Your site is participating in a study where an External Institutional Review Board (IRB) will be the IRB of record. When relying on an External IRB, relying institutions must agree to provide the following important information:

* The requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at Virginia Commonwealth University (VCU).
* Site-specific informed consent information for the respective study using the informed consent template provided by the VCU IRB.
* Site-specific HIPAA authorization form for the respective study using the HIPAA authorization template provided by the VCU IRB/Privacy Board (if applicable).
* **If the study uses Electronic Consent (e-Consent), refer to the** **Annotated Bibliography of Virginia Law-Human Research (Appendix B) for proper use of Virginia Law in relation to e-consenting language (if applicable).** **Consent form templates are available at** [**https://research.vcu.edu/forms/**](https://research.vcu.edu/forms/)**.**

**Please seek guidance from your Human Research Protection Program (HRPP)/Research Office/Institutional Review Board (IRB) regarding how to complete the local context review process at your institution. Most IRBs require a local submission in order to initiate the local context review process.**

The local context form contains three important sections:

* Section 1: Relying Site Study Team Information
* Section 2: Applicable Local Requirements
* Section 3: The Conduct of this Study at VCU

Please follow the steps outlined below to complete the form:

**Step 1**: (Relying site and VCU study team) Carefully review the protocol and consent form provided by the investigators and complete this site-specific form. ***Please note: It is strongly recommended that the information be completed as a collaborative effort between the PI and the local (relying) IRB office.***

**Step 2**: (Relying site and VCU study team) Review the template consent form and provide any site-specific required language [including any changes to the proposed injury language for your site].

**Step 3**: (VCU study team) Please upload the following documents into RAMS-IRB:

* Completed copy of this External IRB of Record Local Context Form
* IRB-approved Protocol(s)
* IRB-approved site-specific Informed Consent Form(s) (ICF) (if applicable)
* IRB/Privacy Board-approved HIPAA authorization approvals (if applicable)
* Site-specific consent/HIPAA authorization forms and other site-specific study materials (if any)
* IRB-approved recruitment materials
* Informatics approval documentation for recruitment and screening
* Financial Interest Reports (FIR) for Conflict of Interest (COI) Investigator
* Subject Injury Language (SIL) Memo for industry-sponsored studies
* Massey Cancer Center Protocol Review and Monitoring Committee (PRMC), VCU Health Protocol Review Oversight Committees (PROCs), Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC) and/or Investigational Drug Service (IDS) Pharmacy approvals as applicable
* CITI training including GCP, Biomedical/ Social Behavioral\*, and HIPAA certifications for all Key Personnel

**\*Biomedical & Social Behavioral may be required as it correlates to the specific study activities**.

* Data Sharing Agreement(s)/Data Use Agreement(s) (if applicable)
* Material Transfer Agreement(s) (if applicable)
* Coverage Analysis Specialist Documentation
* The signed IRB Authorization Agreement or, if using the SMART IRB Agreement, a copy of the SMART IRB Acknowledgment form signed by the relying site’s Point of Contact (POC)

**Before the research can begin at Virginia Commonwealth University, the VCU IRB must activate the external IRB approval. The VCU IRB will verify all local research context requirements.**

Please carefully review the approved protocol and approved master template consent form and complete the local context form below and provide any locally required consent form language using the site-specific template provided. ***Please note: The master template consent is being provided to facilitate your local context review only and is not approved for use to enroll subjects.***

We strongly recommend that the local context form be completed as a collaborative effort. To ensure all necessary information is captured, information from the local site Principal Investigator (PI) and IRB/institutional contact is required. ***Please note: Signatures by both the local site PI and the Institutional Contact are required.*** Please be as careful as possible in completing this form so that the document does not need to be re-signed.

Study team members with questions about completing this local context form can contact VCU’s IRB Reliance Division at irbreliance@vcu.edu. If your organization’s IRB has questions about this form, please contact VCU’s IRB Reliance Division at irbreliance@vcu.edu.

