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I. ANESTHESIOLOGY RESEARCH OFFICE CONTACT INFORMATION

Human subject research:
Kathy Egan, RN, BSN, CCRC
Clinical Research Nurse III
Emory University School of Medicine
Department of Anesthesiology
Woodruff Memorial Building-Room 620
Mailing: 1364 Clifton Rd NE Atlanta, Ga 30322
kfegan@emory.edu
(O) 404-727-8463
(F) 404-712-1351

Animal and Laboratory Research:
Nancy Fox Ciliax
Senior Research Project Coordinator
Emory University School of Medicine
Department of Anesthesiology
Woodruff Memorial Building-Room 617
101 Woodruff Circle
Atlanta, GA 30322
nciliax@emory.edu
(O) 404-727-0530
(F) 404-727-6300

Research Finances:
Sade Loye, MBA
Manager, Financial Planning and Analysis
Emory University Hospital
Department of Anesthesiology
1364 Clifton Road NE
2nd floor, Room C206
Atlanta, Georgia 30322
sade.loye@emoryhealthcare.org
(O): 404-778-7755
(F): 404-778-5194

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schneika.shine@emoryhealthcare.org
(O): 404-778-5462
(F): 404-778-5194
II. GENERAL INFORMATION

The Emory Institutional Review Board (IRB) is charged with overseeing research involving human subjects. The foundational definition for what makes a particular project fall under the purview of the IRB can be found in the "Common Rule," which has the following definitions:

**Research:** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Human Subjects:** 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

The Emory IRB utilizes an electronic system (eIRB) for submission and maintenance of all protocols. See Table of Contents.

**Definition of a clinical trial** (NIH guidelines) from the OCR website:

“A clinical trial, per the NIH, is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions such as drugs, treatments, devices, or new ways of using known drugs, treatments, or devices. Clinical trials are used to determine whether new biomedical or behavioral interventions are safe and effective. Research with human subjects to develop or evaluate clinical laboratory tests or imaging might be considered a clinical trial if the test will be used for medical decision making or if the test itself imposes more than minimal risk for subjects.

The Emory Office of Research Administration “provides collaborative administrative systems and technical expertise to facilitate scholarship, research, and discovery within the Emory community from inception through dissemination and application.”

See [http://www.or.emory.edu/](http://www.or.emory.edu/)

And [http://www.or.emory.edu/about/VP%20Office/org-chart.html](http://www.or.emory.edu/about/VP%20Office/org-chart.html)

for the Organization Chart.

We have also provided instructions for investigators of **animal care and use** protocols. See Table of Contents.

Please contact personnel in the Anesthesiology Research Offices with any questions.
III. TRAINING REQUIREMENTS FOR RESEARCHERS

1. Collaborative IRB Training Initiative (CITI) Training for Human Research

Prior to submitting research protocols for review and approval by the Emory IRB, all Key Research Personnel listed on an Emory IRB submission, regardless of their position, must complete the web-based (CITI) Program in the Human Subjects Research (HSR). HSR content includes two tracks, one with a biomedical focus, and another designed for the social, behavioral, and educational disciplines. The Biomedical module will be required for most anesthesiology research projects. All personnel who will participate in a research study must be listed on the IRB submission application and their role defined. The CITI program is available at https://www.citiprogram.org/Default.asp. This tutorial also satisfies the NIH training requirement for obtaining federal funds.

Once completed, save the electronic certificate and submit to Kathy Egan; the refresher course is required every two years.

See Appendix A for more detailed instructions for the CITI training. If you are participating in research at the Atlanta VAMC and Emory University, please complete the VA modules in Human Subject Protection. Additionally, all AVAMC researchers must satisfy VA specific credentialing and training processes, not included in this document. The Emory IRB has access to Emory CITI training certificates. If you have taken the VA modules, your CIIT certificate will need to be uploaded to eIRB with each project.

For VA specific information see http://www.atlaref.org/vamc/contact.cfm

You may also visit the main AREF (Atlanta Research and Education Foundation) website for more information about research at the AVAMC: http://www.atlaref.org/

2. Key Concepts Training for Investigators (for clinical trials only, see definition page 4)

A mandatory online training course for all investigators conducting clinical trials has been developed by the Clinical Trials Executive Committee, the Clinical Trials Task Force and other clinical trials advisory groups. See this website for registration information:

http://ocr.emory.edu/training/Courses.html

A certificate of completion can be saved to be provided to the Anesthesiology Research Office. See Appendix B for details about this training course. The IRB requires that this certificate is uploaded with each clinical trial submission.
Completion of this course is required every two years. A reminder email will be sent from OCR when it is time to take the refresher course.

