Basic Study Information

1. * Title of study:
   XIRB study-Emory relying on another institution

2. * Short title:
   Include a short title

3. * Brief Description (Lay Summary). Please see our IRB guidelines for required content: Biomedical Guidelines or Sociobehavioral Guidelines.
   Not needed

4. * What kind of study is this?
   Multi-site or Collaborative study

5. * Will an external IRB act as the IRB of record for this study?
   ○ Yes  ○ No

6. Lead principal investigator:

7. * Local principal investigator:
   PI NAME

8. * Does the local principal investigator have a financial interest related to this research?
   ○ Yes  ○ No

9. * Attach the protocol:
<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>XIRB(0.01)</td>
<td>IRB Protocol</td>
<td>12/4/2019</td>
<td>History</td>
</tr>
</tbody>
</table>
1. * Brief description of activities this site will perform: (enter 'ALL' if this site will perform all procedures in the protocol)

Please include all the activities Emory will be performing as part of the study.
1. *External IRB:*
   
   select the name of the reviewing IRB

2. External study ID:
   
   enter the ID number assigned to this study by the reviewing IRB

3. Specify the reason the study should be reviewed by an external IRB:
   
   Please provide the requirement to use an external IRB instead of the Emory IRB.
# Study Funding Sources

1. **Identify each organization supplying funding for the study:**

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor's Funding ID</th>
<th>Emory EPEX ID</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select all funding sources for the study.</td>
<td></td>
<td></td>
<td>Provide Grant (no eNOA)</td>
</tr>
</tbody>
</table>
## Additional Local Funding Sources

1. Identify each organization supplying funding for the local site:

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor's Funding ID</th>
<th>Emory EPEX ID</th>
<th>Attachments</th>
</tr>
</thead>
</table>

Add if applicable
1. **Identify each additional person involved in the design, conduct, or reporting of the research.** In addition to Emory personnel, this may include non-Emory persons with sponsored eIRB accounts, for persons who need access to the eIRB study record. If a name does not appear for selection, the person may not have an eIRB account. For more information about obtaining an eIRB account, [click here](#).

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td>enter names and information for all Emory study team members.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **External team member information** (for non-Emory personnel, under Emory PI’s direction, who will not be logging into eIRB).

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>click +Add to upload a document with information about study team members for this site who are not Emory personnel and are not listed in the response to the previous question. Do not include information about study team members at other sites in this multi-site study.</td>
<td></td>
</tr>
</tbody>
</table>
1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition? ☐ Yes  ☐ No

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? (Note: Knowing what the FDA considers to be a device can be tricky; click on page-level help text for guidance.)  ☐ Yes  ☐ No
## Local Research Locations

1. Identify research locations where research activities will be conducted or overseen by the local investigator:

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
</table>

View [click on +Add to enter information about research locations and provide information for contact person.](#)
1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Attachment Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name</td>
<td>IB or package insert (as applicable)</td>
</tr>
</tbody>
</table>

2. * Will the study be conducted under any IND numbers?
   - Yes
   - No

3. * Identify each IND:

<table>
<thead>
<tr>
<th>IND Number</th>
<th>IND Holder</th>
<th>Other Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include number</td>
<td>Sponsor</td>
<td></td>
</tr>
</tbody>
</table>

4. * Attach files such as IND Exemption Justification form (if drug(s) not used per approved indication) or other information that was not attached for a specific drug.

<table>
<thead>
<tr>
<th>Document Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attach as appropriate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Devices

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Humanitarian Use Device</th>
<th>Attachment Name</th>
</tr>
</thead>
</table>

2. * Device exemptions applicable to this study: IDE

3. * Identify each IDE or HDE number:

<table>
<thead>
<tr>
<th>IDE / HDE Number</th>
<th>IDE / HDE Holder</th>
<th>Other Holder</th>
</tr>
</thead>
</table>

4. Attach files: (such as IDE, HDE, IDE Exemption Request Form, or other information that was not attached for a specific device)

<table>
<thead>
<tr>
<th>Document Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
</table>

Attach as appropriate
Study-Related Documents

1. Consent form templates: (upload “model” consent and/or assent template)

   click +Add and upload the consent form template that has already been approved by the reviewing IRB.

2. Recruitment material templates: (add templates for all material to be seen or heard by subjects, including ads)

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recruitment Materials</td>
<td>12/4/2019</td>
<td>History</td>
</tr>
</tbody>
</table>

   View (0.01) Not needed

3. Other attachments:

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   There are no items to display

*Suggested attachments:*

- Case Report Forms
- Data use agreements
- DSMB Charter
- Surveys, questionnaires, interview guides
- WIRB Form A
- Reliance Agreement
Local Site Documents

1. **Consent forms:** (attach local consent/assent documents)
   
   Click +Add and upload the consent form(s) for this site. Using the model consent approved by the reviewing IRB, insert Emory-specific language using tracked changes. Upload the consent form checklist.

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including
   
   Click +Add and upload only site-specific recruitment materials.