*Disclaimer: VCU applies the 45 CFR 46, Subpart A, Protections of Human Subjects Regulation*

*to all non-exempt human subject research regardless of the study funding source.*

**Glossary of Terms**

**Agreement:** SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

**Confidential Information:** Any non-public, confidential and/or proprietary information, including but not limited to the scientific content of research proposals and information provided by the overall PI or Site Investigator(s) or other research personnel not generally known or available to the public. Information will not be deemed confidential information here­under if such information: (a) is known to the receiving party prior to receipt from the disclosing party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (b) becomes known (inde­pendently of disclosure by the disclosing party) to the receiving party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (c) becomes publicly known or otherwise ceases to be secret or confidential, except through a breach of this Agreement by the receiving party; or (d) is independently developed by the receiving party.

**Conflict of Interest (COI) Investigator:** Designated by the Principal Investigator (PI) on proposals and on IRB and IACUC submissions. A COI investigator is an individual, regardless of title, role, or position, who is responsible for the design, conduct, and/or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigators, subrecipient investigators, medical investigators, collaborators, consultants, students, trainees, or research coordinators. Exceptions include students or personnel whose research activities are directly supervised. The term denotes individuals who must report their interests in RAMS-AIRS, so that these interests can be reviewed in the context of the research; it does not imply that they have a conflict of interest. See VCU’s Conflicts of Interest in Research Policy at <https://vcu.public.doctract.com/doctract/documentportal/08DA32A63EDBCC96C898EA6EC61CFF0A>.

**DHHS:** The United States Department of Health and Human Services (DHHS).

**Federal Policy:** The Federal Policy for the Protection of Human Subjects set forth in the DHHS regulations at 45 CFR part 46, subpart A and corresponding regulations of other federal departments and agencies adopting such policy.

**FWA:** The Federalwide Assurance (FWA) in which a research institution commits to DHHS that it will comply with the Federal Policy.

**Health Insurance Portability and Accountability Act (HIPAA**)**:** Collectively, the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations. The Privacy Rule is codified in 45 CFR 160 and 164.

* Key points:Regulations protect a subset of individually identifiable information, known as Protected Health Information (PHI) from inappropriate disclosure; regulations only protect individually identifiable health information that is held or maintained by covered entities or their business associates that create, use or receive such information in a health care context; specifically addresses the use of Protected Health Information (PHI) for research purposes.

**HIPAA Authorization:** An authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.

**Human Research Protection Program (HRPP):** provides administrative support to the IRB including records management and resources for IRB members and all VCU personnel (investigators and non-investigators who have questions about research protections). This office serves as the public outreach arm of the IRB providing educational opportunities to the research community, overseeing required human subjects training, and coordinating with ancillary committees, groups and individuals on the conduct of human subject research. The office also oversees a post approval monitoring program and compliance activities, including fulfillment of reporting responsibilities to federal authorities.

**Human Subject (as defined by DHHS):** a living individual about whom an investigator conducts research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)]

**Informed Consent:** A general term for the communication process that is used by key research personnel to facilitate an individual’s informed choice about enrolling in a research project. During this process a participant voluntarily confirms their willingness to take part in research, after having been informed of all aspects of the research that are relevant to the participant’s decision to participate.

**Informed Consent Form (ICF):** A document that provides appropriate information about a research study to allow potential research subject to make an informed decision about participation.

**Institutional Official (IO) or Signatory:** The Vice President for Research and Innovation has been designated as the Institutional Official (IO) for VCU on its Federalwide Assurance (FWA). The IO has ultimate responsibility for all aspects of the HRPP at VCU but may delegate responsibilities to other qualified individuals.

**Institutional Review Board (IRB):** The Institutional Official (IO) has delegated to the VCU IRB the responsibility for ensuring that all research adheres to applicable regulations. The VCU IRB constitutes a single panel, Panel A (IRB Registration Number IRB00000410). Additionally, the VCU HRPP enters into reliance agreements to either cede IRB review to, or provide IRB review on behalf of, another institution.

* **Panel A** is a single IRB that is registered with the federal Office of Human Research Protections and fully qualified to act on any research project involving human subjects. Panel A is registered to review studies that are funded by the Food and Drug Administration (FDA). The committee Administration (FDA). The committee generally meets once to twice per week to facilitate a timely review of Full Board research studies.

**IRB Organization:** An independent IRB organization that provides IRB review services and has agreed to become the Reviewing IRB for another Participating Institution for an instance of Research under this Agreement.

