**RELIANCE REQUEST FORM**

**When Collaborating with Non-Emory Researchers**

Investigators engaged in human subjects research must usually be overseen by an IRB. Typically this is the IRB of his or her own institution.

However, an IRB authorization agreement (IAA, or “reliance agreement”) can be established in which one institution delegates its IRB review to another institution.

In cases where a researcher is independent, and *not* affiliated with an institution, an individual agreement (IIA) can be established so that a designated IRB explicitly covers a particular researcher. A similar agreement is possible when a researcher is affiliated with an organization that does not routinely conduct human subjects’ research and thus does not have an FWA.

Link to OHRP guidance: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html>

**MUST READ BEFORE PROCEEDING**

* For exempt studies
  + The Emory IRB will normally not enter into reliance agreements for studies we deem “exempt.” If another IRB wants to provide review for such a study or to rely on Emory IRB’s exemption determination, consultation with the IRB Director is required.
  + An Individual/Independent Investigator Agreement is likewise not required for investigators without an IRB of record who are working on exempt studies. They can be simply added to a new study submission after their training has been verified (amendment not required if adding them after initial approval).
* For international studies:
  + The Emory IRB will generally not agree to rely on international IRB’s/Ethics Committees, but we may enter into a reliance agreement with a domestic (i.e. US) site in a multisite study, where there are also international sites. An international site may request to rely on Emory IRB review if they have no available alternative, but if that site does have an IRB or Ethical Committee available, their review is helpful to satisfy our need for local context input. The IRB Director should be consulted for such requests.
* Recruitment-only sites:
* If a site is simply allowing outside investigators to recruit subjects or conduct a study at their site, without collaborating as researchers on the study that would not make the site “engaged” in the research per OHRP guidance. An agreement will therefore not be needed. Some sites do not observe that guidance, however, and require IRB oversight of their involvement; if such sites request to rely on Emory IRB, consultation with the IRB Director is required.

For additional information, please refer to the [Collaborative Research](http://www.irb.emory.edu/forms/external-irbs/index.html) page of the IRB website.

**Do You Need a Reliance Agreement?**

|  |  |  |
| --- | --- | --- |
| **Please check your response to the following questions:** | | |
| 1. Is this collaborative research, which involves both Emory and Non-Emory personnel? | Yes | Continue to Question 2 |
|  | No | No need for a reliance agreement |
| 2. Is Emory actually ***engaged*** in human subjects’ research?  [*See OHRP guidance*](http://www.hhs.gov/ohrp/policy/engage08.html)*, but typical evidence of being engaged includes any of the following:* | Yes | Continue to Question 3 |
| * Interaction or intervention with subjects * Access to identifiable private information (\*) * Federal research grant awardee | No | No need for a reliance agreement |
| 3. Is the other institution or individual ***engaged*** in human subjects’ research?  *Same criteria apply as in Question 2* | Yes | Continue to Question 4 |
|  | No | No need for a reliance agreement |
| 4. Has one institution already determined that the human subjects’ research is ***exempt*** from IRB review? | Yes | No reliance agreement; please contact IRB to discuss whether Emory IRB submission is necessary. |
|  | No | Continue to Question 5 |
| 5. Will Emory be relying on or be the IRB of record for an international institution? | Yes | No reliance agreement. The international site should have their Ethics committee review their study. |
|  | No | Continue to Question 6 |
| 6. Is the intent for one institution to rely on another for IRB oversight?  *OR* | Yes | **Complete Worksheet Below** |
| In the case of an individual researcher, is the intent for Emory IRB to oversee his or her participation in research? | No | No need for a reliance agreement |

(\*) Information that contains [any of these 18 PHI identifiers](http://irb.emory.edu/documents/phi_identifiers.pdf).

***Proceed to worksheet on following page, if applicable…***

1. **Study Title (Required):** Enter text.
2. **Emory Principal Investigator:**

|  |
| --- |
| Name (with Degrees): Enter text. |
| Email: Enter text. |
| Phone Number: Enter text. |
| If applicable, coordinator name and email: |

1. **Non-Emory Principal Investigator:**

|  |
| --- |
| Institution/Affiliation (if any): Enter text. |
| Does this institution (if any) routinely conduct human subjects research? ☐ Yes ☐ No ☐ N/A |
| Name(s) with Degrees: Enter text. |
| Email: Enter text. |
| Phone Number: Enter text. |
| If applicable, coordinator name and email: |

1. **Collaborator IRB if any** (list primary point of contact)**:**

|  |
| --- |
| Institution/Affiliation: Enter text. |
| Name: Enter text. |
| Email: Enter text. |
| Phone Number: Enter text. |

1. **Which institution is expected to provide IRB review?**

Emory University  Other Institution, Please specify: Enter text.

1. **Is the other institution AAHRPP-accredited?**

Yes  No

1. **Funding Information:**
   1. Is the study funded?  Yes  No

*If Yes:*

1. Specify the source: Enter text.
2. Specify the prime awardee: Enter text.
3. Are federal funds used?  Yes  No
4. **Why is a reliance agreement being requested? (check what applies)**

Sponsor or funding agency requirement

Falls under NIH Single IRB mandate

Study is part of existing network, consortium, or agency which encourages single IRB

Not required, but for efficiency

Someone at Emory desires single IRB (If this, type name and title: Enter text.)