3. Environmental Health and Safety Office Requirements (EHSO)

If you are a laboratory researcher, or if your clinical study requires human specimens to be analyzed in the Department Anesthesiology Lab in the Woodruff building or elsewhere (outside of the Emory Clinical Lab), there are EHSO training requirements. The following required training is online through the Emory Learning Management System (ELMS):

(1) Annual Research Laboratory Safety Training (course code 240150)
(2) Annual Blood Bourne Pathogen Training (course code 240100) and
(3) Biosafety Training every 3 years (course code 240120)

Contact Kathy Egan to assist you in determining whether EHSO requirements are applicable to your clinical project. Instructions for accessing the required training for EHSO can be found online by visiting this website: http://www.ehso.emory.edu/training/index.html

See Appendix C for detailed instructions on registering for the required EHSO courses and printing your certificates.

Some studies require a full Biosafety Review. To determine if this is required for your study see this website: http://www.ehso.emory.edu/programs/research-biosafety/research-protocol.html. If this review is necessary, completion of the Biosafety Notice of Intent Form is required and will request the following information for all study personnel: Employee ID#, vaccination status, training dates for Laboratory Safety and Blood Bourne Pathogen Training and Biosafety. Approval will not be granted until all requirements are satisfied. The Anesthesiology Research Office will facilitate submission of this form if it is required for your project. An annual review of your project by EHSO will subsequently be required.

4. RCR (Responsible Conduct of Research) Training

A number of funding agencies require Responsible Conduct of Research training as a condition of their grant funding, including the National Science Foundation and certain grants from the National Institutes of Health. See CITI RCR modules to assist you in meeting this requirement if applicable. Not all funding agencies/groups allow for only online RCR training/instruction so it is recommended that you check the specifications of your RCR requirements from the funder of your grant.

For more information about training requirements for researchers see: http://www.ctac.emory.edu/clinical_trial_guidebook/emory_training_requirements.html
5. Training for Non-Human (laboratory animal) Research

CITI training, formerly required for animal researchers, has been replaced with new IACUC training. IACUC has implemented the AALAS Learning Library (ALL) as the online resource to be used for mandatory IACUC training as well as to augment animal training of research personnel, students, facility staff, and IACUC members. Courses previously taken at the CITI website do not have to be retaken in the AALAS Learning Library.

For information including access procedures, please see Online Training on the IACUC website at http://www.iacuc.emory.edu/training/web-training.html.

Prior to submitting non-human research protocols for review and approval by the Emory University Institutional Animal Care and Use Committee (IACUC), all Key Research Personnel listed on an Emory IACUC submission, regardless of their position, must complete the IACUC mandated training. This tutorial also satisfies the NIH training requirement for obtaining federal funds. This training should be noted in the appropriate section of the IACUC Credentials form, indicating the species and techniques for which training was completed. The online IACUC Credentials Form is available at http://www.dar.emory.edu/FORMS/iacuc_credentials.php.

For Non-Human Research save the electronic certificate and submit to Nancy Ciliax; the refresher course is required every two years.
IV. ROUTING YOUR HUMAN RESEARCH PROJECT THROUGH THE EMORY SYSTEM

If your project involves human research, determine the type of research and refer to the attached decision trees and guidelines:

1. IRB Biomedical Research Pyramid (Appendix E) - Guidance for Investigators including “is your study considered research?”, exempt, expedited and full board review studies

2. OCR Decision Tree (Appendix D)

If applicable, concurrent review by OCR, OSP, and IRB is encouraged; submit simultaneously to all three Office of Research Administration units.
V. EMORY INSTITUTIONAL REVIEW BOARD (IRB) AND eIRB
http://www.irb.emory.edu/

“The Emory IRB facilitates ethically responsible human subjects research by assuring the rights and welfare of study participants.”

1. See the IRB website for STEPS FOR OBTAINING IRB APPROVAL
http://www.irb.emory.edu/documents/10stepstoapproval.pdf

2. See Appendix F for IRB Protocol Guidelines

3. The IRB staff will help you determine if your project is research.
   See this link for OHRP Human Subject decision charts and other information:
   http://www.irb.emory.edu/forms/new.html

4. Students seeking to do research must find a faculty advisor to provide supervision and responsibility for the study.

5. You may visit the IRB without an appointment during open hours on Fridays 11am-1pm to discuss your project.

6. All studies entered into the eIRB system ultimately require departmental approval (Dr. Laureen Hill)

7. All NEW Phase III studies that are industry-designed, initiated, and sponsored will be sent to Western IRB (WIRB) for review.
   See http://www.irb.emory.edu/forms/external-irbs/WIRB.html for information. Kathy Egan can assist with this submission.