**Investigational Drug Service (IDS) Pharmacy (of the VCU Health System and ACE Affiliates):** provides the support needed to ensure safe and efficient conduct of clinical drug trials. Utilization of the IDS for investigational drug control aids Principal Investigators in protecting human research subjects through improved drug security, safety and accountability. The IRB requires that the IDS Pharmacy be used in accordance with IDS policies and VCU IRB WPP XVI-6.

**Lead Study Team (Referring to Lead Study Contact):** Generally, the Lead Study Team is the study team at the Reviewing IRB’s institution. The Lead Study Team is designated by the Overall PI (see below) and, working in collaboration with the Reviewing IRB, ensures coordination of communication to and from all Relying Site Study Teams (see below), routing all IRB submissions to the Reviewing IRB, and communicating IRB determinations to Site Investigators.

**Lead Principal Investigator (PI):** See Principal Investigator (PI) for additional definition**.**

**Legally Authorized Representative(s) (LAR/LARs):** An individual, or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research. [45 CFR.46 102(c) and 21 CFR 50 3(l)]

**Local Considerations:** Requirements of any applicable state or local laws, regulations, institutional policies, standards or other local factors, including local ancillary reviews, relevant to an instance of Research.

**Participating Institution:** An institution (including an IRB organization) that meets the eligibility requirements set forth in the Agreement and agrees to accept the terms and conditions of the Agreement through the execution of a Joinder Agreement, thereby becoming a signatory party to this Agreement.

**Partial Waiver:** permits access to and use of PHI for recruitment purposes, prior to obtaining authorization. Specifically, it allows for the identification and, as appropriate, contact of potential participants to determine their interest in study participation.

**Principal Investigator (PI):** The Principal Investigator (PI) or the Medically/Psychologically Responsible Investigator (if required for the study) is responsible for ensuring that all personnel engaged in conducting human research are adequately qualified and are provided with appropriate oversight to perform study responsibilities.

**PHI:** Personal/Protected Health Information (PHI) as defined in 45 CFR 160.103.

**Point of Contact (POC):** At least one individual who will serve as the contact person responsible for communicating on behalf of the institution with respect to matters concerning the initial and ongoing implementation of this Agreement. For exam­ple, the POC would be the person designated at each Participating Institution to make determinations regarding requests for their site to serve as the Reviewing IRB for Research or cede IRB review and are likely to be individuals within an IRB office or other component of the human research protection program.

**Massey Cancer Center Protocol Review and Monitoring Committee (PRMC):** reviews all cancer-related research proposals. PRMC conducts pre-study reviews to ensure adequate study design and feasibility and conducts data safety monitoring reviews throughout the life of a study. Verification of PRMC review is required prior to IRB approval.

**VCU Health Protocol Review Oversight Committees (PROCs):** review all research proposals that use VCU Health System patients, data and/or facilities. PROCs conduct pre-study reviews to ensure adequate study design and feasibility. Verification of PROC review is required prior to IRB approval.

**Radiation Safety Committee (RSC):** is managed by the Radiation Safety Section of the VCU Office of Safety and Risk Management. The charge of the RSC is to oversee use of licensed material and radiation-producing devices. The IRB requires documentation of RSC approval prior to IRB approval if the use of radiation is NOT for the subject’s direct clinical benefit.

**Relying Institution:** A Participating Institution that cedes IRB review to a Reviewing IRB for an instance of Research under the Agreement.

**Relying Site Study Team:** Relying site investigators, including any local site personnel designated by the site investigator to carry out the applicable communication, coordination, and administrative procedures described within the Agreement and SOPs.

**Research:** Non-exempt human subject research within the meaning of the federal policy at 45 CFR part 46 or within the meaning of any other federal human subject’s research regulations or policies; clinical investigations within the meaning of the FDA IRB regulations; and any other research, for which any Participating Institution(s) seek or are required to rely on a Reviewing IRB. As used in the Agreement, Research may reference a specific study or protocol in which there will be a reviewing and relying party operating pursuant to the terms of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement, or collectively the studies subject to Ceded Review under the Agreement.