Other: Enter text.

1. **How many total sites are engaged in the study (including Emory and the Other Institution)?** Enter text.
2. **Please check any of the following Emory-affiliated sites which are engaged:**

Grady  VA  CHOA

Saint Joseph’s  Johns Creek  Winship

Other

If other Emory-affiliated site, list here: Click here to enter text.

1. **Is the study FDA-regulated and/or a clinical trial?**

Yes  No

1. **Will a study investigator (at Emory or Other Institution) hold an IND or IDE for the study?**

Yes  No

1. **Is the study going to recruit/enroll any of the following? (check all that apply)**

Pregnant Women

Prisoners

Minors

Cognitively Impaired

Non-English speakers

1. **How far along in the process is this study? (check all that apply)**

Grant application has been submitted

Funding secured

Protocol drafted

Lead site has submitted to their IRB (Other IRB’s protocol #: Enter text.)

Main protocol and model consent forms have been approved by lead IRB

Other: Enter text.

1. **What is your anticipated start date for EMORY’s role(s) in this study?** Enter text.
2. **Study Summary (≈ 5-10 sentences):**

Include the overall aim, procedures involving human subjects or their data, data source, subject population, location, and any other basic information. Please do not copy and paste a lay summary or protocol paragraph. A condensed paragraph that covers the most basic information will help to expedite the reliance agreement process.

Enter text.

**(Continued below)**

**Emory’s Role in the Research:**

Please check all that apply and give further detail.

|  |  |
| --- | --- |
| **ACTIVITY** | **DETAILS** |
| Emory is the coordinating/lead site (the Overall PI and lead study team are here at Emory) | *If checked, please attach a copy of the protocol to your email when you submit this request.* |
| Emory is the prime awardee/direct grant recipient | *If checked, please attach a copy of the grant/award to your email when you submit this request.* |
| Emory is the prime awardee/direct grant recipient BUT Emory-affiliated investigators are NOT conducting any other procedures under the protocol |
| Emory has received a subcontract from the other institution | *If checked, please attach a copy of the subcontract to your email when you submit this request.* |
| Emory is conducting the full protocol (enrolling and consenting, accessing identifiable information, analyzing data, and administering study interventions) | 1. Number of subjects enrolled here: Enter text. 2. Type of identifiable information: Enter text. 3. Type of study interventions HERE?   Biomedical research interventions  Collection of identifiable biospecimens  Sociobehavioral or educational interventions (surveys, questionnaires, etc.)  Other: Enter text. |
| Emory is only conducting some of the procedures specified in the protocol  **Choose all that apply:**  **Enrollment/Consenting Subjects**  **Access to Identifiable Data**  **Data Analysis**  **Administering Study Interventions** |
| Emory-affiliated researchers are solely participating in the protocol on-site at the other institution or assisting the other institution with their protocol  Assisting how? Enter text. | 1. How many researchers? Enter text. 2. If Emory students, are they getting paid or receiving academic credit at Emory?   Payment  Academic/internship credit  N/A |
| Investigator from another institution has now begun employment at Emory and is bringing research with him/her | 1. What is investigator’s role NOW?   Data analysis  Assistance with manuscripts  Other: Enter text.   1. Will funding be transferred to Emory?   Yes  No  Not funded |

**Other Institution/Individual’s Role in the Research:**

Please check all that apply and give further detail.

|  |  |
| --- | --- |
| **ACTIVITY** | **DETAILS** |
| Other Institution is the coordinating/lead site (the Overall PI and lead study team are there) | *If checked, please attach a copy of the APPROVED main protocol to your email when you submit this request.* |
| Other Institution is the prime awardee/direct grant recipient |  |
| Other Institution is the prime awardee/direct grant recipient BUT procedures are being conducted at Emory by Emory researchers instead of the Other Institution’s researchers |
| Emory has subcontracted to the other institution | *If checked, please attach a copy of the subcontract to your email when you submit this request.* |
| Other Institution is conducting the full protocol (enrolling and consenting, accessing identifiable information, analyzing data, and administering study interventions) | 1. Number of subjects enrolled there: Enter text. 2. Type of identifiable information: Enter text. 3. Type of study interventions THERE?   Biomedical research interventions  Collection of identifiable biospecimens  Sociobehavioral or educational interventions (surveys, questionnaires, etc.)  Other: Enter text. |
| Other Institution is only conducting some of the procedures specified in the protocol  **Choose all that apply:**  **Enrollment/Consenting Subjects**  **Access to Identifiable Data**  **Data Analysis**  **Administering Study Interventions** |
| Other institution’s researchers are coming to Emory to assist on-site with our protocol  Assisting how? Enter text. | 1. How many researchers? Enter text. 2. If students, are they getting paid or receiving academic credit at the other institution?   Payment  Academic/internship credit  N/A |
| Former Emory investigator is moving institutions and is taking research with him/her | 1. What is investigator’s role NOW?   Data analysis  Assistance with manuscripts  Other: Enter text.   1. Will funding be transferred from Emory?   Yes  No  Not funded |