**Study Identification Information**

1.0  * Enter the Full title of the study (include any version dates from the sponsor)

    [CIRB-insert study title]

2.0  * Enter a SHORT identifying title for tracking purposes:

    CIRB Study

3.0  What is the estimated start date of this study:

4.0  What is the estimated completion date of this study:

5.0  * Name of Principal Investigator. Limit is one person; Emory affiliation is required. If name does not appear in menu, the person probably does not yet have an eIRB account.  
    [For more information about obtaining an eIRB account, click here.]

    Andrea Goosen  Dept: IRB

6.0  Names of Emory Co-Investigators. May include Emory personnel and non-Emory persons with sponsored eIRB accounts. If name does not appear in menu, the person probably does not yet have an eIRB account.  
    [For more information about obtaining an eIRB account, click here.]

    Last  First  Dept

7.0  Names of Emory Study Coordinators. May include Emory personnel and non-Emory persons with sponsored eIRB accounts. If name does not appear in menu, the person probably does not yet have an eIRB account.  
    [For more information about obtaining an eIRB account, click here.]

    Last  First  Dept

8.0  Names of other Emory Study Staff not listed above. If name does appear in menu, the person probably does not yet have an eIRB account.  
    [For more information about obtaining an eIRB account, click here.]

    Last  First  Dept  Type

9.0  Enter information on Non-Emory Study Staff:  (this is for non-Emory personnel who will not be logging into eIRB)

    Name  Affiliation  Type

**Required Reviews**

All Studies **MUST** have the approval of the Department Chair **OR** Faculty Advisor, which ever one is applicable. eIRB auto populates the Department Approver based on the Principal Investigator’s affiliation. If the listed Dept is not responsible for overseeing your research study then please remove it. Having additional Dept Approvers listed or incorrect Dept Approvers listed will cause delays in the review of the study.

1.0  Department/division Approvals Required - this is determined by the primary department for the PI according to HR. Add any additional Dept/Div approvals that may apply to the PI:

    Department Name  
    [Please fill out]

2.0  * Are you a Student Researcher at Emory College, School of Public Health, School of Law, School of Nursing, Business School, Graduate School or School of Theology?

    * Yes No

    If yes, add your Faculty Advisor:
You must remove the department/division approval in 1.0 if you have chosen faculty advisor approval for this study.

3.0 If a committee is listed, you must apply to each of the listed committees using their current and separate application process.

ID
EHSO - Radiation Safety
Office of Quality Manager

4.0 * Will there be any clinical professional or technical charges (e.g., for drugs, medical devices, laboratory or radiology tests, physician services, or medical procedures) during the course of this study that generate a CPT or CDM code at an Emory or Grady healthcare facility that may be billed to study accounts or third party payors such as Medicare, Medicaid, or health insurance companies?
* Yes No

ID: IRB00064666

Study Sites
• A site is where recruitment will occur
• A site is where the research will take place
• A site is data collection will take place
• A site is where data analysis will take place
• A site is where data will be stored

1.0 * Indicate all locations where the Emory Investigator will conduct this study:
Emory Clinic
Emory University Hospital (non-CIN)
Winship Cancer Institute

2.0 If "Other - ", list all other locations where the Emory Investigator will conduct the study:
Name of the Site
IRB of record for this site
There are no items to display

ID: IRB00064666

Funding

1.0 * Choose the funding status of this study:
This study is currently funded

2.0 For each sponsor providing funding for this study:

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Type</th>
<th>Grant</th>
<th>OSP UPN</th>
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<tr>
<td>View Federal Agency</td>
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</table>

ID: IRB00064666

Research Design

1.0 * Enter or Upload a Lay Summary. This should be a non-scientific summary of the research.
CIRB study
Name
Modified Version
There are no items to display

2.0 * Upload scientific protocol documentation:
Name
Modified Version
Add protocol here.docx 2/11/2013 11:08 AM 0.01

← Please edit to reflect all sites involved
← Please add specific funding information
← Lay summary is not necessary, leave as is
← Please add CIRB protocol
Type of Research

Research is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

Human subjects are defined by the regulations as "living individual(s) 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. Federal requirements to protect human subjects apply to a much broader range of research than many investigators realize, including research that uses human specimens (such as cells, blood and urine), residual diagnostic specimens and medical information.

Intervention 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.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Answer the following questions to help determine the type of research being conducted (Social or Biomedical):

1.0 * Does this study involve any type of medical or physiological interventions with human subjects? See above for definitions of "Human Subjects" and "Intervention"

   Yes No

2.0 * Is this a Clinical Trial (defined as a biomedical or behavioral research study of human subjects that is designed to answer specific questions about interventions such as drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)?

