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| Virginia Tech IRB number:  Virginia Tech PI Name:  The purpose of this worksheet is to provide the Virginia Tech HRPP Office staff with local context information for external sites that rely on the Virginia Tech IRB to serve as the IRB of Record. This form should not be completed if the study activities qualify for an exempt level review. Only non-exempt research is eligible for a reliance agreement. This form must be completed by the Relying Site’s research team and their IRB point of contact. This form should be uploaded into the Other/Misc section of the Supporting Documents in Protocol Management by the Virginia Tech PI or research team member. |
| 1. **Local Site and Study Information**
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| 1. Name of relying Site:
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| 1. Federal Wide Assurance (FWA) number:
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| 1. FWA expiration:
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| 1. Does the institution have an internal Institutional Review Board?  Yes [ ]  No [ ]
 |
| 1. Is the Relying Site’s IRB [AAHRPP](http://www.aahrpp.org/) accredited (If Applicable)?  Yes [ ]  No [ ]
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| 1. Is the Relying Site a member of SMART IRB? Yes [ ]  No [ ]
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| 1. Relying Site PI name:
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| 1. Relying Site PI email address:
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| 1. Relying Site’s Local IRB or SMART IRB point of contact name:
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| 1. Relying Site’s Local IRB or SMART IRB point of contact email:
 |
| 1. \*Is the Relying Site a covered entity? (i.e. Healthcare Entity)  Yes [ ]  No [ ]   N/A [ ]
 |
| 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 new human subjects research proposed at the site?  Yes [ ]  No [ ]
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| 1. If the answer to question 12 was “yes”, please provide additional information regarding investigations, audits or findings that may be relevant.
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| 1. **Regulatory Requirements**
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| 1. Age of majority for research (i.e. Age when one is considered an adult in your state)?
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| 1. Are there any state laws that the Virginia Tech IRB will need to consider when reviewing this study?  Yes [ ]  No [ ]
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| 1. If the answer to question 2 is “yes”, please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).
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| 1. What circumstances affect age of consent in your state? (i.e. in Pennsylvania a minor age 14 or above can consent to their own mental health information.
 |
| 1. Are there any state or local laws or institutional policies that require record keeping for longer than federal law requires under the Privacy Rule or Common Rule?  Yes [ ]  No [ ]
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| 1. If the answer to question 5 was “yes”, please provide additional information regarding the record keeping requirements at your institution.
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| 1. If applicable, please provide any local site policies for the following areas –if applicable (Please provide links to the relevant policy information):
2. Consent process for those with Impaired Decision-Making Capacity:
3. Use of short forms for non-English speaking individuals:
4. Translation of consent forms for non-English speaking individuals:
 |
| 1. Please review the list of study personnel (from the relying institution) who will be engaged in human research and confirm that all have completed required training specific to your institution (i.e. Human Subject Protections Training, GCP Training and HIPAA Training, as applicable):

 [ ]  I have verified that all study personnel listed have completed required training. [ ]  I have identified that some study personnel have not completed required training and will ensure that they are removed from the list until the required training has been completed. |
| 1. Please review the list of study personnel (from the relying institution) who will be engaged in human research and indicate whether a COI is present:

 [ ]  I have verified there are no financial interests to disclose. [ ]  I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable. |
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| 1. **Institutional Requirements**
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| If applicable, for each entry below, provide local template language for the following sections of the consent form:1. **Research Related Injury:**
2. **HIPAA Authorization Language:**
3. **Genetic Testing:**
4. **Please provide any other consent form language required by site policy or state law:**
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| 1. **Community Considerations**
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| 1. Please review the protocol and template consent form and identify whether there are any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study. Please also outline any steps that may be taken to address these concerns:
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| 1. **Signature and Attestations (This form should be signed by the Relying Site PI or a representative from the Relying Site IRB**
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| 1. By signing below, the signatory affirms that they attest to the accuracy and completeness of the information provided herein.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

\*Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.

Researchers are covered entities if they are also health care providers who electronically transmit health information in connection with any transaction for which HHS has adopted a standard. For example, physicians who conduct clinical studies or administer experimental therapeutics to participants during the course of a study must comply with the Privacy Rule if they meet the HIPAA definition of a covered entity.\*