IRB 8.2 External SmartForm

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| Study Update Information | Developer Notes:Only appears for External Update project types |
| 1. \* **Summarize the updates:**
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| --- | --- | --- |
| Basic Information | Green = Help Text | Use this page to fill in basic information about the study and the principal investigator. |
| 1. \* **Title of study:**
 |  |
| 1. \* **Short title:**
 | **Short Title**Select a short title for your study. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters.The short title identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review. |
| 1. \* **Brief description (Lay Summary). Please see our IRB guidelines for required content: Biomedical Guidelines or Sociobehavioral Guidelines.**

 | **Brief Description**In a few words, summarize:The central question the research is intended to answerThe primary objectivesThe methods usedFor example: This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine... |
| 1. \* What kind of study of this?
* Multi-site or Collaborative study
* Single-site study
 | **Kind of Study**A multi-site or collaborative research study is one where two or more institutions collaborate to complete the research outlined in a specific protocol. (Note that a study that utilizes one or more Research Locations at your institution would likely not be considered a multi-site or collaborative research study in this system. Please contact the IRB office for any questions about your study scenario.)A single-site study is one where all research activities occur at one institution. |
| 1. \*Will an external IRB act as the IRB of record for this study?
* Yes
* No
 | **External IRB of Record**For a multi-site study (MSS): Select Yes if an IRB outside your institution will review this study and decide whether to approve it—with permission from the local (your institution's) IRB. For example, if you are a participating site in an MSS, select Yes.If you are the sIRB of record for a multi-site or collaborative study, select No.Related Topics: "Manually Create a Site" in the Multi-Site Study Quick ReferenceFor a single-site study (that takes place at one location only): For an external IRB study, you must also submit the study to the local IRB so they are aware of the research. Talking to the local IRB before submitting the study locally helps prepare your submission for success.External IRB study forms require less study information than normal, but do require information about the external IRB. When the local IRB confirms reliance on the external IRB, the study moves from the Pre-Review state to the Pending sIRB Review state. Once the sIRB makes a determination, the local IRB coordinator records the determination using the Record sIRB Decision activity.Using the Update Study Details button, you can create a follow-on submission in which you can update the study information.**Related Topics** "External IRB Process" in the Coordinator's Quick Reference |
| 1. \*Will your IRB act as the single IRB of record for other participating sites?
 | **Is Your IRB the IRB of Record?**Select Yes if the IRB at your institution will be responsible for reviewing this submission on the behalf of all sites participating in this study. |
| 1. Lead Principal investigator:

 | **Lead Principal Investigator**Select the principal investigator responsible for the entire conduct of the multi-site or collaborative research study. |
| 1. \* Local **Principal investigator:**

 | **Local Principal Investigator**Select the local principal investigator for this study or participating site. If this is a multi-site or collaborative research study for which your IRB will be serving as the IRB of record, then select the name of the principal investigator responsible for the entire conduct of the study. You will enter individual site principal investigators on the site records. |
| 1. \* **Does the local investigator have a financial interest related to this research?**
* **Yes**
* **No**

 **Clear** | **Financial Interest Related to This Research****Definition of financial interest:*** Who holds the interest? The individual involved in the research, or the immediate family of the researcher. Immediate family means the spouse, domestic partner, children, or dependents.
* Interest in what? The study sponsor, a competitor of the sponsor, or a product or service being tested.
* What is an interest? Any of the following:
* Ownership interest of any value including (but not limited to) stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
* Compensation of any amount including (but not limited to) honoraria, consultant fees, royalties, or other income.
* Proprietary interest of any value including (but not limited to) patents, trademarks, copyrights, and licensing agreements.
* Board or executive relationship, regardless of compensation.
* Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.

