review by EHC

• ClinicalTrials.gov Management
  • Facilitates ClinicalTrials.gov for Emory sponsored trials
    o Registers studies
    o Uploads clinical trial number (NCT#) required for Medicare claims
    o Updates records within required federal timeframes
    o Updates amendments
    o 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
  • Fosters partnerships with industry sponsors & CROs (Contract Research Organizations)
  • Quarterly performance metrics by department
Clinical Trial Reporting

- Clinical Trials Website
  - (www.clinicaltrials.emory.edu)
- Tableau
  - Clinical Trial Dashboard
- OCR Quarterly/Annual Scorecard
- Clinical Trial Automated System (CTAS)
  - Investigator Dashboard
- Summary of Transactions (SOT)
- Clinical Trial Invoicing Summary
  - Departmental
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 Infection
Hepatitis C Virus Infection

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

Emory CT Dashboard Accrual Volume & Trends FY13 - FY14
Version 4.03 August 2014
Annual OCR Scorecard for Fiscal Year 2019

As of September 1, 2019, there were 2,108 total active clinical research studies conducted by Emory faculty with 28,129 participants on-study (of which, 188 active research studies at Grady with 4,323 participants on-study). There were 424 studies with no enrollment.

Education & Outreach Team:
- 100 educational seminars/conferences with 3,249 attendees (196 attendees live & 3,053 attendees in person) who were awarded 1,183 CE/CMEs.
- 1,043 of 1,843 investigators completed “Key Concepts in Clinical Research” course or “CTI GCP” course (100% compliant).
- 1,108 of 1,208 study coordinators/other key personnel coordinating FDA-regulated clinical trials completed “Introduction to Clinical Research at Emory” course or “CTI GCP” course (both incorporate “CTI GCP” course as pre-requisite) (100% compliant).
- Help Desk inquiries processed: 2,006, Internal QA projects completed: 0

Pre-Award Team (metrics based on completion date):
- New studies submitted to OCR for review: 786
- Pre-award review completed (budget, PRA, OCR review needed): 742 studies: PRAs completed: 334
- Business days from receipt to submission for 742 all studies (all efforts): 40 mean: 38 median
- Total $ and % difference between OCR requested sponsor budget & sponsor initial offer for 335 studies: $21,351,949; 42% mean; 27% median
- Facilitated invoicing of administrative fees for 10 withdrawn studies totaling $123,002; and 46 studies totaling $506,233 since February 2016
- 44% of studies include externally funded, non-exempt studies, 44% of studies included externally funded, non-exempt studies, 44% of studies included externally funded, non-exempt studies

Data Integrity & Integration Team:

<table>
<thead>
<tr>
<th>Late ERMS Enrollment (Review one month every quarter)</th>
<th>Q1 Oct 2019</th>
<th>Q2 Feb 2019</th>
<th>Q3 Apr 2019</th>
<th>Q4 Jun 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td># Late Enrollers @ High Risk</td>
<td>9</td>
<td>14</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>% Late @ High Risk</td>
<td>0.9%</td>
<td>1.3%</td>
<td>0.4%</td>
<td>1.0%</td>
</tr>
<tr>
<td># CRC2 Occurrence</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td># CRC4 Occurrence</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Improved EMR reporting process started January 2019 based on risk stratification*

*Review one month every quarter started September 2019*

Clinical Trials Studies:
- 430 activated in ERMS & PowerTrials
- On-Study Subjects: 13,290 added to PowerTrials; Off-Study Subjects: 10,242 moved from PowerTrials
- Signed Informed Consent Documents (ICD): 10,452 uploaded to PowerTrials
- Clinical Research Key Points: 354 uploaded to EmFR, 98.5% compliant (average/year)
- IRB Drug Data Sheets: 240 uploaded to EmFR, 93.25% compliant (average/year)
- PRAs: 321 uploaded to EmFR, Revised/Amended PRAs: 221 uploaded to EmFR

ClinicalTrials.gov Team:
- Total eIRB Studies Reviewed: 252; Total Ad Hoc Studies Reviewed: 60
  - ENC Billable: 168 studies not submitted for PRA prior to enrollment/IRB approval: Geriatrics (1); OBGYN (2); Hematology/Oncology (1); Human Genetics (1); Ophthalmology (2); Orthopaedics (2); Otolaryngology (2); Peds Bone Marrow (2); Radiology (1); Radiation Oncology (1); and School of Nursing (2)
  - Non-ENC Billable: 29 studies not submitted to OCR for activation in ERMS