   Yes No

3.0 * Is this secondary data analysis of existing data, no interaction, no observation? ("No Subjects" study) See above for definition of "Human Subjects" and "Interaction"

   Yes No

ID: IRB00064666

Biomedical Research

Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]

- Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

- Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

Emergency Use IND - The need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in the usual manner. In such cases, FDA may authorize shipment of the drug for a specified use [21 CFR 312.36].

The Group C program is a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial.

The Parallel Track policy [57 FR 13250] permits wider access to promising new drugs for AIDS/HIV related diseases under a separate “expanded access” protocol that “parallels” the controlled clinical trials that are essential to establish the safety and effectiveness of new drugs.

A Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD). A HUD is a device that is “intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.”

1.0 * Emergency, One time use and Special considerations:

   None of the Above

2.0 * Medical procedures and considerations
Radiation exposure // Radiation exposure ** Remove any procedures that do not apply.
Blood test
Other medical procedures or considerations
There is no need to add any other procedures.
Cancer Related Research * e.g., human blood, body fluid, fixed / unfixed tissue or other potentially infectious materials (OPIMs); infectious agents; recombinant DNA, creating recombinant DNA/RNA constructs, e.g., pcDNA, pBluescript, any vector/insert manipulation; inserting recombinant DNA/RNA constructs into human cell lines, tissue cultures, or whole humans; human gene transfer; non-replicative viral vectors; prions; biological toxins; nanomaterials, nanoparticles ** e.g., will any radiological tests or treatments be ordered by PI or any member of the research team

3.0 * Data collection types
None of the above
And
There are no items to display

4.0 * Select any Keywords that describe your study:
Cancer/Carcinogenesis

ID: IRB00064666

EHSO - Radiation Safety
For more information, please go to the Environmental Health & Safety website

1.0 * FOR EACH form of Radiation to be reviewed by the Radiation Safety Committee:
Form
View
Conventional diagnostic radiological studies

ID: IRB00064666

HIPAA Determination

The "RWHSC" is comprised of the School of Medicine (SOM), School of Nursing (SON), School of Public Health (SPH), Yerkes Primate Center (YPC), Student Health Services (SHS), Psychological Center (PC), University Counseling Center (UCC), and the Oxford College Student Health & Counseling Center.
For a list of PHI identifiers, go to http://www.irb.emory.edu/researchers/formstools/docs/other/phi_identifiers.pdf

1.0 * Will you be receiving or disclosing any information about a person's health, healthcare or payment for healthcare that has any associated identifiers?
Yes
No

2.0 * Is there any person on the study (Study Staff) that is part of the "RWHSC Covered Entity"?
Yes
No

3.0 * Will any protected health information (PHI) be provided by any component of the "RWHSC Covered Entity"?
Yes
No

ID: IRB00064666

Protected Health Information (PHI)

1.0 * What are your sources of PHI? (Choose all that apply)
There are no items to display
If other, please describe:
If using data previously collected, enter the last date of collection:

2.0 * You will require access to PHI for the following reasons: (Choose all that apply)
   The identification of eligible subjects: Yes No
   The conduct of the study: Yes No

3.0 Do you need access to the entire medical record and/or health information database for recruitment?
   Yes No
   If not, list portions of the medical record and/or health information database for which you will require access for recruitment:

4.0 Do you need access to the entire medical record and/or health information database for conduct of the study?
   Yes No
   If not, list portions of the medical record and/or health information database for which you will require access for conduct of the study:

5.0 * It is assumed that all personnel currently associated to this study will request and/or use the collected PHI. Do you plan to use any other persons to request or collect the PHI?
   Yes No
   If yes, be sure to update the PERSONNEL section of this application!

   Have all persons associated with this study completed Emory’s approved CITI training course?
   Yes No

6.0 * PHI will be shared with the IRB. Please identify any other person or group with whom the PHI will be shared or disclosed:
   There are no items to display
   If Other - please describe:

7.0 * Provide the date and/or event by which you will no longer need to use the collected PHI:
   Date: 
   Event:

ID: IRB00064666

-----------------------------------------------------------------------------------------
HIPAA part 1

1.0 * Will you be using data with the following HIPAA identifiers? (Choose all that apply)
   There are no items to display

2.0 * Check the HIPAA Authorization Type you will be utilizing:
   Stand-alone document

3.0 * Check the type of HIPAA Waiver you are requesting:
   Partial HIPAA waiver for identifying potential subjects and determining eligibility

ID: IRB00064666

-----------------------------------------------------------------------------------------
HIPAA part 2

1.0 * Describe why the research cannot be practicably conducted without authorized access to PHI?