8. See page 15 regarding setting up an eIRB account
VI. THE OFFICE FOR CLINICAL RESEARCH (OCR)

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

“The Emory University Office for Clinical Research (OCR) exists to ensure leading-edge, efficient clinical research, yielding improved patient care and outcomes.”

1. Pre-Award

If a human study research project generates billable procedures at an Emory facility we are REQUIRED to utilize the services of this office. (SEE OCR DECISION TREE, Appendix D For sponsored studies the current charge of $3900 is billed to the department for this service and should ultimately be incorporated into the sponsor’s budget. The department will typically be billed in advance of the final study budget and contract. During the pre-award phase, their services include a prospective reimbursement analysis (PRA) and they will negotiate a budget on our behalf with the sponsor. This fee is waived for certain Investigator initiated projects.

Please see: http://www.ocr.emory.edu/ocr%20submission/index.html to read more about OCR submission. The Anesthesiology Research Staff will facilitate this process for you.

2. Post-Award

The OCR will manage the billing process post-award utilizing the Emory Research Management System (ERMS)*. ERMS is a web-based clinical research financial management tool used to assist Emory Healthcare and Emory University with their joint Research Billing Compliance Program. It facilitates communication of subject enrollment and study visit activity with the impacted billing departments/units. As researchers, we are responsible for entering all enrollment and study visit data for every subject for whom a billable procedure is incurred from within the Emory system.*

If you are conducting a clinical trial with no billable procedures, your study still must be set up in ERMS. Contact the Anesthesiology Research Staff to submit the ERMS activation form to ocr@emory.edu.

Kathy Egan has access to ERMS; for more information and to access training see:

http://www.ocr.emory.edu/erms/index.html

*Every patient enrolled in studies meeting the requirements noted above (i.e. ANY PROJECT THAT GENERATES A BILLABLE PROCEDURE AT AN EMORY FACILITY OR ANY CLINICAL TRIAL WITHOUT BILLABLE PROCEDURES) must be registered in ERMS and a copy of the consent is to be faxed or scanned to OCR with the registration information on the day of consent.
3. How to obtain OCR Review

To obtain OCR review, the OCR submission form is required: http://www.ocr.emory.edu/forms/index.html
Go to OCR/Forms/OCR submission for the most current form

This document will be uploaded to the EPEX system (See next page for information about EPEX). This document and other required documents noted on this form may also be emailed directly to OCR@emory.edu.

4. Clinicaltrials.gov access

The OCR is the official PRS Administrator for all of Emory's clinical researchers. OCR will assist faculty and staff in establishing a user account and password for the Clinical Trials website. Contact OCR@Emory.edu for help with getting access to ClinicalTrials.gov. Additionally OCR monitors the active Clinicaltrials.gov studies for compliance.

5. Training and other Educational Opportunities

The OCR offers “Introduction to Clinical Research at Emory”, an intensive two-day course open to new Emory clinical research employees. This program includes instruction on federal requirements for human subjects' research, reportable events and HIPAA rules and regulations. It also includes Emory-specific training on Institutional Review Board (IRB) submissions, protocol routing, conflict of interest regulations, effort reporting, and research billing compliance. See the OCR website for more detail. http://www.ocr.emory.edu/training/index.html

Investigators and other researchers should subscribe to one of the OCR list serve groups for updates.
VII. OFFICE OF SPONSORED PROGRAMS (OSP)
http://www.osp.emory.edu/

“The OSP, as an integral part of the University’s research infrastructure, collaborates with the Emory community to identify, obtain and administer extramural funding in support of the mission of the University.”

Faculty should consult with Kathy Egan or Nancy Ciliax when considering applications for funding. Faculty may not submit a grant without OSP approval.

1. Emory Proposal Express (EPEX)
http://www.ogca.emory.edu/ra-systems/epex1/index.html

Funded proposals must be reviewed for their scientific merit and adherence to University and agency guidelines. To facilitate this process, we are mandated to use the Emory Proposal Express system (EPEX) for externally funded projects, which is the proposal routing system.