**Important!** If an individual has a financial interest, provide a copy of the Conflict of Interest Committee's determination regarding the interest. Attach a copy using the [Supporting Documents Page](https://emoryonboarding.huronclick.com/IRB/common/a16a0f24a6ac4cc3aba849c7b9b4b9c2/Applications/IRB/Help/Content/PageLevelHelp/SupportingDocumentsPage.htm), which appears later in the submission process. |
| 1. \***Which IRB should oversee this study?**
* IRB 1
* IRB 2
* Not Connected to Exchange
 |  |
| 1. Attach the protocol:

 | **Attach the Protocol**For industry-sponsored or multi-site research, attach the sponsor’s protocol and a site supplement. A site supplement describes any local variations to the protocol being performed at this institution and can be created using the site supplement template provided.For all other research, or research where a sponsor’s protocol is not provided, create and attach a protocol using the template provided. |
| 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)
 | **Brief Description of Activities This Site Will Perform**In a few words, summarize your activities as a participating site in this multi-site or collaborative research study. If your site will be conducting all portions of the research, type “ALL.” If your site will be conducting only certain portions or the research, include a summary.For example:This study includes both adults and children as research subjects; however, at this site, we will include only children. Therefore, we will conduct only those procedures related to children. |

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| External IRB |  |
| 1. **\***  External IRB
 | **External IRB**Select the IRB outside your institution that will act as the IRB of record for this study. If you cannot find the external IRB in the list, contact your institution's IRB for assistance. |
| 1. External study ID:
 | **External Study ID**The external study ID is the ID number assigned to this study in the system of the institution responsible for its IRB  review.You can use the external study ID as a reference when you correspond with the external IRB review institution.If the study has the same ID in your local system and in the external IRB system, you can leave this field blank.*For a multi-site study:*The external study ID is the ID assigned to this study by the sIRB. |
| 1. Specify the reason the study should be reviewed by an External IRB:
 |  |

|  |  |
| --- | --- |
| Study Funding Sources | **Funding Sources Page**Identify all external funding sources, such as industry sponsors and government agencies. The main purpose is to help the IRB identify all studies associated with particular grants.If funding comes from a specific internal funding program, also identify that funding source. |
| 1. **Identify each organization supplying funding for the study**

| Funding Source | Sponsor’s Funding ID | Grants Office ID | Attachments |
| --- | --- | --- | --- |

There are no items to display |  |
| 1. \* **Funding organization:**

1. **Sponsor’s funding ID:** (assigned by external sponsor)

1. **Emory EPEX ID:** (required if applicable)

1. **Attach Files:** (include any grant applications)

 | **Funding Organization**If your funding source is new and does not appear on the list, contact the IRB staff so they can add it. |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |

|  |  |
| --- | --- |
| Additional Local Funding Sources |  |
| 1. **Identify each organization supplying funding for the local site**

| Funding Source | Sponsor’s Funding ID | Grants Office ID | Attachments |
| --- | --- | --- | --- |

 |  |
| 1. \* **Funding organization:**

1. **Sponsor’s funding ID:** (assigned by external sponsor)

**Emory EPEX ID:** (required if applicable)1. **Attach Files:** (include any grant applications)

 | **Funding Organization**If your funding source is new and does not appear on the list, contact the IRB staff so they can add it. |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |

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| 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 |
| --- | --- | --- | --- | --- | --- |

There are no items to display | Study Team MembersAdd information about each person from your site who will be conducting human subjects research (e.g. observing, interacting/intervening with subjects, obtaining informed consent/assent, collecting/accessing private identifiable data, or have access to coded links to identifiers). You do not need to add the principal investigator here.For a multi-site study: Both sIRB and participating site institutions should only include information about team members at your local institution. Other sites involved in the multi-site study will add their own information about local study team members.For studies with international sites:Do not list international collaborators who are not employed by, or do not attend, Emory University in this section. Instead, if they are not listed on their own institution’s IRB record, list them in the “External team member information” section below.Tips: ◾Do not add the study's primary contact person for IRB communications here unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default, and can be changed later as described in "Changing the Primary Contact" in the Study Submission Guide. ◾ If you have difficulty finding the person in the list, they may not yet have an eIRB account. Try typing the beginning of the first or last name. [For more information about obtaining an eIRB account, click here.](http://irb.emory.edu/eirb/how-to.html#faq1) You can also contact the IRB staff for assistance if unable to resolve. |
| 1. **\*** **Study team member:**
2. **Role in research:** (check all that apply)

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 | Co-investigator |
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 | Data Analyst |
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 | Research Assistant |
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 | Statistician |
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 | Lay Observer |

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1. **\*** **Is the team member involved in the consent process?**
* **Yes**
* **No**