2.0 * Describe how the privacy of the PHI will be protected:

3.0 * The investigator believes the use or disclosure of the PHI for this study represents no more than a minimal risk to the privacy of the subject because:
   Identifiers are protected against improper use or disclosure by the following means: (Choose all that apply)
   There are no items to display
   Identifiers will be destroyed upon completion of: (Choose all that apply)
   There are no items to display
   If other, please describe:

4.0 If identifiers will NOT be destroyed, then explain why they must be retained (e.g., longitudinal study; specific federal requirements, etc...)

ID: IRB00064666

-----------------------------------------------------------------------------------------
Study Population

1.0 * Indicate the number of subjects to be enrolled at Emory sites or by an Emory Principal Investigator: ≤ Only add how many subjects are to be enrolled locally 

2.0 * Indicate the number of subjects to be enrolled by all sites:

3.0 * Indicate the subject pool gender:
Male and Female

4.0 * Will the enrollment be limited to a specific ethnic or racial group:
Yes
No

If yes answer the questions below:
Complete and insert the NIH Targeted/Planned enrollment table: (this can be found at http://www.irb.emory.edu/researchers/formstools/docs/other/NIH_Targeted_Planned_Enrollment_Table.doc)

Name Description
There are no items to display

Justify the limiting of the study to the specific ethnic or racial group:

5.0 * Indicate the study population types:
1. You must select Adults and/or Minors.
2. You must select at least one additional population type.

Adults (age 18 and over)

¬ No need to select any other population types

6.0 * Is this a VA study? Yes No

If yes, will non-veterans be enrolled into the study? Yes No

If yes, please justify enrollment of non-veterans:

Recruitment and Payment

Recruitment materials should include the following:
• The name and address of the researcher and where the research will take place
• The condition under study and/or the purpose of the research
• In summary form, the criteria that will be used to determine eligibility for the study
• A brief list of participation benefits, if any
• The time or other commitment required of the subjects
• The person or office to contact for further information

1.0 * Describe in detail how subjects will be identified and recruited:
N/A CIRB Study

2.0 * Describe who will make initial contact and how:
N/A CIRB Study

3.0 * Will physicians or staff refer subjects?
Yes No

Will referring physicians or staff receive any incentives to recommend subjects for study participation:
Yes No

If there will be an incentive, please describe:

4.0 FOR EACH RECRUITMENT ITEM - attach copies of all recruitment materials that will be used:

Material Date Modified
There are no items to display

5.0 * Describe any relationship with the subject’s healthcare provider (recruitment, notification of participation):
N/A
6.0 * Describe the safeguards in the recruitment process to protect against the potential or appearance of coercion:

N/A

7.0* Will participants be paid in this study? Yes No

If yes, please list the amount and schedule of all payments:

If yes, will payments be pro-rated if a participant withdraws early? Yes No

If payments will not be pro-rated in the event of early withdraw, please justify:

ID: IRB00064666

-----------------------------------------------------------------------------------------------------------------------------

Informed Consent Process ←Leave section as is. Only need to upload the HIPAA Authorization in Q14.

1.0 * Describe plans for obtaining informed consent and/or assent, including any requests to the IRB for waivers of elements or documentation of informed consent and/or assent, by checking all the boxes that apply. Note that age of majority is determined by the jurisdiction in which the subjects’ research activity will take place.

Signed consent by adult subject (all elements included)

Note: Upload any Waiver Worksheets and supporting documents below at 14.0 of this section. The IRB will review requests for waivers along with its review of this submission.

2.0 * Provide the number of CONSENTs contained in this submission (do not include Stand-alone or separate HIPAA authorization)

1

3.0 * Provide the number of ASSENTs contained in this submission (do not include Stand-alone or separate HIPAA authorization)

0

4.0 * How will consent be obtained?

N/A

5.0 * Where will consent be obtained? (office, hospital room, phone)

N/A

6.0 * When will consent be obtained? (pre-operatively, days/hours before research is to begin)

N/A

7.0 * Who will be the person(s) obtaining consent? (i.e. the person(s) participating in the informed consent dialogue and/or signing the informed consent document. For large studies, please provide the roles, such as PI, Co-Investigator, treating physician investigator, nurse coordinator, etc...)