The purpose of EPEX is to assist in budget development, electronic routing, and institution approval related to extramural funding at Emory. EPEX is a necessary accompaniment to any Grant or Contract requiring Institutional endorsement. The Anesthesiology research staff will facilitate submission of this application in EPEX.

Your department approver (Finance Administrator), Chairperson, Dean, and OSP will electronically sign off on your proposal. Note also that OSP acts as the authorized office to sign applications for the institution.*

See Appendix G for EPEX instructions.

To access your proposal in EPEX once it has been submitted by the Research Office:

You will logon to compass using your Emory university logon and password

https://compass-login.emory.edu/psp/fsprod9/?cmd=login&languageCd=ENG

- Click on Grants
- Click on Emory Proposal express, under Proposals
- Search for your grant by clicking the search tool next to PI ID and enter your name
- Click on the PI ID, then click search again.

New faculty, students, Postdocs and all staff who will be an investigator must request grants security access. Obtaining EPEX access for a PI is a two step process. See link above (under EPEX) for instructions. The Department Compass ID is 730000.
2. NIH Grants

See the OSP website for grant application kits, proposal development and processing, award administration, and project requirements and closeout
http://www.osp.emory.edu/services/index.html

NIH grants **must** be submitted through the CAYUSE 424 system and will be specific to your funding opportunity announcement. Your research administrator will help you with this.

http://www.ogca.emory.edu/ra-systems/cayuse-424.html

See other information within this document regarding NIH funded research studies.

3. Confidentiality Agreements (CDA) and Clinical Trial Agreements (CTA)

When a *confidentiality agreement (CDA) template is received from a sponsor or CRO, it MUST be submitted to OSP for institutional review and signature. CDAs may be submitted via email to the OSP Department analysts, see: http://www.osp.emory.edu/about/dept-listing.html - timetable for return, approximately 2 weeks
   a. They will review and interact with sponsor or representative to make revisions if necessary
   b. When ready for signature- they will email us to print 2 originals
   c. Request PI signature on both and return to OSP for them to obtain Institutional Signature and then to submit to sponsor for their signature
   d. The sponsor should return one original back to OSP- we usually do not get a copy, but we can request this for the study regulatory file

Clinical Trial Agreements (CTA) are submitted via EPEX. Our sponsored research analysts will negotiate the language in the CTA directly with the sponsor of the funding. This will occur once the School of Medicine has reviewed and approved a study within the EPEX system. This may occur simultaneously with budget negotiation and IRB submission.
VIII. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
http://www.iacuc.emory.edu/

“The Emory University IACUC is an oversight committee charged with the responsibility of ensuring the proper care, use and humane treatment of animals used in research, testing and education.”

Committee approval will be required for animal use in all grants. Please refer to the IACUC website for guidelines.

IACUC Protocol Submission

1. New protocol requests:

You must first request access to TOPAZ. (See Section II, 4, page 8) To create and begin work on a new protocol go to:


Click on “Animal Protocols” with the Mouse icon and select “Create original Protocol”. Then you will select the current application form, which is named “Emory Original (date)”.

2. Amendments (modifications - only available on protocols entered by the PI or his staff):

To create and begin work on an amendment for a protocol that you have entered in TOPAZ, you will click “Animal Protocols” with the Mouse icon and select “Create Amendment Protocol”. Then you will select the protocol that you want to submit an amendment for.

3. Annual Renewals (only available on protocols entered by the PI or his staff):

To create and begin work on an annual renewal for a protocol that you have entered in TOPAZ, you will click “Animal Protocols” with the Mouse icon and select “Create Renewal Protocol”. Then you will select the protocol that you want to submit the annual renewal for.
IX. OTHER REQUIREMENTS FOR RESEARCHERS

1. Electronic Conflict of Interest reporting (eCOI)

All Investigators (anyone responsible for the design, conduct or reporting of research) are required to complete eCOI documentation for all funded projects and projects with materials support only. The study administrator will initiate this process and you will receive an email prompt to complete the required information for the project.

Additionally, the Annual Certification Form (see https://www.ecoi.emory.edu/) must be completed by all faculty and researchers during the annual certification period to confirm their current external activities and financial interest in research are up to date.