**Clear** 1. **\* Does the team member have a financial interest related to this research?**
* **Yes**
* **No**

**Clear**  |  | Study Team MembersAdd information about each person from your site who will be conducting human subjects research (e.g. observing, interacting/intervening with subjects, obtaining informed consent/assent, collecting/accessing private identifiable data, or have access to coded links to identifiers). You do not need to add the principal investigator here.For a multi-site study: Both sIRB and participating site institutions should only include information about team members at your local institution. Other sites involved in the multi-site study will add their own information about local study team members.For studies with international sites:Do not list international collaborators who are not employed by, or do not attend, Emory University in this section. Instead, if they are not listed on their own institution’s IRB record, list them in the “External team member information” section below.Tips: ◾Do not add the study's primary contact person for IRB communications here unless the person is also engaged in the research. The person who creates the study in the IRB system is assigned as the primary contact by default, and can be changed later as described in "Changing the Primary Contact" in the Study Submission Guide. ◾ If you have difficulty finding the person in the list, they may not yet have an eIRB account. Try typing the beginning of the first or last name. [For more information about obtaining an eIRB account, click here.](http://irb.emory.edu/eirb/how-to.html#faq1) You can also contact the IRB staff for assistance if unable to resolve.Financial Interest Related to This ResearchDefinition of financial interest:Who holds the interest? The individual involved in the research, or the immediate family of the researcher. Immediate family means the spouse, domestic partner, children, or dependents.Interest in what? The study sponsor, a competitor of the sponsor, or a product or service being tested.What is an interest? Any of the following:* Ownership interest of any value including (but not limited to) stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
* Compensation of any amount including (but not limited to) honoraria, consultant fees, royalties, or other income.
* Proprietary interest of any value including (but not limited to) patents, trademarks, copyrights, and licensing agreements.
* Board or executive relationship, regardless of compensation.
* Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.

Important! If an individual has a financial interest, provide a copy of the Conflict of Interest Committee's determination regarding the interest. Attach a copy using the [Supporting Documents Page](https://emoryonboarding.huronclick.com/IRB/common/a16a0f24a6ac4cc3aba849c7b9b4b9c2/Applications/IRB/Help/Content/PageLevelHelp/SupportingDocumentsPage.htm), which appears later in the submission process. |
| 1. **External team member information** (for non-Emory personnel, under Emory PI’s direction, who will not be logging into eIRB).

| Name | Description |
| --- | --- |

There are no items to display | External Team Member InformationAttach information about members of your research team who were not listed for selection in the previous question. People listed here are considered part of your institution’s study team (instead of part of another participating site’s study team), but are not directly employed or affiliated. Unlisted people are likely to be outside your institution, or perhaps students or other groups your institution doesn't include in the system. For more information about what to attach to the smartform, click here.For a multi-site study: Both sIRB and participating site institutions should only include information about local team members who fit the criteria above. Do not include information about team members at other sites involved in the multi-site study.For studies with international sites:Include collaborating study team members at international sites that are under the Emory PI’s oversight, but who are not directly employed attender affiliated with Emory University. For example, these may be independent enumerators, interviewers, research assistants, co-investigators, or research nurses that are hired by the Emory study team under a sub-contract.Important! Do not attach information about team members you were able to select in the previous question. For people listed in the system, the information should be added to their profiles in the system instead. If you are unsure how to proceed, contact your IRB staff for assistance. |
| Title: **\***File:  |  |

|  |  |
| --- | --- |
| Study Scope | **Study Scope Page**Identify factors involved in the study that may require review of additional details. Your answers determine whether you must provide additional information.After answering these questions and clicking Continue, you can use the Jump To navigation element located at the top of the page to skip between any of the forms you need to fill out. You can also exit the form and return later to add information before submitting the study for review. |
| 1. **\*Does the study specify the use of an approved drug or biologic, use an approved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
* Yes
* No
 | **Drug or Biologic Used?**"Specify the use of” means the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care. Example: If the protocol indicates that “Subjects in group 1 will take 650 mg of aspirin in response to a headache,” the use of aspirin is specified by the protocol. In contrast, if the protocol indicates that “Subjects in group 1 may take 650 mg of aspirin in response to a headache,” the use of aspirin is not specified by the protocol. |
| 1. **\*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 button above for guidance.
* Yes
* No
 |  |

