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| **IRB RELIANCE AGREEMENT REQUEST FORM**  **UVA IRB-HSR to serve as IRB of Record** |
| **INSTRUCTIONS AND INFORMATION:**  Relying Sites should only complete this request form **AFTER** the UVA IRB-HSR has approved the study locally. One form is to be completed for **EACH** institution that agrees to rely on the IRB-HSR.  **Submit the following documents to the Relying site for completion:**   1. IRB Reliance Agreement Request Form UVA IRB-HSR to serve as IRB of Record (***complete UVA study information***) 2. Current approved IRB-HSR protocol, consent(s)/assent(s) (if applicable) 3. Relying Site Local Context Template **(Appendix A) -**used to add local context to the UVA IRB approved consent/assent documents (TRACK CHANGES MUST BE TURNED ON)   **Submit the following documents to the UVA IRB to add a relying site**   1. Completed IRB Reliance Agreement Request Form UVA IRB-HSR to serve as IRB of Record 2. Completed [Modification Request form](https://research.virginia.edu/sites/vpr/files/2022-03/ModificationRequestForm031622.docx) 3. Tracked copy of the consent/assent which includes the relying site LOCAL CONTEXT information included.   **NOTE:** See Page 6 for complete list of potential documents to be submitted to the UVA IRB from the Relying Site   1. If applicable, copy of the relying site’s Stand-Alone HIPAA authorization if Relying site chooses to serve as their own HIPAA Privacy Board. 2. SOM CTO review/approval for EACH addition of Relying Site: Contact Lori Elder for review and approval: [lje5u@virginia.edu](mailto:lje5u@virginia.edu)     UVA study team or Data Coordinating Center will submit all requested documents via IRB PRO as a MODIFICATION. |

**Submission Date:**       **Submitted By:**      **Email:**

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| **Study Information** | |
| **UVA Study Tracking #:** |  |
| **UVA Principal Investigator:** |  |
| **Protocol Title:** |  |
| **Data Coordinating Center** | N/A **Center Name and Contact email:** |

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| **UVA IRB for Health Sciences Research (IRB-HSR) Contact Information** | |
| **Name of Institution/FWA#/IRB Registration#** | University of Virginia/00006183/00000447 |
| **IRB Contact/Email/Phone#** | Eileen [Sembrowich/ecs3b@virginia.edu](mailto:Sembrowich/ecs3b@virginia.edu) /434-243-6542 |
| **Institutional Official/Phone #** | Melur K. “Ram” Ramasubramanian/434-924-3606 |
| **Institutional Official Address** | VP for Research University of Virginia PO Box 400301 136 Hospital Drive  Charlottesville, Virginia 22904 |

*\*\*\*\*\*RELYING SITE START HERE\*\*\*\**

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| **Relying Institution Information**  A representative from the Relying Institution should complete the remaining sections of this document for EACH new protocol. | |
| **Relying Institution Name** |  |
| **Relying Institution FWA#** |  |
| **Address** |  |
| **IRB Contact Name/Email** |  |

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| **Institutional Official Name** |  |
| **Institutional Official Phone #/Email** |  |