2. Emory IRB (eIRB) account

If you are using the eIRB for the first time, try logging on to the Emory IRB website with your Emory University ID and password.

https://eresearch.emory.edu/Emory/Ro mms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5B0%5D%5B149874E902185897C144551%5D%5D&redirect=https%3A%2F%2Feresearch.emory.edu%2FEmory%2F

If you are unable to log on, see the following webpage for additional instructions to obtain an account. Notify the Research Department when your account is set up.

http://www.irb.emory.edu/researchers/eresearch/getacct.cfm

Please access IRB training videos here if desired:
http://www.irb.emory.edu/training/how-to-access-eirb.html#

3. Credentialing

All non-MD research personnel must have a sponsor in the department and MUST go through the credentialing office in order to be granted privileges to perform any research duties that require interaction with human subjects within the Emory system. Once a new employee completes the initial HR process, he/she should be directed to Myra Kitchin (contact information below) prior to performing any research duties. Completion of this process takes approximately two months, and it is possible to start some of the requirements prior to hire date.

Contact for details:
Myra Kitchin, BSN, RN
Office of Credentialing
F-213, 1364 Clifton Road
Atlanta, GA 30322
Telephone: 404-712-0510
Confidential Fax: 404-712-4976
4. Shipping and handling of infectious and biological substances:

The shipping of infectious and biological substances can be done by anyone who has been officially trained and certified. In the Anesthesiology Department, Kathy Egan maintains this certification for clinical research and Nancy Ciliax maintains it for basic science research. It is good for two years. Contact Melissa Blackmon, the Biosafety Administrative Assistant to register for upcoming shipping training. For details on the next training class, visit the EHSO website: http://www.ehso.emory.edu/training/courses.html

5. Access to TOPAZ is required for research involving animals

You must request access to TOPAZ at http://www.iacuc.emory.edu/topaz/ Your login is your Emory University assigned username and password. All individuals need to REQUEST access to TOPAZ before being able to login to the system. The IACUC office will need information about your research for your request in order to set up your account. *Please note, the IACUC office strongly recommends that each applicant attend a TOPAZ training session prior to gaining access to TOPAZ.

6. Accessing Cayuse 424

Cayuse 424 is available to Emory investigators for the submission of federal grant proposals. Your research administrator, Nancy Ciliax, will set up your grant proposal in Cayuse 424.

7. eRA Commons ID

For NIH grants you must obtain an Electronic Research Administration (eRA) commons ID; this ID can be requested from our OSP analyst (See OSP section for website), also see http://era.nih.gov/

Our current OSP analyst for NIH grants is Cassandra Murphy 404-727-2339, cmurph5@emory.edu.

She will request the user’s preferred username, if any, email address and study role in setting up your eRA Commons ID. She will email your password to you.
X. CLINICAL TRIALS AUDIT AND COMPLIANCE OFFICE

http://www.ctac.emory.edu/

The Clinical Trials Audit and Compliance (CTAC) department is an Emory University Trustee established department reporting to the Executive Vice President for Health Affairs and Vice President for Research for Woodruff Health Science Center. Their goal is to be a value based program that will ensure subject safety, foster a culture of responsibility, and ensure high quality research in accordance with ethical principles, federal regulations and Institutional policies. To accomplish their mission, their team reviews a sample of clinical trials being conducted in each department and provides education, tools, and corrective and preventive action plans, when needed.

There are multiple tools for managing your study located on the CTAC website. http://www.ctac.emory.edu/clinical_trial_resources/Clinical%20Trial%20Tools.html
XI. CLINICAL TRIALS.GOV

This website was initiated in 2000 to increase transparency in Clinical Trials, currently regulated by “FDAAA 2007” and ICMJE, requiring prospective registration of all clinical trials. Non compliance enforcement provisions are serious and include fines up to $10,000/day and withholding of NIH grants funding. Registration requirements include:

All intervention studies (all phases) (drugs, biologics and devices- as defined by the US FDA). For further definitions, clarification of registration requirements and information on results reporting requirements, see the Clinicaltrials.gov website http://prsinfo.clinicaltrials.gov/registering.pdf

Once a study is entered into Clinical Trials.gov (https://register.clinicaltrials.gov/) by the owner and you are listed as the responsible party (i.e. PI), by that owner, the record can only be verified (for correct information), approved and released for publishing by you the PI. The OCR (see information, page 8) will provide initial access.

From the OCR website:
"There is a new federal regulation for billing Medicare recipients participating in clinical trials. As of January 1, 2014, the clinicaltrials.gov number (NCT#) assigned to the study must be listed on Medicare claims for services provided to clinical trial participants. If the number is not listed on the claim, payment will be denied. If your assistance is needed, we will contact you directly.”
XII. INFORMATION REGARDING NIH FUNDED RESEARCH STUDIES

It is important to note that, while Cayuse 424 is available for roughly 97% of federal grant opportunities available in Grants.gov, there may be a few programs for which Cayuse 424 cannot be used.