**Research Personnel:** Members of the research team (including Overall PI and Site Investigator(s)) engaged or involved in an instance of Research. These individuals may include, as applicable, physicians, research nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers, and/or other personnel.

**Reviewing IRB:** The “IRB of record” (including an IRB Organization) to which authority for IRB review and oversight has been ceded by another Participating Institution for an instance of Research under the Agreement.

**Reviewing IRB Institution:** The Participating Institution whose IRB has become the Reviewing IRB for another Participating Institution for an instance of Research under this Agreement.

**Single IRB (sIRB):** is the IRB of Record, selected on a study-by-study basis, which provides the ethical review for all sites participating in a multi-site, collaborative human subjects study. Common Rule agencies/funding sponsors (e.g., NIH) require an sIRB for domestic multi-site, collaborative studies.

**Site Investigator(s):** An investigator(s) responsible for the conduct of the Research at his/her Participating Institution.*See Lead Principal Investigator (PI) & Principal Investigator (PI) for additional definitions.*

**Streamlined, Multisite, Accelerated Resources for Trials (SMART IRB):** is designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants.

SMART IRB is not an IRB; rather, it's a platform that offers a master IRB reliance Agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for Participating Institutions and their investigators to request, track, and document study-specific reliance arrangements. Investigators and their study teams, together with institutional and HRPP/IRB offices, use the SMART IRB platform to initiate single IRB review of a study.

**Subject Injury Language (SIL):** No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. [45 CFR 46.116]

**Unanticipated Problems that may Involve Risks to Subjects or Others (UPIRSOs):** The phrase “unanticipated problems involving risks to subjects or others” is found but not defined in the HHS regulations at 45 CFR part 46. The Office of Human Research Protections (OHRP) considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Waiver of Documentation of Informed Consent**: A waiver of documentation of informed consent may be requested of the IRB under three circumstances, as outlined in 45 CFR 46.117(c) and provided below.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern;
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; [Note: this condition is also applicable to FDA regulated studies - 21 CFR 56.109(c)(1).]
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

**Waiver of HIPAA Authorization:** The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
* an adequate plan to protect the identifiers from improper use and disclosure;
* an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
* adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
1. The research could not practicably be conducted without the waiver or alteration; and
2. The research could not practicably be conducted without access to and use of the protected health information.

**Study Title**: Click or tap here to enter text.

**Overall Study Principal Investigator (PI)**: Click or tap here to enter text.

**External IRB of Record:** Click or tap here to enter text.

**VCU IRB Protocol HM# (VCU Internal use only):** Click or tap here to enter text.

**Section 1: Relying Site Study Team Information**

|  |  |
| --- | --- |
| 1. **Legal Name of Participating Institution:**
 | Virginia Commonwealth University |
| 1. **Name of Relying Site Principal Investigator (PI):**
 | Click or tap here to enter text. |
| 1. **Relying Site PI Phone #:**
 | Click or tap here to enter text. |
| 1. **Relying Site PI Email:**
 | Click or tap here to enter text. |
| 1. **Name of Relying Site Lead Study Contact:**
 | Click or tap here to enter text. |
| 1. **Relying Site Lead Study Contact Phone #:**
 | Click or tap here to enter text. |
| 1. **Relying Site Lead Study Contact Email:**
 | Click or tap here to enter text. |
| **Federalwide Assurance (FWA) #:** | FWA00005287 |
| **FWA Expiration Date:** | 12/8/2026 |
| 1. **Does your FWA require you apply 45 CFR part 46 to all studies regardless of funding source (e.g., "check the box")?**
 | YES [x]  NO [ ]  |
| **List all institutions that are considered components under your FWA:** | - Virginia Commonwealth U IRB #2 Panel A- National Cancer Inst Central IRB #1 (Adult)- National Cancer Inst Central IRB #2 (Pediatric)- WCG IRB |
| **Does your site have an IRB?** | YES [x]  NO [ ] **If YES**, provide the IRB contact information:Office Name: VCU Human Research Protection Program Responsible Person: Dr. Sanjur Brooks Phone #: 804-828-0131 Email Address: brookss15@vcu.eduURL for the IRB/HRPP (*if applicable*):[*https://research.vcu.edu/human-research/hrppirb/*](https://research.vcu.edu/human-research/hrppirb/) |
| 1. **Is your site Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accredited?**
 | YES [x]  NO [ ]  |
| **Does your institution require HIPAA authorizations to be separate, or can they be included in the consent form?** | Must be separate [ ] Can be included in ICF [x] *Provide any site-required language in the site-specific consent information [SSCI] template. If your site does not have any specific HIPAA authorization language requirements, the VCU HIPAA language [already incorporated into the SSCI template] will be used for your site.* |
| **Please review the planned list of personnel who will be engaged in human subject’s research at your institution and verify that all of your institutionally-required training for the conduct of the research [including human subjects protections training, Good Clinical Practice (GCP) training, and HIPAA training, as applicable] has been completed for each individual.** | Training completed for each individual. [ ] Training not completed for each individual. [ ]  |
| **Are all involved individuals from your institution credentialed and/or appropriately qualified and meet the institution's standards for eligibility to conduct the research as described in the approved protocol?** | I confirm that all involved individuals are credentialed and/or appropriately qualified. [ ] *Please note: This form should not be submitted for central review unless all individuals are credentialed and/or appropriately qualified.* |
| **Did the institution determine there is a relevant individual or institutional financial COI for this protocol?** | YES [ ]  NO [ ] **If YES:**(1) Provide a summary of the conflict and management plan or attach documentation:Click or tap here to enter text.(2)Provide an institutional Point of Contact (POC) for questions related to the local management plan [This person should be someone in the office/entity who prepared the management plan]:Click or tap here to enter text. |