As of August 31, 2019, Emory listed as sponsor in clinicaltrials.gov for 990 studies (293 active studies with outstanding queries in 33 records)
- ClinicalTrials.gov queries for updates: 1,952; EMRS review for NCT numbers for billing compliance: 381
- OCR-initiated study registration for 88 studies, updated 422 study records, addresses 32 NIH QA Review Comments, updated records for 29 amendments, & entered results for 42 studies.
- % of Clinical Trials Registered Prior to 1st Subject Enrolled: 94% (46/68)
- % of Reports Released Before Deadline (Primary Completion Date): 83% (33/42)

Invoicing Team (as of August 31, 2019)

- Active Studies: 1194; Active Research Participants with Invoicing Activity: 6,176; Research Voids Reviewed: 22,427
  - Outstanding Invoicing as of August 31, 2019 (excluding withheld): $5,094,817
  - Outstanding Non-Invoicing as of August 31, 2019 (excluding withheld): $6,007,691
  - Outstanding Monies Withheld as of August 31, 2019: $726,693
  - Payments Received & Reconciled in FY19: $20,988,319, from inception (active studies): $219,355,919
  - Payments Received, NCT Reconciled in FY19: $34,807,849, from inception: $7,287,847
  - Overpayments in FY19: $178,718, from inception: $937,096
  - Advance Payments in FY19: $283,681, from inception: $5,053,260
  - Expenses Paid by OCR in FY19: $696,392, from inception: $2,279,501
- EMRS Audit Entries Initiated: 998; EMRS Full Budgets Uploaded: 922; EMRS Amended Budgets Uploaded: 179

*Partial budgets entered in ERMS after EMRS if no subjects enrolled at end of quarter; full budget entered upon consent of 1st subject entered in ERMS.*
Investigator Dashboard

Funding from Georgia Clinical and Translation Science Alliance provides the CRN Service.

Information you will see:
- New studies submitted to OCR
- Federal/Non-Federal
- EHC billable items/services
- If not consented or enrolled 1st subject

Information you will not see:
- Studies not routed to OCR
- Amendments
- Pediatric studies

To access, enter https://bpm.emory.edu/teamworks/login.jsp

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.
Who is behind the Investigator Dashboard?

Clinical Research Navigator

• Collects, uploads and manages clinical trial data in the Clinical Trial Automated System (CTAS)
• Identifies data driven gaps, trends, system or staff problems as they become evident
• Facilitation and Follow-up of preventable delays in the pre-award approval process
• Escalates delays as indicated
• Linked to MYRESEARCHNAVIGATOR@LISTSERV.CC.EMORY.EDU
  • Guarantees 24 hour follow-up on queries
Summary of Transactions

Date: January 9, 2020

Office for Clinical Research

1599 Clifton RD NE, 5th Floor
Atlanta, GA 30322-4250
Phone: 404-778-6360
Fax: 404-778-5699
OCR_Invoicing@emory.edu

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Protocol</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Payments Received

<table>
<thead>
<tr>
<th>Date</th>
<th>Statement</th>
<th>Transaction</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/27/2016</td>
<td>Invoice 0000055555-231352</td>
<td>Check 715025</td>
<td>5,320.00</td>
</tr>
<tr>
<td>12/22/2016</td>
<td>Invoice 0000055555-285560</td>
<td>Check 713223</td>
<td>975.00</td>
</tr>
<tr>
<td>2/24/2017</td>
<td>Invoice 0000055555-296510</td>
<td>Check 712007</td>
<td>2,010.00</td>
</tr>
<tr>
<td>12/25/2018</td>
<td>Invoice 0000055555-263936</td>
<td>Check 716523</td>
<td>2,910.00</td>
</tr>
<tr>
<td>1/25/2019</td>
<td>Invoice 0000055555-296591</td>
<td>Check 716524</td>
<td>2,910.00</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>Invoice 0000055555-351637</td>
<td>Check 720096</td>
<td>15,660.00</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>Invoice 0000055555-310106</td>
<td>Check 720096</td>
<td>360.00</td>
</tr>
<tr>
<td>7/25/2018</td>
<td>Non-Invoiceable 351822</td>
<td>Check 720096</td>
<td>9,525.48</td>
</tr>
</tbody>
</table>