To submit those applications which cannot be submitted through Cayuse 424, investigators must identify the Funding Opportunity Announcement (FOA) for the program to which you wish to submit. This FOA will contain the application package and instructions. Your research administrator, Nancy Ciliax, will use the Adobe forms kit and submit the kit in its final form to OSP using Emory Proposal Express (EPEX).

Proposals to be submitted using Cayuse must be routed to OSP using EPEX. Nancy Ciliax will enter your proposal in Cayuse and also into EPEX. You will be asked to approve the proposal in EPEX before it is routed to OSP.

After all approvals (including the Department and the School of Medicine) have been received in EPEX the proposal will be routed to OSP for final review. If they have any questions, they will work with you and Nancy Ciliax to resolve all issues prior to submission. After submission, if the application has validation errors, they will work with you and Nancy Ciliax to correct and re-submit the application prior to the deadline.
XIII. OTHER IMPORTANT INFORMATION FOR RESEARCHERS

1. **Effort Calculation Reports**

   [http://ocr.emory.edu/forms/effort-calc.html](http://ocr.emory.edu/forms/effort-calc.html)

   These forms are required for the EPEX submission of clinical research, funded studies.

2. **SOM Routing Sheets** (the “School of Medicine Proposal Checklist” also known as the Blue Sheet)

   Nancy Ciliax and Kathy Egan have these documents. They must be completed and signed by all parties within the department and then scanned into the EPEX system for all funded studies.

3. **The Office of Research Compliance** was created to ensure that Emory University complies with the various federal, state, and local regulations impacting research. Refer to their website, for more valuable tools and information:

   [http://www.orc.emory.edu/](http://www.orc.emory.edu/)

4. **Investigational Drug Service (IDS)** is an integral part of the research process at Emory University. Since January 1, 2008, University policy has required that investigators who conduct drug studies use IDS for the management and dispensing of research drugs. The policy applies to all investigational drugs or drugs provided free of charge for clinical studies. For more information:

   [http://www.ocr.emory.edu/ids/index.html](http://www.ocr.emory.edu/ids/index.html)

5. A complete research protocol must be submitted and approved by the Grady Research Oversight Committee **BEFORE** research can begin in the Grady Health System. See the IRB website New Submission Guidance/ **Ancillary Review** section. [http://www.irb.emory.edu/forms/index.html](http://www.irb.emory.edu/forms/index.html)

6. There are many categories of human subject research projects. After reviewing the tools provided in this guide, please confer with Kathy Egan, Clinical Research Nurse III, **prior to submitting your proposal to the IRB, etc.** for guidance with the process.

7. Please consult Nancy Ciliax, Senior Research Project Coordinator, **prior to initiating your animal research project.** She is also expert in managing NIH funded projects.
Appendix A
CITI Instructions for Human Subjects Research

Required for every researcher every two years.
Please see the following IRB website for more details if desired:
http://www.irb.emory.edu/training/index.html

How to Access CITI

- Go to http://www.citiprogram.org/

NEW USERS:
- Create an account if you have never taken a course
- Affiliate with Emory University* (use Emory employee ID number)**
- Complete your profile and answer the enrollment questions – in most cases for Anesthesiology related projects, enrollment in the BIOMEDICAL course for Human Subject Protection will be the option to select.
- The courses that you are required to take will appear on the next screen and will be ready for your access
- Save copy of certificate electronically and email to kfegan@emory.edu

If PREVIOUSLY REGISTERED:
- From the Main menu: click on ‘Add a course or update your learner groups’
  - select option 1 – "I am engaged in or supervise human subjects research, or must otherwise take human subjects coursework (this includes both biomedical and social/behavioral studies)."
  - click Next
  - choose option 1 – “I need to complete coursework in human subjects protection for biomedical investigators.”
  - click Next
  - choose "Does not apply to me at this time." for the RCR training course (unless required for your specific project- see Section III of this guidebook)
  - click Next

Note regarding research at AVAMC:
If you are conducting research at the AVAMC you are required to complete the VA CITI modules, known as the VA Pride Curriculum. These modules are accepted for research at other Emory institutions (EUH, EUHM, Grady). However, Emory modules are not accepted at the AVAMC.
Appendix B
Key Concepts Training Guidelines

To register for each module, please complete the following steps:

1. Login: [https://elmprod.emory.edu/](https://elmprod.emory.edu/).
2. Enter your University ID and Password.
3. Select “Search Catalog.”
4. Select “Programs” in the Basic Search Category.
5. Type in the words “Key.”
6. Click “Register.”
7. On the program Details Page, each module activity will be listed. There are 11 modules to complete.
8. Click on the module you wish to take, e.g. “FDA 1572.”
9. Click “Enroll.”
10. Click “Submit Enrollment.”
11. Click “Launch.”
12. Click “Launch” – again.
13. The module will load for you to complete.