|  |  |
| --- | --- |
| Local Research Locations | **Local Research Locations Page**Identify research locations where research activities will be conducted. These research locations have been included because they are locations within your institution where institutional leadership would like to track human research activities, or because they are locations outside of the institution where your institution’s principal investigators conduct human research. Research locations are not participating sites in multi-site or collaborative research with separate principal investigators. If your research location is not included for selection, you may enter information manually about that location. Please contact your IRB Office if you are unsure whether your research location should actually be a participating site.For example:A PI has an appointment at the university. If the PI conducts research in a local elementary school, a nursing home, or a private physician’s office, those may be considered research locations.*For multi-site or collaborative research studies:* Do not include other participating sites as research locations. Those sites will likely need to rely on the reviewing IRB separately. Please contact your local IRB office with any questions. |
| 1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

| Location | Contact | Phone | Email |
| --- | --- | --- | --- |

There are no items to display1. \* **Select the research location:**

If you cannot find the research location in the list above, enter its information here: * 1. Location name:
	2. Location address**:**Address line 1:

Address line 2: Address line 3: City: State or province:Postal code:Country * 1. Contact name:

* 1. Contact phone:

* 1. Contact e-mail:

  |  |

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| --- | --- |
| Drugs | **Drugs Page**Identify all drugs to be used on human subjects as part of this study. In particular, include all information the IRB needs to identify and evaluate any investigational new drug.An investigational new drug (IND) number identifies a drug that the FDA allows to be transported across state lines for use in clinical studies prior to receiving marketing approval. The study sponsor and the FDA should provide any IND information.Identify each IND used in the study. For each IND number, attach one of the following:* Sponsor protocol with the IND number
* Communication from the FDA or sponsor with the IND number
 |
| 1. **\* List all drugs, biologics, foods, and dietary supplements to be used in the study:**

| Generic Name | Brand Name | Attachment name |
| --- | --- | --- |

There are no items to display  |  |
|  Add Drug Information 1. **Select the drug:**

If you cannot find the drug in the list above, enter its information here:**Generic name:**  **Brand name:** 1. **Attach files related to this drug:**

| Document | Category | Date Modified | Document History |
| --- | --- | --- | --- |

 There are no items to display Attachments may include a copy of the package insert, investigator brochure, product labeling, or verification of any IND number. | **Select the Drug**Identify the drug, biologic, food, or dietary supplement to be used in the study.To quickly find an item:1.Click inside the box.2.Start typing the name.3.When the drop-down list appears, use the down arrow key to highlight your selection, and press Enter.Alternatively, you can click the Select button, select an item from the list, and click OK.**Note:** If an item is already selected, you can click Select to choose a new item, or click Clear to start over with a blank box. |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **\* Will the study be conducted under any IND numbers?**
* **Yes**
* **No**

**Clear** | **Study Conducted Under IND**If this is an investigator-initiated drug study and you are not using an IND number, be sure the protocol document fully describes:◾All drugs used in the research, including the purpose of their use and their regulatory approval status◾Your plans to store, handle, and administer those drugs so they will be used only on subjects and only by authorized investigatorsExemptions from IND requirements are described in 21 CFR 312.2(b). |
| 1. **\* Identify each IND:**

| IND Number | IND Holder | Other holder |
| --- | --- | --- |
| There are no items to display |

 |  |
| 1. **\* IND Number:**

1. **\* Who holds the IND?**
* **Sponsor**
* **Investigator**
* **Other**

**Clear**1. **If “Other”, identify the IND Holder:**

 |  |
| 1. **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. Always attach Drug Handling and Storage Worksheet.

| Document | Category | Date Modified | Document History |
| --- | --- | --- | --- |