Total Payments Received: 49,918.44

Study Expenses/Subject Reimbursement

This section only includes expenses paid by OCR Invoicing. It excludes auto-debits by hospital, clinic, pharmacy, effort, supplies and equipment assessed by department. We also use this section to document Sponsor Refunds as a result of Overpayments, if applicable.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/6/2018</td>
<td>Travel Expense-00000378818.16</td>
</tr>
<tr>
<td>7/6/2018</td>
<td>Travel Expense-00000365573.16</td>
</tr>
</tbody>
</table>

Total Expenses Paid: 1,140.34

Outstanding Unpaid Invoices

This section does not include non-invoiceable expenses 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’s reconciliation and verification.

<table>
<thead>
<tr>
<th>Date</th>
<th>Statement</th>
<th>Amount</th>
</tr>
</thead>
</table>

This Statement is generated from ERMS by the Office for Clinical Research.
Office for Clinical Research

Transforming Research ... Together!

**Centralized Invoicing for the School of Medicine commenced on November 1, 2014**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual Received and Reconciled</td>
<td>$39,078,968</td>
<td>$23,651,122</td>
<td>$25,453,511</td>
<td>$30,977,969</td>
<td>$5,577,044</td>
<td>$7,757,176</td>
<td>$7,926,473</td>
<td><strong>$140,422,263</strong></td>
</tr>
<tr>
<td>Actual Received Not Reconciled1</td>
<td>$417,763</td>
<td>$194,933</td>
<td>$213,460</td>
<td>$909,342</td>
<td>$197,805</td>
<td>$387,895</td>
<td>$1,541,076</td>
<td><strong>$3,862,275</strong></td>
</tr>
<tr>
<td>Advance Payments2</td>
<td>$1,648,611</td>
<td>$365,868</td>
<td>$1,055,443</td>
<td>$610,600</td>
<td>$208,712</td>
<td>$147,557</td>
<td>$177,411</td>
<td><strong>$4,214,203</strong></td>
</tr>
<tr>
<td>Overpayments3</td>
<td>$127,451</td>
<td>$67,639</td>
<td>$95,172</td>
<td>$97,198</td>
<td>$63,257</td>
<td>$62,922</td>
<td>$49,881</td>
<td><strong>$563,521</strong></td>
</tr>
<tr>
<td><strong>Total Actual RECEIVED</strong></td>
<td><strong>$41,272,794</strong></td>
<td><strong>$24,279,563</strong></td>
<td><strong>$26,817,587</strong></td>
<td><strong>$32,595,109</strong></td>
<td><strong>$6,046,818</strong></td>
<td><strong>$8,355,550</strong></td>
<td><strong>$9,694,841</strong></td>
<td><strong>$149,062,262</strong></td>
</tr>
</tbody>
</table>

**Encumbrances**

| Outstanding Non-Federal Invoices | $19,999 | $63,309 | $158,781 | $836,188 | $631,111 | $1,795,202 | $3,316,831 | **$6,821,422** |
| Outstanding Non-Invoiceable Visits4 | $91,906 | $211,469 | $586,851 | $2,084,728 | $1,021,325 | $1,629,584 | $3,355,679 | **$8,981,542** |
| Outstanding Monies Withheld5 | $86,329 | $169,547 | $447,264 | $605,656 | $168,458 | $237,165 | $208,191 | **$1,922,610** |
| Federal Encumbrances | $776,372 | $391,726 | $358,310 | $1,364,246 | $70,246 | $31,149 | $18,422 | **$3,010,472** |

**Expenses Paid**

| The Emory Clinic | $700,707 | $305,851 | $560,460 | $578,366 | $95,894 | $119,239 | $148,379 | **$2,508,886** |
| Refunds from The Emory Clinic | $21,671 | $-    | $-    | $-    | $-    | $-    | $-    | **$21,671** |
| EUH/EUHMS | **-** | **$231,271** | $1,533,354 | $2,014,209 | $569,393 | $506,771 | $520,718 | **$5,375,715** |
| Miscellaneous Study Expenses | $406,367 | $317,412 | $423,317 | $494,070 | $76,051 | $80,907 | $154,691 | **$1,952,815** |
Questions?
Introduction to the Graduate Division of Biological and Biomedical Sciences: GDBBS

Lanny S. Liebeskind, PhD
Interim Director
Graduate Division of Biological and Biomedical Sciences
Laney Graduate School
see biomed.emory.edu

October 1, 2020
School of Medicine New Faculty Orientation
Emory University Academic Administrative Structure

- 3 Executive Vice Presidents reporting to the President: Health Affairs, Academic Affairs (and Business and Administration).