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| **Name, credentials, training, and contact information of the person responsible for the research conducted at this relying site.**  **Include copy of PI CV** | Local PI Name       Credentials (e.g., MD, PhD)  Training (e.g., NIH, CITI)  Contact Info (e-mail/phone) |
| Do you confirm the relying site is a member of [SMART IRB](https://smartirb.org/participating-institutions/) and will conform to their [SOP’s](https://www.google.com/url?client=internal-element-cse&cx=000741335895712361513:s7gfmll2gx8&q=https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf&sa=U&ved=2ahUKEwj0uNak3KzqAhVSmXIEHTA7DgcQFjAAegQIAxAB&usg=AOvVaw2yOrQ4DhmcG_iEuaJL2bBU)? | YES  NO  **If NO**, the UVA IRB-HSR will provide a Reliance Agreement prepared for signatures AFTER completion and review of this request form. |
| The relying institution verifies that all personnel engaged in this research have completed the organization’s required human subject protection training, including Good Clinical Practice training, if applicable. | YES |
| Does the relying institution apply its FWA to all research? | YES  NO  If no, describe what research is not covered by their FWA:  **Note:** Oversight provided by the UVA IRB serving as the sIRB must satisfy the terms of the relying institution’s FWA. One of the eligibility criteria for participation in SMART IRB is that the institution requires IRB review and institutional oversight for their human subject’s research regardless of funding source. |
| Will the Relying Institution enroll subjects? | YES  NO IF yes, N= |
| Indicate the roles & responsibilities of the Relying Institution’s researchers. | **(S*elect all that apply)*:**  ☐Recruitment  ☐Obtaining consent  ☐Data collection  ☐Implementing/administering research intervention  ☐Identifiable data/sample analysis  ☐De-identified (coded) data/sample analysis  ☐Anonymous data/sample analysis  ☐Other – specify: |
| Populations requiring additional protections enrolled at Relying Site | ***(Select all that apply):***  ☐Children  ☐Neonates  ☐Pregnant women  ☐Prisoners  ☐Adults with impaired decision-making capacity  ☐Employees  ☐Students  ☐Active military personnel  ☐Other – specify: |
| Do you confirm that UVA IRB-HSR will serve as the HIPAA Privacy Board for this relying site for this particular study? | YES ***If YES, this means:***   1. UVA will grant all HIPAA Waivers 2. The Relying Institution agrees to use UVA’s Privacy Section in the consent. 3. The Relying Institution agrees to use UVA’s HIPAA Authorization language in the consent 4. 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 "Preparatory to Research" activities)?   ☐ Yes☐ No☐  NO **If NO, this means:**   1. The Relying Institution HIPAA Privacy Board will grant all HIPAA waivers/partial HIPAA Waivers. 2. The Relying Institution will use their own institutional HIPAA Privacy Authorization Form. Your institutions language will not be included in the IRB approved consent form. |
| Describe how the relying site study team will protect the privacy of participants: | **Describe:** |
| Describe the local recruitment procedures at the relying site. | Not applicable to this study or site  **Describe:** |
| Describe any differences in research procedures (from the UVA IRB approved protocol) that will be done at the relying site: | Not applicable to this study or site  **Describe:** |
| Describe how study data and/or specimens will be stored and protected from unauthorized access at the relying site. | **Describe:** |
| Do you confirm that the relying site has the adequate resources (including space, equipment, and personnel) for conducting the study? | YES |
| Do you confirm that the Relying Study Team will carry out their responsibilities at [Reviewing and Relying Site Responsibilities](file:///\\pi11.admin.virginia.edu\vprweb-users\IRB\IRB-HSR\WEBSITE\Website%20pages%20final%20and%20drafts\Responsibilities%20of%20UVA%20Study%20team%20and%20Relying%20Site%20Study%20Team_UVA%20serving%20as%20the%20overall%20sIRB_03-19-21.docx).? | YES |
| Are there any other names by which the relying site is known, or, does business and any corporate affiliations it has with other organizations, such as a university or hospital network? | YES  NO  If yes describe: |
| If any of the sites identified above are within a network or system, do they have a separate FWA? | YES  NO  N/A  If yes, identify the sites with the separate FWAs: |
| 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 subject’s research proposed at the site? | YES  NO  If yes, “yes”, please explain the outcome of any investigations, audits or findings that may be relevant. |

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| Does the relying institution have a post- approval monitoring program, quality assurance/audit group or other regulatory oversight for ongoing research? If yes, provide contact information for person in charge of Post-Monitoring Program.  Name  Email  Phone | YES  NO  If yes, does the post-approval monitoring program or other regulatory oversight monitor studies that have been deferred, to an external IRB?  Provide a link (URL) to the post approval monitoring program/regulatory oversight information or paste information here. |
| Does the organization have other oversight mechanisms?  YES  NO  If yes, provide contact information for person in charge of quality assurance/audit or other oversight mechanism | If YES, please describe mechanisms:  Name  Email  Phone |