3. **Other attachments:**
   
   Click +Add and upload any of the following applicable documents: the local context review form provided by the reviewing IRB, study approval letter from the reviewing IRB including any applicable waivers granted for the study as a whole, reliance agreement provided by the reviewing IRB, completed reliance request form, reliance instructions provided by the reviewing IRB.

   **Suggested attachments:**
   - Completed checklist of funding agency requirements, if applicable
   - Other site-related documents not attached on previous forms
   - Case Report Forms
   - Data Use Agreements
   - DSMB Charter
   - Surveys, Questionnaires, Interview Guides
Waiver Requests and Ancillary Considerations

1. * Is this study designed/initiated by an Emory investigator?  
   - Yes  
   - No  
   (If yes, and clinical research: please see our Clinical Study Initiation and Tools webpage)

2. * Will there be any international sites overseen by Emory investigators, and/or will data be obtained from international subjects by Emory investigators?  
   - Yes  
   - No  
   (If yes: see our International Research webpage)

3. Is any licensed Emory intellectual property used in this project?  
   - Yes  
   - No

HIPAA Applicability and Waivers Requested

Important: You must complete the HIPAA Applicability and Waiver Worksheet. Attach this document under question 4. (Required even if study is under external IRB review).

1. * Based on the above-referenced Checklist, will your data be covered by HIPAA once it is in your research records?  
   - Yes  
   - No

   If answering NO to the above question, please answer the following:

2. Based on the above-referenced Checklist, will you be obtaining PHI from a covered entity, and thus require subject authorization or a waiver of authorization before that data may be disclosed to you for
**Informed Consent Process and Waivers Requested**

1. **Methods of Consent and Assent:**
   a. * Please mark all methods that will be used to obtain **consent** and/or parental permission:
      - Signed, in person
   
   b. Please mark all methods that will be used to obtain **assent** (see Emory’s assent age-based guidelines for types of assent)
      - There are no items to display

2. If applicable, mark all waivers of consent and/or assent that you are requesting. Please first review our guidance on waivers.
   - There are no items to display

3. If different waivers are being requested for different cohorts or portions of the study, provide a brief explanation.

**Ancillary Review Information**

1. * Does this study relate to cancer *in any way*, even if sociobehavioral, or secondary analyses only?
   - Yes  ☐ No

   If yes: requires submission to the CTRC (Clinical and Translational Review Committee);
The remaining questions in this section are ONLY for biomedical research.

2. Does this study include:
   None of the above

   If either of the first two options are checked, the study requires review by EHSO Biosafety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

3. Exposure to any radiation? (Respond yes if protocol dictates timing or type of scans, even if they would be done as part of routine care outside of this study.)
   ○ Yes  ● No

   If yes, requires review by EHSO Radiation Safety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

4. The administration of any investigational radioactive drugs?
   ○ Yes  ● No

   If yes, requires review by EHSO Radiation Safety office (or VA or other site equivalent, if applicable); see "Ancillary Review" section under Study Submission Guidance on our website.

5. Human embryonic stem cells?
   ○ Yes  ● No

   If yes, requires review by HESC Committee; see "Ancillary Review" section under Study Submission Guidance on our website.

6. The use of human fetal tissue?
   ○ Yes  ● No
If yes, the IRB may have additional considerations as part of their review.

7. **Administration of any Schedule I controlled substances?**
   - Yes
   - No
   If yes, see the "Drugs, Devices, and Other FDA Regulated Products" section under Study Submission Guidance on our website.

8. **Administration of drug under the FDA REMS program?**
   - Yes
   - No
   If yes, see the "Drugs, Devices, and Other FDA Regulated Products" section under Study Submission Guidance on our website.

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**For Clinical Research Only (click here for more guidance on clinical research)**

1. **Is this an 'applicable clinical trial' or a study that otherwise requires registration in ClinicalTrials.gov?** See FAQ's here, and if unsure, contact Emory's Office for Clinical Research.
   - Yes
   - No
   a. If yes, has the trial been registered with ClinicalTrials.gov?
     - Yes
     - No

2. **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 (regardless of funding source or if the charges might be considered 'standard of care') that may be billed to study accounts or third party payors such as Medicare, Medicaid, or health insurance companies?** (This determines if the study must be routed for billing analysis.)
   - Yes
   - No
3. Is this an expanded access submission for an unapproved drug or device?
   - Yes  - No

   (If yes, please review our guidance for expanded access submission. Single-use (one patient) uses can we done via an alternative method. See the guidance for more information. Please complete Clinical Research Key Points Summary and attach it below.

4. Clinical Research Key Points Summary: If your study meets all of the criteria referenced here, please upload a completed Clinical Research Key Points Summary.

5. Sensitive Study Status Requests: If this study meets the criteria for 'sensitive study' status (per Emory's Sensitive Studies Policy), are you requesting Sensitive Study Status? Emory IRB will review and inform you if the status is granted.
   - Yes  - No