- 9 Schools led by Deans Reporting to the EVPs: Medicine, Public Health, Nursing, Arts and Sciences, Business, Law, Theology, Oxford and Laney Graduate School.

- Within the Schools: Departments, Programs, Divisions. Yerkes and Winship Cancer Institute are semi-autonomous but rely on the Schools for faculty.

- The Laney Graduate School (LGS) oversees >40 PhD and MS Programs and 15 Certificate Programs across many academic domains.

- The Graduate Division of Biological and Biomedical Sciences (GDBBS) is an interdisciplinary Division of the Laney Graduate School (biomed.emory.edu).
The 8 Graduate Programs of the GDBBS

The GDBBS is a Division of the Laney Graduate School. It represents about 25% of the LGS: currently 372 participating faculty members and 404 students. There are 8 PhD Programs within the GDBBS:

**Interdepartmental and Interdisciplinary Programs***

**BCDB**: Biochemistry, Cell & Developmental Biology  
**CB**: Cancer Biology  
**GMB**: Genetics & Molecular Biology  
**IMP**: Immunology & Molecular Pathogenesis  
**MMG**: Microbiology & Molecular Genetics  
**MSP**: Molecular & Systems Pharmacology  
**NS**: Neuroscience  
**PBEE**: Population Biology, Ecology, & Evolution

---

*Programs typically have faculty from around 6 to 12 different departments for broad-based education.*
LGS + GDBBS Partnership: Infrastructure and Support

The Laney Graduate School and the GDBBS interact in many ways

- **Admissions**

- **Diversity and Inclusion** (Amanda Marie James, Associate Dean for Diversity, Inclusion and Community Engagement)
  - IMSD Program, BUILD Partnership, Pathfinder Series, National Recruiting Partnerships

- **Professional Development and Career Planning** (Rob Pearson, Assistant Dean)
  - Pathways Beyond the Professoriate, Emerging Leaders Network, Professional Development Support Funds

- **Mentoring**
  - Atlanta Society of Mentors, Mentoring Guides

- **Student Support Services** (Jennifer Cason, Assistant Dean of Student Affairs), including Mental Health and Well-being

- **TATTO** (Teaching Assistant Training and Teaching Opportunity) Program

- Etc, etc.
Faculty Demographics: GDBBS has a total of 330 training faculty from ~30 basic science and clinical departments.

- School of Medicine, 263, 80%
- School of Public Health, 50, 15%
- Yerkes, 6, 2%
- Emory College, 30, 10%
- School of Nursing, 1, 0%

80% of GDBBS faculty are within the School of Medicine.

~60% of all GDBBS training faculty are within these ten (10) academic areas.
Student Demographics

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

Not pictured are students that are non-US or unidentified home state.
Top Career Outcomes - GDBBS Alumni (2009-current)

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>ALUMNI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCDB</td>
<td>104</td>
</tr>
<tr>
<td>CB</td>
<td>30</td>
</tr>
<tr>
<td>GMB</td>
<td>103</td>
</tr>
<tr>
<td>IMP</td>
<td>151</td>
</tr>
<tr>
<td>MMG</td>
<td>77</td>
</tr>
<tr>
<td>MSP</td>
<td>87</td>
</tr>
<tr>
<td>NS</td>
<td>188</td>
</tr>
<tr>
<td>PBEE</td>
<td>57</td>
</tr>
</tbody>
</table>

NOTE: Population 797

50% of the alumni (2009+) are pursuing additional training.

