*If you are not certain that your project meets the federal definition of human subjects research, complete the* [*Not Human Subjects Research Determination Form*](http://www.irb.emory.edu/forms/review/request.html) *and save your response.*

**STEP 1:** Complete the Reliance Agreement Eligibility section below

|  |
| --- |
| **IRB Reliance Agreement Eligibility** |
| 1) Is this collaborative research (i.e. research involving Emory and non-Emory personnel)?  | [ ]  **YES** | ***Continue to*** ***Question 2*** |
| [ ]  **NO** | **No need for a reliance agreement** |
| 2) Is Emory engaged? [OHRP Guidance on Engagement of Institutions in Human Subject Research](http://www.hhs.gov/ohrp/policy/engage08.html). ***Note:*** *Institutions that receive an award directly from HHS for non-exempt human subjects research, even where all activities involving human subjects are carried out by another institution, are considered engaged.*  | [ ]  **YES** | ***Continue to*** ***Question 3*** |
| [ ]  **NO** | **No need for a relianceagreement** |
| 3) Is the other institution/investigator engaged? [OHRP Guidance on Engagement of Institutions in Human Subject Research](http://www.hhs.gov/ohrp/policy/engage08.html).  | [ ]  **YES** | ***Continue to*** ***Step 2*** |
| [ ]  **NO** | **No need for a reliance agreement** |

**Step 2:** Mark the reason for completing the form

|  |  |
| --- | --- |
| [ ]  Requesting Emory IRB rely on another IRB | **Complete Study Information and *Section 1*** |
| [ ]  Requesting Emory IRB serves as the reviewing IRB for: [ ]  domestic site(s) that have local IRBs[ ]  investigator(s) and/or site(s) that ***do not*** have IRBs | **Complete Study Information and *Section 2*** |

***Note:*** *The Emory IRB does not provide IRB oversight to research sites located outside of the U.S.*

**STEP 3:** Study and Contact Information

|  |  |
| --- | --- |
| **Study Title** |  |
| **Funding Source**  |  |
| **Prime Awardee Institution** |  |
| **Is the use of a single IRB required by the funding agency, regulation, or policy?** | [ ]  Yes (specify): [ ]  No (provide reason for this request below) |
| **Reason for requesting reliance** |  |

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| **Emory Principal Investigator (PI) and/or Collaborator**  |
| **Name** |  | **Degree(s)** |  |
| **Email** |  | **Phone #** |   |
| **Emory Primary Contact (if different from above)** [ ] Coordinator [ ] Student [ ] Other:  |
| **Name** |  | **Title** |  |
| **Email** |  | **Phone #** |   |

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| **Other Institution’s PI and/or Lead Collaborator** |
| **Name** |  | **Degree(s)** |  |
| **Email** |  | **Phone #** |  |
| **Institution/Affiliation** |  |

**SECTION 1
*Request Emory IRB rely on another IRB***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Name of Proposed Reviewing IRB** |  |
| Has the IRB agreed to serve as the IRB of Record? | [ ]  Yes  | [ ]  No  |
| Is the IRB AHHRPP Accredited?  | [ ]  Yes  | [ ]  No  |
| Has the study already been approved by the IRB? | [ ]  Yes  | [ ]  No  |

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| **Proposed Reviewing IRB Reliance contact information *(only list IRB personnel here)*** |
| **Name** |  | **Title** |  |
| **Email** |  | **Phone #** |  |

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| --- |
| **Emory Research Activities (mark all that apply)** |
| [ ]  | Lead site (Overall PI and lead study team are here) |
| [ ]  | Prime awardee of grant |
| [ ]  | Prime awardee/direct grant recipient **but** Emory-affiliated investigators are **NOT** conducting any other procedures under the protocol |
| ☐ | Conducting the full protocol here (enrolling, analyzing data, and administering study interventions or procedures) |
| ☐ | Only conducting some part(s) of the protocol  |
| [ ]  | Enrollment/Consenting Subjects |
| [ ]  | Access to Identifiable Data |
| [ ]  | Access to De-identified Data |
| ☐ | Data Analysis |
| [ ]  | Data Storage/Banking |
| [ ]  | Administering Study Interventions/Procedures/Interactions |
| [ ]  | Medical records review  |
| [ ]  | Emory-affiliated researchers are solely participating in the protocol on-site at the other institution or assisting the other institution with their protocol. |

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| **Financial Interest Disclosure** |
| [ ]  **Yes** | Does the Emory 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. |
| [ ]  **No** |
| **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.*
 |

 |

 **SECTION 2
*Complete if requesting Emory IRB serve as the reviewing IRB for investigators or sites external to Emory. Enter the name and mark applicable research activities.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Each Institution or Site:** |  |  |  |
| Enrollment/Consenting Subjects | [ ]  | [ ]  | [ ]  |
| Access to Identifiable Data | [ ]  | [ ]  | [ ]  |
| Access to De-identified Data | [ ]  | [ ]  | [ ]  |
| Data Analysis | [ ]  | [ ]  | [ ]  |
| Data Storage/Banking | [ ]  | [ ]  | [ ]  |
| Administering Study Interventions, Procedures, and/or Interactions | [ ]  | [ ]  | [ ]  |
| Data Collection | [ ]  | [ ]  | [ ]  |
| Medical Records Review  | [ ]  | [ ]  | [ ]  |
| Prime Awardee of Federal Grant | [ ]  | [ ]  | [ ]  |

 **STEP 4:** Email the completed form, the protocol, and if applicable, the Single IRB Plan submitted in the grant application to irb.reliance@emory.edu (**include this e-mail address on all correspondence).**

**STEP 5:** Once you have received confirmation of Emory’s agreement to this reliance request, follow the guidance posted on our [Collaborative Research](file:///%5C%5Ceu-securefile-ts.eu.emory.edu%5Cfinadmin-ts%5Cora%5Cirb%5Cirb_shared%5CGeneral%5CExternal%20IRB%20Relationships%5C06.%20Forms%20and%20Checklists%5CCollaborative%20Research) page to complete your submission to the IRB.