I. Contact Information

**GW Principal Investigator (PI)**

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| --- | --- |
| Name (Last name, First name MI): | Highest Earned Degree: |
| Mailing Address:  Phone Number: | Email: |
| GWID: | Department:       School: |

GW Primary Contact (if different from PI)  Student  Coordinator Other

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| --- |
| Name:       Email:  Phone (Day): |

**Other Institution’s PI and/or Collaborator**

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| --- | --- |
| Name (Last name, First name MI): | Highest Earned Degree: |
| Mailing Address:  Phone Number: | Email: |
| GWID: | Department:       School: |

II. Project Details

1. Research Title:
2. Is the study funded? Yes No
   1. If yes, specify the funding source:
   2. Describe the flow of funding (e.g. subaward from GW to collaborating institution, vice versa, or other arrangement):
3. Is this research:

Multisite (the same research activities will be followed at each institution)

Collaborative (different research activities will happen at each institution)

GW is acting as a data coordinating center (GW will not participate in data collection activities but will receive identifiable data)

1. Who is the lead institution and will be designated the IRB of Record (the reviewing IRB)?

GW Other institution. Specify:

1. List GW personnel involved in the research. For each person, list any Conflicts of Interest (COI) in the research, and human subjects training status:

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| Key Personnel | COI | Human Subjects training status |
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1. If GW will be the IRB of record, specify below all participating institutions, personnel, COI status, and human subjects training status:

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| --- | --- | --- | --- |
| Institution | Key Personnel | COI | Human subjects training status |
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1. If GW will be the IRB of Record, explain how the GW PI will train and supervise the research team members at the other institution.
2. If GW will be the IRB of Record, please provide the GW IRB number for the research:
3. Provide a brief (one paragraph) summary of the overall study.
4. Specify the roles and responsibilities of the GW staff.
5. Specify the roles and responsibilities of the other institutions staff.
6. Local Context Issues in the research:

Local Context Issues are localized human subjects protection concerns such as state or regional laws, institutional requirements, cultural norms, etc. that are specific to each research site.

When GW is the IRB of Record:

* 1. Are there any state, local, or regional laws at the relying sites that require special consideration for this study(ies)?  Yes No
  2. Is there a need for ancillary reviews (IBC, radiation safety, etc.) at any site?

Yes No

If yes, specify which site, type of review, and timeline for approval:

* 1. Are there any regional norms or cultural issues at the relying sites that require special consideration for this study(ies)?  Yes No
  2. Does the relying site have any institutional requirements (e.g. language regarding HIPAA authorization) that needs consideration for inclusion in the research protocol or study documents?  Yes No

When GW is relying on another institution:

1. Is there a need for ancillary reviews (IBC, radiation safety, etc.) at GW?

Yes No

If yes, specify which site, type of review, and timeline for approval:

1. Does your school or department require any specific language to be included in study documents (such as HIPAA language or FERPA language)?
2. Site Specific Consent forms:

Per 45 CFR § 46.116 - General requirements for informed consent, consent forms require IRB approval prior to their use.

When GW is the IRB of Record:

* 1. Does the relying site require site-specific template language?  Yes No
  2. If yes, specify which site:

Please work with the relying site’s IRB to answer and complete the “Institutional Profile and Study Specific Local Context Worksheet for Relying Sites” form. The GW IRB must approve any site-specific required consent language before it is used.

When GW is the relying on another institution:

1. Will GW be consenting participants?  Yes No

If yes, the consent form approved by the IRB of Record must be adapted for use at GW and must conform to institutional requirements. Along with this form, please provide us with the revised consent template for our review and approval.

1. Provide the IRB contact information for the other institution.

III. Signatures

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| **GW Principal Investigator Signature:** My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as outlined in [Federalwide Assurance of Protection for Human Subjects](http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html), for which GW is registered with OHRP/DHHS, and as detailed in GW HRPP policies & procedures. I will be guided by the principles contained in the [Belmont Report](http://www.hhs.gov/ohrp/policy/belmont.html) and The Code of Federal Regulations governing research with human subjects ([45CFR46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)) and [21CFR50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=50). I have verified that all members of the research team have agreed to accept the responsibilities required of their roles and I provide my assurance that all will be kept fully briefed on the details of the study. I have queried all members of the research team to determine if they have a conflict of interest in this study as defined by GW policies. | |
| **GW PI Signature (required):** | Date: |
| GW Department Chair Signature: My signature indicates that this project has been reviewed by the appropriate departmental parties who have judged that 1) there is a scholarly and scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) the GW PI is sufficiently qualified by training and experience to conduct the research, 3) that the department has made the space and time commitment necessary to carry out the project, 4) that the financial implications of the research have been considered and deemed acceptable to the department and 5) that all ethical principles have been appropriately addressed. | |
| GW Department Chair (required): | Date: |
| Required additional signatures for research that involves EITHER GW Hospital and/or MFA data and/or patients OR if the GW PI is MFA faculty:  Signature of Radwa Aly:  Signature of Dr. Mardi Gomberg-Maitland: | Date:  Date: |