Alumni Outcomes 2009-Current
N=797

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDITIONAL TRAINING</td>
<td>26.3%</td>
</tr>
<tr>
<td>RESEARCH</td>
<td>23.8%</td>
</tr>
<tr>
<td>BUSINESS</td>
<td>7.0%</td>
</tr>
<tr>
<td>TEACHING FACULTY</td>
<td>6.3%</td>
</tr>
<tr>
<td>SCIENCE WRITING &amp; COMMUNICATION</td>
<td>4.6%</td>
</tr>
<tr>
<td>ADMINISTRATION</td>
<td>3.6%</td>
</tr>
<tr>
<td>DATA SCIENCE, ANALYTICS, ETC.</td>
<td>3.0%</td>
</tr>
<tr>
<td>GOVERNMENT</td>
<td>1.9%</td>
</tr>
<tr>
<td>MEDICINE</td>
<td>1.8%</td>
</tr>
<tr>
<td>SCIENCE EDUCATION &amp; OUTREACH</td>
<td>1.3%</td>
</tr>
</tbody>
</table>
The Well-Rounded Graduate Experience

Main student focus

Professional Development

Career Planning (LGS Office of Professional Development and Career Planning)

Critical thinking; Problem solving; Technical skills; Generating new knowledge; Science communication.

Team Building

Leadership

Time Management

Business/Law of Science

Innovation

Conflict Management

Project Management

Communication
Student Financial Support in the GDBBS

Students are supported by “central” funds from the Laney Graduate School for the first 21 months, without tuition charge.

After this time, they are supported from their advisor’s funds (including start-up funds), or on a fellowship – NRSA, T32, etc.

How do you get involved in the GDBBS?

Membership requires a written application. Start by contacting the Program Director(s) for your Program(s) of interest (see http://biomed.emory.edu/about-us/leadership.html) for guidance.

Each Program has its own process. Paperwork at the Program level will be routed to the GDBBS for Division approval (contact Maureen Thomas (maureen.thomas@emory.edu), Administrative Assistant). The GDBBS will then route the application to the LGS Dean for final approval.
# Appendix - Program Abbreviations

<table>
<thead>
<tr>
<th>Full Program Name</th>
<th>Program Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemistry, Cell and Developmental Biology</td>
<td>BCDB</td>
</tr>
<tr>
<td>Cancer Biology</td>
<td>CB</td>
</tr>
<tr>
<td>Genetics and Molecular Biology</td>
<td>GMB</td>
</tr>
<tr>
<td>Immunology and Molecular Pathogenesis</td>
<td>IMP</td>
</tr>
<tr>
<td>Microbiology and Molecular Genetics</td>
<td>MMG</td>
</tr>
<tr>
<td>Molecular and Systems Pharmacology</td>
<td>MSP</td>
</tr>
<tr>
<td>Neuroscience</td>
<td>NS</td>
</tr>
<tr>
<td>Population, Biology, Ecology and Evolution</td>
<td>PBEE</td>
</tr>
</tbody>
</table>
School of Medicine Postdocs

- Approximately 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 2020</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 - 2017</td>
<td>0</td>
<td>$52,704</td>
<td>$4,392</td>
</tr>
<tr>
<td>2017 - 2018</td>
<td>1</td>
<td>$53,076</td>
<td>$4,423</td>
</tr>
<tr>
<td>2018 - 2019</td>
<td>2</td>
<td>$53,460</td>
<td>$4,455</td>
</tr>
<tr>
<td>2019 - 2020</td>
<td>3</td>
<td>$55,596</td>
<td>$4,633</td>
</tr>
<tr>
<td>2020 - 2021</td>
<td>4</td>
<td>$57,456</td>
<td>$4,788</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>$59,580</td>
<td>$4,965</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$61,800</td>
<td>$5,150</td>
</tr>
<tr>
<td></td>
<td>7 or More</td>
<td>$64,008</td>
<td>$5,334</td>
</tr>
</tbody>
</table>

No exceptions for the minimum stipend.
One year appointments

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td>'97</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'03</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'05</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'07</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'09</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EMORY | SCHOOL OF MEDICINE
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

- **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
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)

W. David Martin, PhD, CPIA
Director-IACUC Office
Oversight and continuing review of the Universities 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
IACUC Website and Office Assistance

Direct Access to eIACUC solution

Protocol Submission and Review Guidance

IACUC Office (RPA) Contact Information

Facilitation Program Contacts
eIACUC Solution Help and Instruction

Emory IACUC Protocol Submission Guide
Emory IACUC Member Review Guide
Substance Administration Worksheet download
Protocol and Amendment Checklists
Searching with % Wildcard
NAVIGATION HOME – Table of Contents