N/A

8.0 How will verbal consent/assent be documented:

9.0 * Will all adult subjects have the capacity to give informed consent?

Yes No

How will the capacity to give informed consent for adult subjects be assessed?

10.0 If subjects are unable to give consent (e.g., minors or cognitively impaired), describe how consent of the legally authorized representative and assent from the subject will be obtained: (Include information on ongoing consent, waiting periods and independent monitors as applicable)

11.0* What measures will minimize the possibility of coercion or undue influence?

N/A

12.0 * What information will be communicated to the participant or legally authorized representative?

N/A

13.0 * Will the consent be released to the subject’s health care provider?

Yes No

14.0 * Upload waiver worksheets, consent forms, assent forms, HIPAA forms, scripts and/or information sheets here. Be sure to use the current Document Stamping Template and include a version date!

Note: If this study has a Certificate of Confidentiality, please do not upload it here. Please upload it in Data and Safety Monitoring Plan below, at 6.0.

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<thead>
<tr>
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<tr>
<td>Awaiting CIRB ICF.docx</td>
<td>2/11/2013 11:19 AM</td>
<td>0.01</td>
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<tr>
<td>Please upload your HIPAA document here.docx</td>
<td>2/11/2013 11:18 AM</td>
<td>0.01</td>
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Data and Safety Monitoring Plan

Ways to monitor for safety:

1. Surgical procedures if deemed necessary will be performed in an operation room.
2. Administration of any drugs will be performed by a physician or by a certified Health Care Professional (nurse practitioner, physician assistant or registered nurse).
3. Blood tests and physical examination will be performed regularly to detect side effects.
4. Case report forms will be completed in a timely fashion so as to be reviewed by the PI, monitor, sponsor, et al.
5. The participant will be contacted at regular intervals to identify any adverse events that may have occurred following administration of any drugs, and the IRB will be informed promptly of any unanticipated adverse events.
6. Once an unanticipated event is recognized and reported, the event will be investigated to determine if the event represents an unreasonable risk to the subject so as to terminate all or part of the study.
7. Confidentiality will be protected.

1. **Will the data be reviewed by a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)?**
   - Yes
   - No

1.1 **If yes**, answer the below questions:
   - Describe the composition and frequency of meetings:
     - Cooperative group monitoring
   - Choose the type of DSMB/DMC:
   - Describe the "Stopping Rules":
   - Is this DSMB/DMC independent of the sponsor?
     - Yes
     - No
   - Provide a copy of the DSMB/DMC Charter if available, or refer to its description in the protocol documentation:
     - Upload Charter:

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There are no items to display

1.2 **If no DSMB/DMC**, describe the "Plan" to be put in place to minimize risks and ensure the safety of subjects:

**Data Safety Plan Upload:**

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<th>Name</th>
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There are no items to display

2. **Is this a multi-site study in which the Emory PI is the lead investigator?**
   - Yes
   - No

2.0 **If yes**, describe the safety management plan to coordinate communication among the participating sites about: unanticipated problems involving risks to subjects or others, interim results, and protocol modifications:

3. **How will any electronic data be secured?**

   There are no items to display

   If other, describe:

4. **How will any hard copy data be secured?**

   There are no items to display

   If other, describe:

5. **Will all of the results of research tests be placed in the subject’s Emory medical record?**
   - Yes
   - No

5.0 **If no**, please be sure the informed consent form identifies which results will and will not be placed in the Emory medical record.

6. **Describe additional procedures to be used to:**

   a) protect the privacy of subjects (for example, interviews will be held in private rooms, a Certificate of Confidentiality is in place or is applied for, sensitive questions will be asked only as needed for scientific...
b) maintain the confidentiality of the study data (for example, removal of identifying information, encryption of systems).

If the study has a Certificate of Confidentiality, upload it here.

Data Confidentiality Upload:

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ID: IRB00064666

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**Emory Healthcare Office of Quality**

Based on your application so far, it appears that this study requires the completion of the Emory Healthcare Office of Quality Clinical Research Readiness Checklist. Please download the checklist and submit it to the Office of Quality, not the Emory IRB. Submission instructions are on the Checklist. If you require a stamped approved consent form for a site initiation visit before the Checklist is complete, please ask the IRB analyst for a special version release for site initiation visits only.

1.0

**Office of Quality Checklist Complete:**

Office of Quality Notes:

2.0 *

**Sensitive Study Determination Request**

Do you request a determination of Sensitive Study status for this study? If you do, use the field below to explain why. The IRB will make a determination based on current criteria (see Policies & Procedures at the IRB website). If the IRB makes a determination of Sensitive Study status, a copy of the informed consent document will NOT be placed in each participant's Emory medical record, and the Clinical Research Key Points (Key Points Summary) to be placed there will NOT include certain potentially stigmatizing information.