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| **Local Context Issues**   **NA – subjects not enrolled at relying site** |
| 1. Are there any state or local laws that the Reviewing IRB will need to consider that would impact a research protocol or informed consent document (wards of state, emancipated minors, results of pregnancy testing)?   YES  NO If YES, describe:   1. Are there any local, community or cultural issues that may be different for your population of subjects that require consideration?   YES  NO If YES, describe:   1. Is 18 the Age of Majority for the state in which your site is located?   YES  NO If No, identify the age:  4. Is there anything described in the protocol that would not fall within the policies and practices of your institution that the  IRB-HSR needs to be aware of?  YES  NO If yes, describe:  **NOTE**: *It is the responsibility of the Relying Institution, to inform the Reviewing IRB of any changes to the state or local laws that could affect a research protocol or informed consent document.*  **Site Policies  NA – subjects not enrolled at relying site**   1. Does the site have a posted policy for any of the following?  YES  NO If YES, complete details below   **NOTE: Please only select those for which there is a posted institution policy; (generally accepted practice and guidance are not policy)**  **Age of Assent Policy or**  **NA no Minors are enrolling in this project.**  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Consent Process for those with Impaired Decision-Making Capacity or**  NA No cognitively impaired subject to enroll  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Use of short forms for non-English speaking individuals or**  NA No non-English speaking subjects to enroll  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Translation of consent forms for non-English speaking individuals or**  NA No non-English-speaking subjects to enroll  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |  1. Provide the name of the person/office that will provide additional protections if a Ward of the State should be approached to enroll a minor.   NA: No children will be enrolled  NA- No subjects will be enrolled at Relying Institution  **Local Consent Requirements: (no URL; paste language directly into document)**  **NA – subjects not enrolled at relying site.**   1. Provide institutionally required language regarding compensation in the event of a research related injury:      1. Provide any institutionally required language for pregnancy testing in minors:      1. Provide any institutionally required language for genetic testing:      1. Provide any other language required by site policy or state law:      1. Is there a Conflict of Interest in this study?  YES  NO   Note: Each Institution is responsible for reviewing the protocol and determining if a conflict of interest exists in accordance with the Institution’s policies. The Conflict of Interest Management Plan must be disclosed to the IRB-HSR.  If YES, provide the language the institution requires in the consent form regarding the conflict.   1. Any additional local language to be included in Header/footer of document (e.g., relying institution study tracking #)   NO YES: |

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| **Indicate which of the following site-specific documents are being submitted to the UVA IRB-HSR:**  \*Required for all studies - Relying site PI’s curriculum vitae or Bio sketch  Site-specific Consent/Assent documents: List:  Site-specific recruitment materials: List:  Site-specific HIPAA Authorization form (separate from consent form)  Site-specific measure(s) (e.g. surveys, observation forms, interview guides etc.) List:  Relying site Conflict of Interest management plan List:  Other – specify: |

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| **APPENDIX A: RELYING SITE LOCAL CONTEXT TEMPLATE** |
| **INSTRUCTIONS AND INFORMATION**  This Appendix provides guidance on how to convert the UVA IRB approved consent/assent form(s) into a consent form(s) that is specific to a relying site when the UVA IRB is serving as the IRB of Record for a multisite study.    **Tracking:** When submitting for initial review of the site-specific content, tracking, and highlighting of ALL administrative and major changes is necessary to facilitate a timely review. If any changes are necessary beyond filling in the placeholders with site-specific information, it is recommended, that you include comment bubbles in the tracked consent form or a cover letter to provide clear rationale for why the UVA IRB approved language in that specific section is being changed for the local relying site.  **Version Tracking:** All site versions should have the same content in the footer, which should include the consent form site-specific version date. For example: Version: 02-28-19 should be converted to placeholder [Site Name] Version dated [MM-DD-YY] |

**FRONT PAGE CONSENT**

*INSTRUCTIONS: Replace with Relying site name*

In this consent, “we” means the researchers and staff involved in running this study at the [ADD LOCAL SITE NAME].