1. PROTOCOL SUBMISSION OVERVIEW
   1.a. Submission Process
   1.b. Pre-submission Step 1: Key Elements
   1.c. Pre-submission Step 2: Research Team Setup
   1.d. Pre-Submission Checklists by Protocol Type
   1.e. All Submission Types: Help and Guidance
   1.f. Quick Reference Submission Guide

2. PROTOCOL SUBMISSION INSTRUCTIONS
   2.a. Basic Information
   2.b. Experimental Research Protocol Addition
   2.c. Protocol Team Members
   2.d. Funding Sources
   2.e. Scientific Aims
   2.f. Experiments
   2.g. Procedures
   2.h. Procedure Personnel Assignment
   2.i. Strains
   2.j. Animal Justification
   2.k. Alternatives and Duplication Searches
   2.l. Breeding
   2.m. Housing and Use
   2.n. Disposition
   2.o. Supporting Documents

3. SPECIAL GUIDANCE AND CONSIDERATIONS
   3.a. Searching with %Wildcard
   3.b. Standard and Team Procedures
   3.c. Revising Team Procedures
   3.d. Addition of Substances to Protocols
   3.e. Use of Standard Procedure Formularies
   3.f. Addition of All Other Administered Agents

4. PROTOCOL REVIEW: RESEARCHER GUIDANCE
   4.b. IACUC Clarification Requested
   4.c. Responding to Reviewer Comments
   4.d. PI Response
   4.e. Reviewer Response
   4.f. Reviews Notes Tab

5. REFERENCE
   5.a. Contact Information
   5.b. Definitions
   5.c. Four Main eIACUC Workspaces

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 Townes sickle cell mouse model. To evaluate safety, compounds will be administered for 2 weeks via IP injection in incremental doses using Townes 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 producing maximum induction of HbF 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 only one drug approved 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.

Briefly describe the significance and overall benefit of the studies in light of the expected pain and stress caused to experimental animals. This is commonly referred to as a harm/benefit analysis and is a regulatory requirement. For example, the development of new therapeutic agents to treat lung cancer would be expected to cause pain and stress in animals. However, if these results improve overall quality of life, are cost effective, and do not outweigh the potential for harm, this would provide a benefit that would outweigh the potential for harm.

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.
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/

IACUC Chair

Jeffrey H. Boatright, PhD, FARVO
Professor of Ophthalmology
Emory University School of Medicine
Core Director & Research Biologist
Atlanta VAMC Center for Visual & Neurocognitive Rehabilitation
The Emory Integrated Core Facilities: Force Multipliers for Your Research

Michael E. Zwick, PhD
Associate Vice President for Research
Woodruff Health Sciences Center

Professor
Department of Human Genetics
Associate Dean of Research
Emory University School of Medicine
How should we conceive of core facilities?
Cores can be conceived as a firm

“The way economists understand firms is largely based on an insight of the late Ronald Coase. Firms make sense when the cost of organising things internally through hierarchies is less than the cost of buying things from the market; they are a way of dealing with the high transaction costs faced when you need to do something moderately complicated.”*

Ronald Coase
Nobel Prize in Economics, 1991
29 December 1910 - 2 September 2013

But are scientific cores really just a “firm”?  

The Core as a Force Multiplier

Force Multiplier: An attribute which dramatically increases the effectiveness of a team or organization.

Global Positioning System - GPS

Food!
Our Cores as a Force Multiplier

Force Multiplier Core Facility

- SERVICES
- FINANCES
- RECRUITING
- DEI
- RETENTION
- COLLABORATION
- PLATFORMS
- CENTERS
- GRANTS
- EDUCATION

cores.emory.edu
Integrated Core Facilities at Emory

cores.emory.edu/integrated

@EmoryEICF

Core Funders: 40% Average Subsidy
Other Core Facilities at Emory

And many more . . .

www.cores.emory.edu/other-cores/
How do you access core facility services?

1. Establish a PPMS account
2. Email the core facility
3. Submit a service request
Grant Materials, Methods, Letters of Support

- **Grant Materials**: Facility & Resources, Major Equipment
- **Methods**: Text Descriptions of Assays
- **Policies**: Relevant Policies (e.g. data retention)
- **Letters of Support**: Email the Core (EIGC@Emory.edu)
  - PI(s) Names and Academic Positions
  - Grant Title
  - Specific Aims
Georgia Core Facilities Partnership

Georgia Research Alliance Core Exchange

http://gra.org/

https://gra.org/page/1074/core_exchange_categories.html

Questions?