Yes No

2.0.1 If yes please provide any additional notes or comments:

ID: IRB00064666

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1.0 **Clinical Research Key Points (This section replaces the previous Key Points Summary document)**

IRB#: IRB00064666
Title: (CIRB - insert study title) ←Please complete this section
Short Title: CIRB Study
Principal Investigator: Andrea Goosen

2.0 *

**PI and Study Team Contact Details:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Email Address</th>
<th>Daytime Phone</th>
<th>Pager</th>
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There are no items to display

3.0 **24 Hour Emergency Contact:**

* Name:
  Email Address:
  Phone Number:
  Pager Number:

4.0 *

**Alternate 24-Hour Emergency Contacts:**
Potential Safety Issues (from Protocol):

5.0* Clinical events or laboratory findings that require immediate notification of study investigator/team:

6.0* Clinical procedures that are contraindicated or that are associated with increased risk in study participants:

7.0* Any other important information for healthcare providers engaged in a healthcare encounter with this study participant:

8.0* Brief Summary of Study Purpose (2-3 sentences):

9.0* Study Design Characteristics (check as appropriate):

10.0* Name(s) of Study Medications (list):

ID: IRB00064666

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**Miscellaneous Documents**

1.0 Upload any additional documents:

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2.0 Upload CITI and Key Concepts (if applicable) Training Certification here:

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←Please upload the Key Concepts Certification for PI and CO-I’s here

ID: IRB00064666

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**Conflict of Interest**

* For more information about Emory COI policies, click here.

1.0* Institutional Financial Interest

Is any licensed Emory intellectual property used in this project?

Yes No

2.0* Investigator Financial Interest

Does the PI/Project Director, any individual listed as Senior/Key Personnel on the grant/contract, and/or any individual identified by the PI/Project Director as having responsibility and substantial independence in decision making for the design, conduct or reporting of this protocol have any of the following financial relationships with (a) the study sponsor; (b) a company whose products or services are used or studied in the research; and/or (c) the technology being studied? In calculating aggregate totals, the individual should include those financial interests of his/her spouse, same-sex domestic partner and/or dependent children as his/her own.

The answer is YES if any of the following apply:

- Payments of $5,000 or more including salary; consulting fees; honoraria; and/or gifts received within the past 12 months or anticipated for the next 12 months (excluding salary, grant support, and other payments for services received from Emory University)
- Equity or ownership interest (including stock options) valued at $5,000 or more as determined by reference to the entity’s publicly listed price (excluding mutual funds)
- Any equity or ownership interest in an entity if the entity’s value cannot be determined by reference to publicly listed prices (e.g., privately-held companies, such as start-up companies)
- A position as director, officer, partner, trustee, employee, or any other position of management
- Receipt of licensing fees or royalties from intellectual property rights (patent, copyright, trademark, trade secrets, etc.) that are more than $5,000 annually from an entity or for a technology related to an Investigator’s teaching, research, administrative, or clinical duties at Emory
- Any compensation whose value could be affected by the outcome of the research.

Yes No

2.0.1 If yes, please provide ID# from the eCOI Proposal Financial Interest in Research Report (in format FXXXXXX-00):
You have completed your application!

Please click "Finish" to finalize and exit the application. The application will still be editable until it is submitted by the Principal Investigator. "Finish" will NOT submit the application for review.

Please note that a submission may only be forwarded for review by the Principal Investigator. To do this, the Principal Investigator must select "SUBMIT" in the study workspace.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB (irb@emory.edu or 404.712.0720 or http://www.emory.edu/irb) with any questions or concerns.

Things to remember:
- If your study needs Conflict of Interest, Radiation Safety or BioSafety approval, you must apply to those committees separately using the process in place for those committees.
- If your study needs Human Embryonic Stem Cell Committee approval, you must apply to the HESC separately using the process in place for the HESC. You must also note this on the "Required Reviews" section.
- If your study is to be conducted at the VAMC, you must apply to the VA R&D Committee separately using the process in place for the VA R&D Committee.
- If your study is to be conducted at Grady Health Systems, you must apply to the Grady Research Oversight Committee separately using the process in place for the Grady Research Oversight Committee.
- If your study is a Clinical Trial, you must ensure the sponsor has registered this trial at Clinicaltrials.gov.

←Only change if there is a conflict of interest