**Institutional Profile and Local Context Form**

For Relying Sites/Individual Investigators

You or your site are participating in a study for which you are requesting that George Washington (GW) IRB will be the IRB of Record (or “Reviewing IRB”).

**Contact Information**

**GW Principal Investigator:**

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| Name: |
| Email: Phone number:  |

**Non-GW Principal Investigator:**

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| Name: |
| Email: Phone number:  |
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**Institutional Profile**

**Relying Site / Individual**

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| Institution/Affiliation:  |
| Address:  |
| Type of Site (hospital, medical office, etc.): |
| Primary Reliance Point of Contact Name: Email: Phone number: |
| Institutional Signatory Official (name, title, email address):  |
| OHRP FWA: [ ]  The FWA has been extended to non-federally funded research.  |
| List other names the site is known by:  |
| Is your site AAHRPP accredited? [ ]  YES [ ]  NO |
| SMART IRB Participating Institution: [ ]  YES [ ]  NO |
| Is your site a covered entity under HIPAA? [ ]  YES [ ]  NO |
| Identify affiliations of the site that are relevant to the study (e.g. university, clinic, hospital):Indicate whether those sites are engaged in the research: [ ]  YES [ ]  NOIndicate whether those engaged sites are within a network or system [ ]  YES [ ]  NOName of System: FWA:  |
| Anticipated Start Date for Relying Site’s Participation in the research: |

|  |  |
| --- | --- |
| [ ]  Yes [ ]  NO | Are there any investigations, audits, or findings (e.g. OHRP, FDA, local audit) over the past 3 years that would be relevant to the conduct of new human subjects research proposed at the site? If YES, please explain:  |
| [ ]  Yes [ ]  NO | Does your institution have a post approval monitoring program or other regulatory oversight for ongoing research? If YES, please indicate whether the post approval monitoring program or other regulatory oversight monitors studies that are reviewed by an external IRB: [ ]  Yes [ ]  NOIf YES, please briefly describe the program:  |

**Study Title:**

**GW IRB#:**

**Financial Interest Disclosure and Conflict of Interest (COI) Management**

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| You must select one of the boxes on the left:  |
| [ ]  | Researchers engaged in the research at this institution do NOT have a COI |
| [ ]   |  One or more researchers engaged in the research at this institution have a COI with the proposed research. The COI Management plan is attached.  |

**Research Personnel and Training**

**List Relying Sites Research Team Members** [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) **in the research;**

*\*\*If the Relying Site Research Team list changes, please submit an updated list to the GW Overall PI.*

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| **Research Team Member Name** |
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[ ]  **The Research Team Members listed above possess the required qualifications and training to engage in the research.**

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| --- | --- |
| **Role** | **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 private, 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.[ ]  Obtain consent from participants.[ ]  Obtain 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.*[ ]  Obtain 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.* [ ]  Obtain 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 that will be conducted at the site:       |

**Local Context**

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| [ ]  YES [ ]  NO | There are local or state laws or institutional requirements in addition to those established by federal regulations. If YES, describe here or provide a document describing local law or local context:  |
| [ ]  YES [ ]  NO | There are community or cultural differences for the local population of subjects that require consideration. If YES, describe the relevant information:  |
| [ ]  YES [ ]  NO | Is 18 the age of majority for the state in which your site is located? If NO, please state the age of majority:  |
| [ ]  YES [ ]  NO | Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g. the institution does NOT consider this activity “preparatory to research” activities)?  |
| [ ]  YES [ ]  NO[ ]  N/A, no PHI | Will the institution submit a combined HIPAA authorization/ consent form document? If NO, the relying institution will conduct review of the standalone HIPAA authorization and submit to GW IRB.  |
| [ ]  YES [ ]  NO | Ancillary reviews are required for this research. If YES, The Relying institution will conduct institution-required ancillary reviews and ensure approval prior to commencing the research. [ ]  YES [ ]  NOList the Ancillary Reviews:       |

**Consent**

[ ]  Consent is waived or not being conducted at this site. (*Skip the remainder of Consent section.*)

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| Indicate whether your institution has a policy for the following. *Note: only select those for which there is an institutional policy; generally accepted practice and guidance are not policy.* |
| [ ]  Age of Assent Policy | Please provide a link or attach the policy. |
| [ ]  Consent Process for those with Impaired Decision-making Capacity | Please provide a link or attach the policy.  |
| [ ]  Use of short forms for non-English speaking individuals | Please provide a link or attach the policy.  |
| [ ]  Translation of consent forms for non-English speaking individuals. | Please provide a link or attach the policy.  |
| Consent form language:  |
| Provide institutionally required consent form language for ***compensation in the event of research-related injury*** | State here or attach a document:  |
| Provide institutionally required consent form language for ***pregnancy testing in minors*** | State here or attach a document:  |
| Provide institutionally required consent form language for **genetic testing** | State her or attach a document |
| Provide ***any othe***r consent form language required by site policy or state law | State here or attach a document |

**SIGNATURES**

ONTACT INFORMATION

|  |  |
| --- | --- |
| **[ ]  The Relying Institution/PI maintains responsibility for ensuring that Research Team Members are qualified to conduct research at this institution.** **Non-GW PI/Individual Investigator (name):** | Date: |
| Signature:  |