There are no items to display | **Attach Files For Drugs**For each IND number, attach one of the following:◾Sponsor protocol with the IND number◾Communication from the FDA or sponsor with the IND numberRelated TopicsDrugs Page |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |

|  |  |
| --- | --- |
| Devices | **Devices Page**Identify all devices to be used as an HUD or evaluated for safety and effectiveness on human subjects as part of this study. In particular, include all information the IRB needs to identify and evaluate any device with exemptions or claimed exemptions. Also attach information from the study sponsor or the FDA verifying the exemption status of each exempt device.**Definitions**HUD: The designation of humanitarian use device (HUD) applies to devices intended to benefit patients by treating or diagnosing a disease or condition that manifests itself in fewer than 4,000 individuals in the United States per year. The HUD designation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.IDE #: An investigational device exemption (IDE) number identifies a device approved by the FDA for use in a clinical study to collect safety and effectiveness data needed to support further applications to the FDA. Approved IDEs are exempt from several regulations.HDE #: A humanitarian device exemption (HDE) number identifies a device approved by the FDA as a humanitarian use device (HUD) with limited potential patients, without meeting the effectiveness requirements of premarket approval. The FDA agrees that the device does not pose an unreasonable or significant risk of illness or injury, and the probable benefit to health outweighs the risk of injury or illness from its use. Abbreviated IDE: The device is considered to pose nonsignificant risk of harm. If the IRB approves the study—including the device as not posing a significant risk—no FDA approval is needed to proceed with the study. |
| 1. **\* Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

| Device | Humanitarian Use Device | Attachment Name |
| --- | --- | --- |

There are no items to display  |  |
|  Add Device Information 1. **Select the device:**

If you cannot find the device in the list above, enter its information here:**Device Name:**  **Is this a humanitarian use device (HUD):** * **Yes**
* **No**

**Clear**1. **Attach files related to this drug:**

| Document | Category | Date Modified | Document History |
| --- | --- | --- | --- |

 There are no items to display Attachments may include a copy of the package insert, investigator brochure, product labeling, or verification of any IND number. | **Select the Device**Identify the device to be used in the study.1. To quickly find an item:
2. Click inside the box.
3. Start typing the name.

When the drop-down list appears, use the down arrow key to highlight your selection, and press Enter.Alternatively, you can click the Select button, select an item from the list, and click OK.Note: If an item is already selected, you can click Select to choose a new item, or click Clear to start over with a blank box. |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **\* Device exemptions applicable to the study:**
* IDE number
* HDE number
* Claim of abbreviated IDE (nonsignificant risk device)
* Exempt from IDE requirements

**~~Clear~~** | **Device Exemptions**If this is an investigator-initiated device study and you are not claiming an IDE, be sure the protocol document fully describes:◾All devices used in the research, including the purpose of their use and their regulatory approval status◾Your plans to store, handle, and administer those devices so they will be used only on subjects and only by authorized investigatorsExemptions from IDE requirements are described in 21 CFR 812.2(c). |
| 1. **\* Identify each IDE or HDE number:**

| IDE / HDE Number | IDE / HDE Holder | Other holder |
| --- | --- | --- |
| There are no items to display |

 |  |
| 1. **\* IDE or HDE Number:**

1. **\* Who holds the IND?**
* Sponsor
* Investigator
* Other

**Clear**1. **If “Other”, identify the IDE/HDE Holder:**

 |  |
| 1. **Attach files:** (such as IDE, HDE, IDE Exemption Request Form, or other information that was not attached for a specific device)

| ~~Document~~ | ~~Category~~ | ~~Date Modified~~ | ~~Document History~~ |
| --- | --- | --- | --- |

~~There are no items to display~~ | **Attach Files for Devices**For each IDE / HDE number, attach one of the following:◾Sponsor protocol with the IDE / HDE number◾Communication from the FDA or sponsor with the IDE / HDE number**Related Topics:**Devices Page |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |

|  |  |
| --- | --- |
| Study-Related Documents |  |
| 1. **Consent form templates:** (upload “model” consent and/or assent template)

| Documents | Category | Date Modified | Document History |  |
| --- | --- | --- | --- | --- |
| There are no items to display |  |

 |  |
| 1. **File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

| Documents | Category | Date Modified | Document History |
| --- | --- | --- | --- |
| There are no items to display |  |  |  |

 |  |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **Other attachments:**

| Documents | Category | Date Modified | Document History |
| --- | --- | --- | --- |
| 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
 |

