**RELIANCE REQUEST FORM**

Collaboration with Non-GW Researchers

Institutions [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) in non-exempt human subject research require IRB oversight.

In most instances, 45CFR46.114 requires a single IRB for cooperative federally funded research involving more than one institution in the United States. A “Reliance” occurs when one institution relies on another institution for IRB oversight. An IRB Authorization Agreement is required when a Reliance occurs. This agreement is also referred to as an IAA or Reliance Agreement.

When a GW Researcher collaborates with an investigator who is not affiliated with an institution or belongs to an institution that does not have an [Federal Wide Assurance](https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/fwa-instructions/index.html) (FWA), GW IRB can enter into an [Individual Investigator Agreement](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html) (IIA) with that investigator.

**Read Before Completing this Form**

The requirements for entering into a reliance agreement with GW:

1. **Engagement**: Both GW and the collaborating institution/individual must be engaged in non-exempt human subject research. Engagement occurs when an institution:
	* Is the primary grant recipient.
	* Obtains consent from research participants.
	* Interacts or intervenes with participants to obtain data about them, or biospecimens from them; **or**
	* Obtains private, identifiable information about research participants.
2. **Exempt Research:** GW will not enter into a reliance agreement if a relying site’s involvement in the research is limited to:
* Participation in research that meets the requirements for an exempt determination. (**Note:** An IIA is not required from external independent investigators collaborating on exempt research. Add the collaborators to the GW iRIS application after verification of appropriate training, other credentials, and disclosures of related interests.)
* Allowing outside investigators to access data to identify potential participants; or
* Distribution of recruitment material to potential participants.
1. **International Research**: Generally, GW will not rely on an international IRB /Ethics Committee.
2. **Data Use Agreement/ Material Transfer Agreements:** When research data or materials will be transferred, investigators are required to ensure that proper agreements are executed, regardless of whether the Reliance Agreement or IIA has been finalized.

**CONTACT INFORMATION**

**GW Principal Investigator:**

|  |
| --- |
| Name:       |
| Email:       Phone number:       |
| If applicable, contact person’s name and email:       |

**Non-GW Principal Investigator and Affiliation:**

*If more > 1 collaborating PI/ Institution, please copy and paste the box below.*

|  |
| --- |
| Name:       |
| Email:       Phone number:       |
| If applicable, contact person’s name and email:       |
| **Collaborating IRB(s) / Institution**(s): |
| Type of Site (hospital, medical office, etc.):      *If multiple sites, please add a table to the last page of this form and include: Institution Affiliation, Site Name, Site Address, Site PI/POC and their contact information.* |
| Primary Point of Contact Name: Email:       Phone number:       |
| Collaborating Institution’s IRB/Reliance Manager contact for execution of the AgreementName:      Email:       Phone number:       |

**List GW researchers engaged in the research; indicate COIs and CITI training**:

*If GW is the relying site and there are changes to the GW research team after initial submission of this form, please copy and paste the table below and send a letter addressed to the GW IRB to* *ohrirb@gwu.edu* *with an updated list of engaged GW researchers.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Research Team Member** | **COI (YES\*/NO)** |  **CITI Training Name\*\***  | **Exp. Date** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\**If YES, please contact the GW OHR.*

*\*\*Biomedical or SBR, HIPS when HIPAA-regulated, and GCP for clinical trial research.*

**Anticipated Start Date for GW’s role in the research:**

**DETAILS OF COLLABORATION**

ONTACT INFORMATION

**Study Title**:

[ ]  I am submitting a copy of the protocol and protocol documents (survey(s), consent(s), recruitment material, etc.) with this request.

Or

[ ] GW is the requested reviewing IRB and the protocol documents are available in iRIS. **IRB #:**

1. **Institution requested to serve as the Reviewing IRB:**

**[ ]** GW University OR [ ]  Other Institution/IRB Name:

[ ]  Check if the other institution is a [SMART IRB Participating Institution](https://smartirb.org/participating-institutions/)

[ ]  Ancillary Reviews are required for the research occurring at GW (e.g. Biosafety, Export Control, etc.). List Ancillary Reviews:

1. **Funding Information**:

[ ]  Study is federally funded. Name of funding source:

[ ]  Study is industry-sponsored.

[ ]  Other. Describe:

Name the prime awardee:

1. **Reason for reliance request** (check all that apply):

[ ]  Sponsor or funding agency requirement.

