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| **Institutional Profile and Study Specific**  **Local Context Worksheet**  **for Relying Sites** |  |

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| **Instructions:** Your site is participating in a study for which the George Washington University (GW) IRB will be the IRB of record. The following information is needed in order for the GW IRB to conduct its review:   * The requirements of any state or local laws, regulations, institutional policies, standards, or other local factors, including site-specific ancillary reviews, relevant to the research, that could affect the conduct or approval at your institution * Site-specific language for the customizable sections of the informed consent form (ICF) for this study     This form contains four sections:   * Section 1: Institutional Profile – Relying Site * Section 2: Study Specific Local Context Information including Financial Conflicts of Interest and Regulatory Requirements * Section 3: Institutional Requirements & Ancillary Reviews * Section 4: Community Considerations   Please follow the steps outlined below to complete the form:  **Step 1**: (Participating site) Carefully review the protocol and consent form (if applicable) and complete this site-specific form. *Note: It is strongly recommended that the information be completed as a collaborative effort between the PI and local (relying) IRB.*  **Step 2**: (Participating site) Review the template consent form (if applicable) and provide any site-specific required language [including any changes to the proposed injury language for your site].  **Step 3**: (GW study team) Email the following documents to the GW’s Office of Human Research (OHR) at [ohrirb@gwu.edu](mailto:ohrirb@gwu.edu):   * Completed and signed IRB Record Request form * Completed Institutional Profile and Study Specific Local Context Worksheet (this form) * If applicable, site-specific consent/HIPAA authorization forms and other site-specific study materials * Completed and signed Institutional Review Board (IRB) Authorization Agreement (IAA) form. The relying site needs to sign the IAA form before GW signs. The GW OHR will get the appropriate GW signature as the final step.   For questions about this form or other reliance forms, contact GW OHR at 202-994-2715 or [ohrirb@gwu.edu](mailto:ohrirb@gwu.edu) |

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| **Section 1: Institutional Profile** –**Relying Site** | | | |
| **Institution Name** |  | | |
| Street Address: |  | | |
| City: | State: | Zip: | |
| **OHRP Federalwide Assurance (FWA#)** |  | *Does the FWA extend to non-federally funded research?*  YES NO | |
| **Institutional Signatory Official** | | | |
| First Name: | Last Name: | | Degree: |
| Role: | Email Address: | | |
| Telephone Number: | Extension: | | |
| **Signatory Primary Contact Person(s)** – Individual(s) who will serve as the primary point of contact for relying site IRB related issues at the institution | | | |
| First Name: | Last Name: | | Degree: |
| Role: Point of Contact | Email Address: | | |
| Telephone Number: | Extension: | | |
| **Does your site have an IRB?** | YES NO  If the IRB is not internal, please state the primary external IRB: | | |
| **Is your site AAHRPP accredited?** | YES NO | | |
| **Does your site have a quality assurance (QA)/monitoring group responsible for overseeing ongoing research?** | YES NO  *If YES, provide the QA contact information:*  URL for the QA/HRPP (*if applicable*): | | |
| **Is your site a covered entity under HIPAA?** | YES NO  *If YES, is research considered a covered function?*  YES NO | | |
| **Personnel Training and Experience**  Indicate the CITI human subjects protection training course(s) researchers take at your site.  Other human subject protection training (describe):  Note: The GW IRB requires that all relying site study personnel complete CITI human subjects research training by either completing the Social & Behavioral Research course or the Biomedical Investigators course, or the equivalent.  If HIPAA is involved, then relying site research personnel must also complete the CITI Health Information Privacy and Security (HIPS) for Clinical Investigators course, or the equivalent.  CITI courses can be accessed at: <https://citiprogram.org>.  **Does your IRB certify that all relying site personnel on the study listed in Section 2 have the required training to engage in human subject research activities?** YES NO | | | |

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| **Section 2: Study Specific Local Context Information** | | |
| **Study Title** |  | |
| **GW IRB Protocol #** |  | |
| **GW PI** |  | |
| **Relying Site Institution Name** |  | |
| **Relying Site PI** | | |
| First Name: | Last Name: | Degree: |
| Role: | Email Address: | |

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| **Financial Conflicts of Interest (FCOI)**  For any interests determined to constitute an FCOI or require a management plan, provide the applicable approved management plan with this completed site-specific information sheet. | |
| **For this study, please list any study team members at your site identified as having significant financial conflicts of interest** | None |
| **Site Specific Activities**  Will the site complete all activities described in the protocol or is participation limited to specific activities? | Full protocol Limited protocol  Describe limited protocol activities for this site: |
| **Regulatory Requirements**  Please review the protocol and template consent.   * Identify unique state, local, or federal laws that apply to this study (e.g. legally authorized representatives, state laws regarding confidentiality of specific types of health information, age of emancipated minors) * Describe any steps that must be taken to adhere to these requirements. | |
| **Describe any state, local, or federal laws or requirements that apply to this study which require changes to the study conduct at your site** | None |
| **Please outline specific changes to the research based on the requirements identified above** | None |

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| **Section 3: Institutional Requirements & Ancillary Reviews**  Please review the protocol and template consent.   * Identify any applicable unique *institutional* requirements and policies that require changes to the study conduct at your site (e.g. recruitment, data security, remuneration, etc.) * Describe any changes to the study as a result of these requirements. Include changes to the consent form (i.e. consent for future use of bio-specimens, site-specific injury language, coverage of treatment costs for research-related injuries, etc.) * If any changes are required based on ancillary reviews that have not yet been completed at the time this site-specific information sheet is submitted, these changes must be separately communicated to the GW IRB. | |
| **Describe any institutional requirements that apply to this study which require changes to the conduct of the study at your site** | None |
| **List any ancillary reviews required at your site [e.g. radiation safety review, institutional biosafety (IBC) review for research with bio-specimens, etc.]** | Are any ancillary reviews required?  YES NO  *If YES, list ancillary reviews:* |
| **Template consent form requires site-specific language changes** | Is site-specific template language required? If yes, please attach  YES NO |
| **HIPAA authorization language** | Will a site-specific, stand-alone HIPAA form be used?  YES NO Not applicable  Alternatively, does your site permit a combined ICF/HIPAA form?  YES NO Not applicable |
| **Short-form consent** | Does your site allow a short-form consent process for non-English speaking participants?  YES NO Not applicable  *If YES, please provide a URL to the short-form consents available at your site:* |

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| **Section 4: Community Considerations**  Describe any local, community, or cultural considerations specific to the targeted subject population, and the site plan to account for the considerations during the conduct of the study. | |
| Are there any special community characteristics/concerns or subject population concerns of which the GW IRB should be aware for this study? | YES NO Not applicable  *If YES, please describe:* |

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Name of Relying Site Individual Completing Questionnaire

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role of Relying Site Individual Completing Questionnaire

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Signature Date