EMORY eIRB

Date: Saturday, January 18, 2020 9:37:10 PM Print Close

STUDY00111876 View: Emory SF: Basic Study Information

Basic Study Information

1. * **Title of study:**
   Name of Study (add CIRB prefix)

2. * **Short title:**
   Add short name to easy identify your study (add CIRB prefix)

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

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:**
   NAME OF PI

8. * **Does the local principal investigator have a financial interest related to this research?**

   ○ Yes ● **No** If yes, COI review will be required

9. * **Attach the protocol:**

	Document	Category	Date Modified	Document History
View	Protocol.docx(0.01)	IRB Protocol	10/29/2019	History

Basic Local Site Information

1. * **Brief description of activities this site will perform:** (enter 'ALL' if this site will perform all procedures in the protocol)
   Not needed

External IRB

1. * **External IRB:**
   CIRB

2. **External study ID:**
   CIRB study number

3. **Specify the reason the study should be reviewed by an external IRB:**

   Leave blank

STUDY00111876

View: Emory SF: Study Funding Sources (not integrated with Grants)

Study Funding Sources

1. Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Emory EPEX ID	Attachments
NAME	Grant ID or Contract ID	EPEX ID	

Additional Local Funding Sources

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

Funding Source	Sponsor's Funding ID	Emory EPEX ID	Attachments
NAME if applicable	134	123456	

Local Study Team Members

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.**

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
View	NAME	Study Coordinator	no	yes	Email	

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

Name	Description

Add if applicable

Study Scope

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 Select if applicable

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 Select if applicable

Local Research Locations

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

Location	Contact	Phone	Email

View Select applicable locations

Drugs

1. * **List all drugs, biologics, foods, and dietary supplements to be used in the study:**

Generic Name	Brand Name	Attachment Name
ADD	ADD	Drug IB.docx

2. * **Will the study be conducted under any IND numbers?**

● **Yes** ○ No Answer as applicable to your study

3. * **Identify each IND:**

IND Number	IND Holder	Other Holder
12345	Sponsor	

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.**

Document	Category	Date Modified	Document History
There are no items to display			

Devices

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

Device	Humanitarian Use Device	Attachment Name
NAME	no	Device manual.docx

2. * **Device exemptions applicable to this study:** IDE

3. * **Identify each IDE or HDE number:**

IDE / HDE Number	IDE / HDE Holder	Other Holder
123456	Sponsor	Answer as applicable to your study

4. **Attach files:** (such as IDE, HDE, Device Checklist, or other information that was not attached for a specific device)

Document	Category	Date Modified	Document History
There are no items to display			

Study-Related Documents

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

	Document	Category	Date Modified	Document History
View	CIRB approved consent document(0.01)	Consent Form	1/18/2020	History

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

	Document	Category	Date Modified	Document History
View	NOT NEEDED-needs to be sent to CIRB(0.01)	Recruitment Materials	1/18/2020	History

3. Other attachments:

	Document	Category	Date Modified	Document History
View	CIRB approval letter(0.01)	Other	1/18/2020	History

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)

	Document	Category	Date Modified	Document History
View	Site-Specific Consent-HIPAA Addendum. (0.01)	Consent Form	1/18/2020	History

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

	Document	Category	Date Modified	Document History
View	NOT NEEDED-needs to be sent to CIRB(0.01)	Recruitment Materials	1/18/2020	History

3. Other attachments:

Document	Category	Date Modified	Document History
There are no items to display			

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

ANSWER THE NEXT QUESTION AS APPLICABLE

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**

   (If yes, the study may need to be reviewed by an external IRB due to institutional conflict of interest, if it is not already; IRB analyst will consult with IRB leadership.)

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**

your research?

● **Yes** ○ No

3. **If the answer to either above question (1 or 2) is YES, please mark all waivers of HIPAA Authorization that you are requesting (if any). Please first review our** guidance on waivers**.**

   Partial Waiver of HIPAA Authorization (to use or disclose PHI in order to identify and recruit potential research subjects, who will later provide HIPAA authorization)

4. **Upload** HIPAA Applicability and Waiver Worksheet **here:**

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, chart review, or secondary analyses only?**

   ● **Yes** ○ No

   If yes: requires submission to the CTRC (Clinical and Translational Review Committee);

see "Ancillary Review" section on our website.

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.

For Clinical Research/Expanded Access 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**

CRKP.docx

5. **Sensitive Study Status Requests: If this study meets the criteria for 'sensitive study' status (per Emory's Sensitive Studies Policy), are you are requesting Sensitive Study Status? Emory IRB will review and inform you if the status is granted.**

◯ Yes ● **No**