**FRONT PAGE ASSENT**

*INSTRUCTIONS: Replace with Relying site institution*

Doctors at the [ADD LOCAL SITE NAME].

This study will take place here at [ADD LOCAL SITE NAME].

**Is there a possible conflict of interest?**

*INSTRUCTIONS: Language that indicates the investigator at the relying site has a potential conflict of interest, should be in a template placeholder as noted below.*

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of this study team have a conflict of interest with this study which is explained below. [SITE PI has the following conflicts:]

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| **Principal Investigator:** | [Insert name, address, and phone # of Relying Site PI] |

**# Of subjects enrolled at Relying Site:**

*INSTRUCTIONS: Include the # of subjects to be enrolled at the relying site.*

Up to ***insert #******of people who will sign consent at the relying site -*** people will be in this study at [ADD LOCAL SITE NAME].

**FOR ASSENT:**

*INSTRUCTIONS for GIRLS (if age appropriate)-check with relying site what the state law requires in terms of reporting*

If you are pregnant or think you might be pregnant, please tell us so we may talk about this with you.

***(If applicable*)** If you are female and of child-bearing potential, your blood sample will be tested to find out if you are pregnant. This test must be negative in order to continue study participation. The results of the pregnancy test will be provided to you.  Also, Virginia law requires release of the test results to your parent(s)/legal guardian if they request the results or request a copy of your medical records.

**What are your other choices if you do not join this study?**

*INSTRUCTIONS: Remove the language that indicates patients of UVA or employees will not have their care*

*affected by study participation.*

If you are a patient at UVA, your usual care will not be affected if you decide not to participate in this study.

If you are an employee of UVA, your job will not be affected if you decide not to participate in this study.

**Will You Be Paid for Participating in this study?**

*INSTRUCTIONS: Local site compensation/reimbursement language to be added to this section if differs from UVA local consent. In addition, if relying site is from the state of Virginia, language noted below should be included, otherwise, DELETE.*

The money you earn may be reported to the IRS as taxable income.

**What if you are hurt in this study?**

*INSTRUCTIONS: Review the relying site’s compensation in case of injury local context language and include their required response.*

**What happens if you leave the study early?**

*Instructions: add site specific information*

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the [ADD LOCAL SITE NAME].

**How will your personal information be shared?**

*INSTRUCTIONS: Review the relying site’s determination as to whether or not to have UVA serve as the HIPAA privacy board. If they choose to use the UVA template, replace [UVA RESEACHERS] with [RELYING SITE NAME]. Include local data retention requirements if different from UVA.*

*IF UVA is not serving as the HIPAA Privacy Board, the information provided above with the question asking if UVA will serve as the Privacy Board is answered NO.*

The [ADD LOCAL SITE NAME] are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at [ADD LOCAL SITE NAME].

Some of the people outside of [ADD LOCAL SITE NAME] who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

*INSTRUCTIONS: Include the following paragraph if information /samples will be shared outside of UVA. Replace [UVA RESEACHERS] with [RELYING SITE NAME]*

Information about you and/or samples from you may be given to other researchers outside of the [ADD LOCAL SITE NAME]. **INSERT AS APPLICABLE:** after all identifiers such as name, address, phone # have been removed. **OR** with identifiers such as name, address, phone#.

Some of the people outside of [ADD LOCAL SITE NAME] who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

**Copy of Consent in Local Medical Record**

*INSTRUCTIONS: Review the relying site’s local context language and confirm if copies of the consent will be placed in the subject’s medical chart. If not, DELETE the statement below.*

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

**Certificate of Confidentiality**

*INSTRUCTIONS: The statement regarding protection by a Certificate of Confidentiality should only be included if the main locally approved UVA consent contains the statement.*

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA and ADD LOCAL SITE NAME] will not use it in the following cases.

* You have agreed in writing to allow UVA and ADD LOCAL SITE NAME] to share the information with your employer, your insurance company for billing purposes, or someone else
* Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.
* ***If dealing with a situation that could involve infectious diseases insert the following sentence***: Reports to authorities if you have an infectious disease that health care providers are required to report by law.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.