 |  |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. \***Category:**

1. **Version number:**

 |  |

|  |  |
| --- | --- |
| Local Site Documents | Local site-specific documents may include local versions of consent forms or recruitment materials.For multi-site studies: Some documents and consent forms will be applied to the multi-site study as a whole. Others may be specific to your institution. On this page, only include the documents that are specific to your institution. |
| 1. **Consent forms:** ( attach local consent/assent documents)

| Documents | Category | Date Modified | Document History |  |
| --- | --- | --- | --- | --- |
| There are no items to display |  |

 | **Consent Forms**If consent will not be documented in writing, attach a script of information to be provided orally to subjects. Make sure the consent documents, the protocol document, and the contract all use consistent language. |
| 1. **File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

| Documents | Category | Date Modified | Document History |
| --- | --- | --- | --- |
| There are no items to display |  |  |  |

 |  | **Recruitment Materials**Important attachments include:◾Advertisements (printed, audio, and video)◾Recruitment materials and scripts◾Evaluation instruments and surveys |
| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. **Version number:**

 |  |
| 1. **Other attachments:**

| Documents | Category | Date Modified | Document History |
| --- | --- | --- | --- |
| There are no items to display |  |  |  |
| Suggested attachments:* Completed checklist of meeting Department of Energy requirements, if applicable
* Other site-related documents not attached on previous forms
* Case Report Forms
* Data Use Agreements
* DSMB Charter
* Surveys, Questionnaires, Interview Guides
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| 1. \***File to attach:**

1. **Name:** (if not supplied, the file name will be shown)

1. \***Category:**

1. **Version number:**

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**Waiver Requests and Ancillary Considerations**

**(\*= required question)**

1. \* Is this study designed/initiated by an Emory investigator?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
(If yes, and clinical research: please see our [Clinical Study Initiation and Tools](http://www.irb.emory.edu/forms/clinical.html) 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  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
(If yes: see our[International Research](http://irb.emory.edu/forms/international.html) webpage)
3. \*Is any licensed Emory intellectual property used in this project?

 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

(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 Checklist](http://www.irb.emory.edu/documents/Combined_Waiver_Consent_HIPAA_Elements.docx). 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  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

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

1. 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  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
2. 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](http://irb.emory.edu/forms/Waivers/index.html).

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 | Waiver of Elements of HIPAA Authorization (for certain parts of the authorization such as a signature) |
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 | 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) |
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 | Complete Waiver of HIPAA Authorization (because it is impracticable to obtain signed HIPAA authorization from participants) |

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1. Upload [HIPAA Applicability and Waiver Checklist](http://www.irb.emory.edu/documents/Combined_Waiver_Consent_HIPAA_Elements.docx) here: (SPACE TO ATTACH WORKSHEET HERE)

**Informed Consent Process and Waivers Requested**

1. Methods of Consent and Assent:
	1. \* Please mark all methods that will be used to obtain consent and/or parental permission:

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 | No informed consent will be sought (e.g. in retrospective chart review with waiver) |
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 | Signed, in person  |
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 | Verbal, without signature (by phone or in-person; upload script in Local Site Documents |
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 | Electronic/Online without electronic legal signature (IRB may require consent discussion by some means) |
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 | Electronic/Online with electronic legal signature (IRB may require consent discussion by some means) |
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 | By mail, with signature (IRB may require consent discussion by some means) |
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 | Consent for future research was already obtained in prior study (i.e. secondary use of existing research data)  |

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1. Please mark all methods that will be used to obtain assent (see [Emory's assent age-based guidelines](http://irb.emory.edu/documents/assent-template.doc)for types of assent)

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 | No verbal/written assent will be sought from any age group (explain reasoning in the protocol or site-specific addendum, if Emory is IRB of record) |
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 | Signed, in person, per age-based guidelines  |
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 | Electronic/Online with electronic legal signature per age-based guidelines  |
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 | Electronic/Online without an electronic legal signature  |
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 | By phone, without a signature, per age-based guidelines (upload script in Local Site Documents |
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 | Remote, with signature per age-based guidelines (Ex: by mail; may require assent discussion by some means) |

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1. If applicable, mark all waivers of consent and/or assent that you are requesting. Please first review our [guidance on waivers](http://irb.emory.edu/forms/Waivers/index.html).