[ ]  Study is part of existing network, consortium, or agency encouraging sIRB.

[ ]  Not required, but for efficiency

[ ]  Other:

**GW’s Role in the Research** *(check all that apply and provide detail, where applicable):*

|  |  |
| --- | --- |
| **Role** | **Details** |
| Define GW Researchers’ Engagement in the Research[ ]  International Research OR [ ]  N/A* List the study procedures that will take place internationally:
* List the study procedures that will take place in the US:
 | [ ]  Prime Award Grant Recipient[ ]  Data Coordinating Center involving identifiable data.[ ]  Interacting /intervening with participants to obtain data about them or specimens from them, including administration of a test article.[ ]  Collecting information from participants through surveys or interviews.[ ]  Obtaining consent from participants.[ ]  Obtaining private, identifiable data about participants through review of records /info that were collected for another purpose (e.g. EMR, student records, records from another study). *NOTE: Do NOT check this box if the data received are coded and linked to the participant’s identity and the researchers will not have access to the identities.*[ ]  Obtaining anonymous or de-identified data about participants that were collected for other purposes (e.g. a different research study, or de-identified database). *NOTE: Check this box if you are receiving a Limited Data Set with a DUA or when the data are coded and linked to the identity and the researchers will not have access to that link.* [ ]  Obtaining identifiable human biospecimens that were collected for another purpose. *NOTE: Do NOT check this box if the biospecimens are coded and linked to the participant identity when the researchers receive them and the researchers will not have access to that link.* [ ]  None of the above. Describe the procedures you will be conducting:  |

**Other Institution/Individual’s Role in the Research** *(check all that apply and provide detail, where applicable).*

*For > 1 other Institution, please copy and paste the table below and provide 1 table per institution.*

|  |  |
| --- | --- |
| **Name of Institution:**  | **Details** |
| Other Institution/Individual’s Engagement in the Research[ ]  International Research OR [ ]  N/A* List the study procedures that will take place internationally:
* List the study procedures that will take place in the US:
 | [ ]  Prime Award Grant Recipient[ ]  Data Coordinating Center involving identifiable data.[ ]  Interacting /intervening with participants to obtain data about them or specimens from them, including administration of a test article.[ ]  Collecting information from participants through surveys or interviews.[ ]  Obtaining consent from participants.[ ]  Obtaining private, identifiable data about participants through review of records /info that were collected for another purpose (e.g. EMR, student records, records from another study). *NOTE: Do NOT check this box if the data received are coded and linked to the participant’s identity and the researchers will not have access to the identities.*[ ]  Obtaining anonymous or de-identified data about participants that were collected for other purposes (e.g. a different research study, or de-identified database). *NOTE: Check this box if you are receiving a Limited Data Set with a DUA or when the data are coded and linked to the identity and the researchers will not have access to that link.* [ ]  Obtaining identifiable human biospecimens that were collected for another purpose. *NOTE: Do NOT check this box if the biospecimens are coded and linked to the participant identity when the researchers receive them and when the researchers will not have access to that link.* [ ]  None of the above. Describe the procedures you will be conducting:       |

**SIGNATURES**

ONTACT INFORMATION

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| **GW Principal Investigator attests to the following:** [ ]  GW researchers are appropriately trained and qualified to perform their roles.[ ]  When GW researchers have access/store/analyze identifiable research data or specimens, the GW PI ensures the appropriate data management and security procedures are in place for research data or specimens held or accessed by GW. [ ]  The GW OHR / IRB will be informed of changes to the GW engaged researchers, their COIs, and updates to training (CITI).[ ]  Congruency between the research documents, Clinical Trial Agreement, Data Use/Material Transfer Agreement, and grant contract.  |
| **GW PI Signature (required):** | Date: |
| GW Department Chair Name: My signature indicates that this project has been reviewed by the appropriate departmental parties who have judged that:[ ]  The GW PI is sufficiently qualified by training and experience to conduct the research.[ ]  The department has made the space and time commitment necessary to carry out the project.[ ]  The financial implications of the research have been considered and deemed acceptable to the department. |
| GW Department Chair Signature (required):  | Date: |
| For research that involves EITHER GW University Hospital and/or MFA data and/or patients OR if the GW PI is MFA faculty, an Office of Clinical Research (OCR) signature is required: Signature of Dr. Radwa Aly OR Dr. Mardi Gomberg-Maitland:  | Date: |