Steps #7-13 must be completed for each module listed within the program.

**To Print Certificate of Completion:** (This may take a few minutes to process)

- Log in using your university network ID & password: [http://elmprod.emory.edu](http://elmprod.emory.edu)
- Click on the All Learning link
- Click on the printer icon in the ‘Certificate’ column to print a certificate
Appendix C
Environmental Health and Safety Office (EHSO) Lab Training Requirements

For all personnel, including volunteers, or work study students who work with bacteria, biotoxins, viruses, biological vectors, fungus, animal tissues/fluids, or chemicals there is required EHSO training. These certificates should be maintained within the laboratory manual. Documentation of this training is also required for submission of the *Biosafety Notice of Intent Form*, a review of protocols using biological toxins, recombinant DNA, infectious agents or human cells, tissues, etc.

Training is available online in the Emory Learning Management System (ELMS). Training should be current at time of submission of a protocol. At time of approval, Personnel with outdated or incomplete training will not be added to the protocol.

Training Instructions (*preferred browser is Mozilla Firefox*):

http://elmprod.emory.edu: access ELMS, log in with university ID & password
- Click on the 'Search Catalog' link on left side of screen
- Click on ‘Advanced Search’
- Select ‘Online’ from the ‘Type:’ drop-down menu
- Type the Course Code in the 'Code' text field
- Click on ‘Search’
- Scroll to find the desired course; click on the ‘Enroll’ link on the right side of the screen
- Click on the ‘Enroll’ button at bottom of page
- Click on the ‘Submit Enrollment’ button
- Click on the ‘Launch’ link at bottom
- Click on the ‘Launch’ link in the table of contents and the file will open

**NOTE:** If you need to stop before completing the course, you can re-launch it by going to the Self Service, My Learning option, & clicking on the Launch button

**Biosafety Courses**

**Research Laboratory Safety Training (Course Code 240150):** Lab Safety Training is required once a year for the PI and all personnel listed on protocols.

**Bloodborne Pathogens (BBP) for Research Training (Course Code 240100):** BBP Training is in addition to Lab Safety Training and is required for the PI and all personnel listed on protocols that involve human bloodborne pathogens which include human blood, certain body fluids, unfixed tissues, cells and cell lines. This training is required once a year.

**Biosafety Training (Course Code 240120) – NEW:** This training is required every 3 years for the PI and all personnel listed on the protocol.

**To Print Certificate of Completion:** 
(This may take a few minutes to process)
- Log in using your university network ID & password:  http://elmprod.emory.edu
- Click on the **All Learning** link
- Click on the **printer** icon in the ‘Certificate’ column to print a certificate
Appendix D

DOES YOUR STUDY REQUIRE OCR REVIEW?

1 Human subject as defined by OHRP “means 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.”

2 Intervention as defined by OHRP “includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.”

3 Complete Package includes OCR Request for PRA and Budget Development Form, protocol, clinical trial agreement, investigator effort calculations report, draft budget, informed consent—sponsor and Emory drafts, most recent FDA communications, signed Blue Sheet, and SPEX submission.

Version Date: January 6, 2011
Conducting Research Guide for Anesthesiology Investigators

Appendix E

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

Emory University IRB
Guidance for Investigators

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
Appendix F
Emory IRB Guidance for eIRB Protocols

1. Full title, short title (if any), Investigators’ names, draft date

2. Précis/Abstract: A brief (usually 400 words or fewer) description of the study objectives, population, design, and outcome measures

3. Introduction and Background: A summary of the primary hypothesis, purpose, scholarly rationale, and prior literature.

4. Objectives: The primary and secondary aims and outcome measures.

5. Study design and methods: The procedures to be performed (distinguish between the procedures performed for diagnostic or treatment purposes and those for research); risks/discomforts and potential benefits if any to subjects, patient class, science/society (whether direct or indirect); what type of information will be collected; what specimens will be collected, if any; and randomization and blinding. If applicable: if data/samples collected for this study will be saved/banked/archived for future uses beyond the scope of this study, describe plans for identifying and storing data/samples for such future uses.