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 | Waiver of any or all elements of the informed consent or assent process/form |
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 | Waiver of documentation of informed consent or assent (i.e. signature will not be obtained) |

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1. 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 socio-behavioral, chart review, or secondary analyses only?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes: requires submission to the CTRC (Clinical and Translational Review Committee); see the "[Ancillary Review](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse13)" section under Study submission guidance on our website.

**The remaining questions in this section are ONLY for biomedical research.**

1. Does this study include:

[ ]  Recombinant or synthetic nucleic acids (DNA, RNA, CRISPR, oligonucleotides, etc.), or deliberate transfer of recombinant or synthetic nucleic acids into human research participants

[ ]  Any of the following: microorganisms or infectious materials; human cells, cell lines, serum, stool samples, or any other human source materials; nanomaterials; genetically modified primary cells or cell lines; genetically modified live or live-attenuated microbes,; human or non-human primate blood that is brought to a laboratory for further experimentation and transferred to a central lab; arthropods; plant products; toxins; environmental samples

[ ]  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 the "[Ancillary Review](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse13)" section under Study Submission Guidance on our website.

1. 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  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes, requires review by EHSO Radiation Safety office (or VA or other site equivalent, if applicable); see the "[Ancillary Review](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse13)" section under Study Submission Guidance on our website.
2. The administration of any investigational radioactive drugs?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes, requires review by EHSO Radiation Safety office; see the "[Ancillary Review](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse13)" section under Study Submission Guidance on our website.
3. Human embryonic stem cells?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes, requires review by the HESC Committee; see the "[Ancillary Review](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse13)" section under Study Submission Guidance on our website.
4. The use of human fetal tissue?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes, the IRB may have additional considerations as part of their review.
5. Administration of any Schedule I controlled substances?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
 If yes, see the “[Drugs, Devices, and Other FDA Regulated Products](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse11)” section under Study Submission Guidance on our website.
6. Administration of drug under the [FDA REMS program](https://www.accessdata.fda.gov/scripts/cder/rems/)?
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
 If yes, see the “[Drugs, Devices, and Other FDA Regulated Products](http://www.irb.emory.edu/forms/Study%20Submission.html#collapse11)” section under Study Submission Guidance on our website.

**For Clinical Research/Expanded Access Only (click for more**[**guidance on clinical research**](http://irb.emory.edu/forms/clinical.html)**)**

1. Is this an “applicable clinical trial” or a study that otherwise requires registration in ClinicalTrials.gov? See [FAQ’s here](http://www.ocr.emory.edu/ct.gov/index.html), and if unsure, contact Emory’s Office for Clinical Research.

 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

If yes, has the trial been registered with ClinicalTrials.gov?

 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

1. 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  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)
2. \* Is this an expanded access submission for an unapproved drug or device?

 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

(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](http://www.irb.emory.edu/forms/Expanded_Access/index.html) for more information. Please complete [Clinical Research Key Points Summary](http://ocr.emory.edu/documents/word/CRKP.docx) and attach it below.

1. Clinical Research Key Points Summary: If your study meets all of the [criteria referenced here](http://irb.emory.edu/forms/clinical.html), please upload a completed [Clinical Research Key Points Summary](http://ocr.emory.edu/documents/word/CRKP.docx%22%20%5Ct%20%22blank)
*(attach here)*
2. Sensitive Study Status Requests: If this study meets the criteria for 'sensitive study' status per Emory's [Sensitive Studies Policy](https://secure.web.emory.edu/med/research/ocr/secure/Sensitive%20Studies%20Policy.pdf), are you requesting Sensitive Study Status? Emory IRB will review and inform you if the status is granted.
 Yes  No  [Clear](https://mpclkemystage2.huronclick.com/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5BOID%5B748511C4EB6B11E94E8467F296565000%5D%5D&doValidation=False&DestURL=https%3A%2F%2Fmpclkemystage2.huronclick.com%2FIRB%2Fsd%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5B7485124BEB6B11E94E8467F296565000%5D%5D&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5BOID%5B59DDAF4BC8EE11E94C8467F296565000%5D%5D)

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| You have reached the end of the IRB Submission form. Read the next steps carefully:  |

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.
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