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| To be filled out by relying site Human Research Protection Program (or equivalent office) personnel:The purpose of this form is to provide the George Mason University IRB Office staff with local context information for external sites that rely on the George Mason University IRB to serve as their IRB of Record. At a minimum, this form must be completed every three years. If there are significant changes to local context information before every three years, the form should be updated as soon as possible. |
| 1. Site Information
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| 1. Legal name of Site:

1a. List all other names by which this Site is known:       |
| 1. Federal Wide Assurance (FWA) Number:

2a. FWA expiration: 2b. Does this Site’s FWA extend to non-federally funded research? That is, does this Site “check the box”? Yes [ ]  No [ ] 2c. List all institutions or affiliates that are components under the Site’s FWA: 2d. Describe any institutional relationships or affiliations relevant to this Site:  |
| 1. Does this Site have an internal Institutional Review Board? Yes [ ]  No [ ]

3a. Is the Site's IRB [AAHRPP](http://www.aahrpp.org/) accredited? Yes [ ]  No [ ]  N/A [ ] a. If "no," describe the Site's research compliance (e.g. post-approval monitoring) resources:  |
| 1. Is this Site a covered entity\* (i.e., healthcare entity)? Yes [ ]  No [ ]  N/A [ ]

4a. Provide any relevant information on this topic on behalf of the Site and its affiliates:  |
| 1. Site HRPP (or equivalent office) Point of Contact Information:

Name: Email: Phone #:  |
| 1. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of human subjects research at this Site?

6a. If "yes", provide additional information regarding investigations, audits, or findings that may be relevant:  |
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| 1. State Law and Site Policy Requirements
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| 1. Provide any state or local laws that the George Mason University IRB may need to consider when reviewing this Site. For example, this may include but is not limited to: state privacy laws, laws related to sensitive data collection, age of majority, legally authorized representative(s), etc. Provide descriptions and/or brief summaries of relevant laws:
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| 1. What is the age of majority for research in this Site’s state (i.e., age when one is considered an adult in your state)?
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| 1. Provide any site policies that the George Mason University IRB may need to consider when reviewing this Site. For example, this may include but is not limited to: data retention, e-Consent, consent processes for minors, consent processes for those with Impaired Decision-Making Capacity, use of short forms for non-English speaking individuals, translation of consent forms, etc. Provide descriptions and/or brief summaries of relevant policies:
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| 1. Provide information on any ancillary reviews that the George Mason University IRB must verify are completed before studies can begin. This excludes ancillary reviews or processes that the relying site is responsible for:
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| 1. Will this Site verify that all Site personnel engaged in human research are appropriately qualified and up-to-date on this Site's institutionally-required training (e.g., human subjects protections or HIPAA training)? Yes [ ]  No [ ]
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| 1. If an individual or institutional financial conflict of interest is present, will this Site provide a management plan? Yes [ ]  No [ ]
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| 1. Does this Site conduct administrative or institutional reviews of all ceded studies to ensure state and local laws and institutional policies are adhered to before activities at this Site begin? Yes [ ]  No [ ]
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| 1. Informed Consent Requirements
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| 1. Is the Site agreeable to retaining responsibility as the HIPAA Privacy Board (if applicable)? N/A [ ]  Yes [ ]  No [ ]  Other [ ]

1a. If "No" or “Other,” provide further information:       |
| 1. Provide this Site's required informed consent language, verbatim, in the spaces below:

4a. Subject Compensation:      4b. Research Related Injury:       4c. Provide any other consent form language required by state and local laws and institutional policies: 4d. Other:       |
| 1. Are there additional informed consent considerations that the George Mason IRB should be aware of (e.g. inclusion of logos in headers)?
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| 1. Will this Site conduct an administrative or institutional review of its site-specific informed consent form(s) to ensure all state and local laws and institutional policies are adhered to before activities at this Site begin? Yes [ ]  No [ ]
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| 1. Community Considerations
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| 1. Identify any special characteristics and/or concerns of your community which the reviewing IRB should be aware for this Site. Please also outline any steps that are recommended to be taken to address these concerns:
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| 1. Signatures and Attestations
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| By signing below, the signatory affirms that they attest to the accuracy and completeness of the information provided herein.The Site is solely responsible for consulting with its own legal counsel to determine whether research reviewed by the George Mason IRB (including but not limited to any consent process, participant documentation, or HIPAA documentation) meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Site's Human Research Protection Program (or equivalent office) Authorized Individual \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Printed Name and Title of Authorized Individual Date |