6. Participant selection: Requested sample size and expected refusal or withdrawal rate; inclusion/exclusion criteria with justification; subject recruitment plan; screening for eligibility; and withdrawal from study. (Informed consent information may be included here in addition to the eIRB section on Informed Consent Process.)

7. Statistical analysis: Sample size determination and power; interim monitoring and early stopping; analysis plan; and statistical methods.

8. Adverse event reporting: Description of plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the Emory IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.

9. Data and safety monitoring plan (DSMP): Plans for monitoring the progress of the trial and safety of participants; description of the mechanism for reporting adverse events to the IRB and federal agencies (see above, too); and plans for assuring data accuracy and protocol compliance. If a data and safety monitoring board (DSMB) will be used, include information about its charter, frequency of meetings, and constituents.

10. If applicable: pharmaceutical, biologic, and device information

11. References and appendices
Your research administrator will complete this submission. Please see below for documents required for submission and how to enter your electronic approval in EPEX.

A. There are three ways to approve your EPEX proposals before they routed.
   Log into EPEX at: https://compass-login.emory.edu/

   1. After logging into EPEX: Go to Grants>Proposals>Emory Proposal Express. Business Unit = GRANT, enter Proposal ID. Click search. Click on the link to the Proposal ID. Once in the proposal, scroll to the bottom of the first page and click on the "Approve" button. If you do not know your Proposal ID, you may locate it using the PI last name. See page 12.

   2. Through the email you will receive: click on the link in the email. Log into Compass. Go back to the email again and click on the link. This will take you directly to the proposal. Scroll to the bottom of the first page and click on the "Approve" button.

   3. Through the Approval Inbox: Navigate to the approval inbox: Smart Solutions>Smart Workflow>Transaction Approval>Approval Inbox. Search Type = Grants Proposal. Click Search. The list of all proposals currently awaiting your approval will show up below. Click on the link to the proposal ID. If nothing happens, make sure your pop-up blocker is disabled and try again. Once in the proposal, scroll to the bottom of the first page and click on the "Approve" button.

B. For NIH sponsored grants the following documents are required for EPEX submission:
   1. eRA Commons ID – get from OSP
      a. Nancy will contact OSP
   2. Conflict of Interest (COI) – for all key personnel
      a. Nancy will initiate
      b. You will receive an email
   3. Budget
      a. Initial period
      b. Entire budget period spreadsheet
   4. Biosketch
   5. Cover letter
   6. Project summary/abstract
7. Project narrative
8. Specific Aims
9. Research Strategy (final due 5 days before due date to OSP)
   a. Be sure to check the page limit
10. Bibliography
11. Environmental impact
12. Facilities
13. Equipment
14. Vertebrate Animals/Human subjects

C. For Industry sponsored clinical research the following documents are required:
1. Proposed Agreement (CTA) template (a CDA has already been signed by the institution) and contact information for the sponsor
2. Proposed sponsor budget
3. Effort Calculation Reports (Complete for each investigator and Sub-I through the following link: http://ocr.emory.edu/forms/effort-calc.html)
4. Protocol
5. IRB approval (if available)
6. Emory Informed Consent Form
7. eCOI summary report as a PDF (see page 15)
8. Signed and scanned SOM checklist/blue sheet
9. OCR submission form
APPENDIX H
IACUC Training
Animal Species/Techniques Description

(This module must be completed in order to obtain IACUC credit for training)

This course is designed with the following specific goals in mind:
1. Help investigators fill out animal protocol forms and interact effectively with the Institutional Animal Care and Use Committee (IACUC);
2. Provide a review of basic issues with which IACUC members must become familiar to effectively review animal research proposals;
3. Provide information on important issues that must be addressed in a typical animal protocol form; and
4. Provide training required by the USDA Animal Welfare Act Regulations and Public Health Service Policy.

Working with Animals (SPECIES) in Research Settings
The goal of this course is to cover important information about using animals in biomedical research settings. If you are responsible for handling animals or if you must write an animal use protocol, this course will be useful by providing you with:
1. Information on key regulatory issues.
2. Guidance on searches for alternatives in the care and use of animals.
3. Highlights of unique biological features of these animals.
4. Overviews of acceptable basic methodologies.
5. Requirements for supportive care procedures.