**Section 2: Applicable Local Requirements**

|  |  |
| --- | --- |
| 1. **Please review the protocol and template consent and identify areas where there are unique state, local or federal regulatory requirements that apply to the conduct of this study at VCU (e.g., legally authorized representatives (LARs), state laws regarding confidentiality of specific types of health information, emancipated minors) and describe any steps that must be taken to adhere to these requirements.**

*Please note: Only include what is relevant to the conduct of this study at VCU. Please outline any specific changes needed to ensure adherence with the requirements you have identified. This may include site-specific consent form language based on state law requirements [e.g., reportability of test results for infectious diseases]. This information needs to be considered as part of the External IRB review.* | **Regulatory requirements:**Click or tap here to enter text.**Do any of the applicable local regulatory requirements noted in this section have associated consent form language requirements?**YES [ ]  NO [ ] **If YES**, please ensure the applicable consent form language is include in the site-specific consent information pages for VCU. |
| 1. **Please review the protocol and template consent and identify any institutional requirements (e.g., policy or procedural requirements such as recruitment, data security, remuneration) that apply to this study and describe any steps that must be taken to adhere to these requirements.**

*Please note: Only include what is relevant to the conduct of this study at VCU. Please outline any specific changes needed to ensure adherence with the requirements you have identified. This may include changes to the consent form to include any language required based on local site requirements [e.g., any specific local site policy requirements related to consent for future use of biospecimens]. This information needs to be considered as part of the External IRB review.*  | **Institutional requirements:**Click or tap here to enter text.**Do any of the applicable institutional requirements noted in this section have associated consent form language requirements?**YES [ ]  NO [ ]  **If YES,** please ensure the applicable consent form language is include in the site-specific consent information pages for VCU. |
| **Does your organization require that the IRB grant a waiver of privacy authorization under HIPAA for any of the following recruitment activities? (select all that apply)** | * [ ]  Medical record review or other access to PHI (of potential subjects who are patients of the research team)
* [ ]  Medical record review or other access to PHI (of potential subjects who are not patients of the research team)
* [ ]  Telephone or in-person screening prior to the signing of a written privacy authorization

[ ]  N/A to the conduct of this study at this site |
| **Please identify the ancillary reviews [e.g., radiation safety review, review for research with bio-specimens, drug/device safety review, etc.] that are applicable to this study and are required before the study may be initiated at VCU.***Please confirm that these ancillary reviews have been completed and provide the outcome of those reviews (including any changes required to the conduct of the study).*  | **Ancillary reviews:**Click or tap here to enter text.N/A – no ancillary reviews [ ] Ancillary reviews completed[ ] Provide the ancillary review outcome(s) and attach any relevant documentation:Click or tap here to enter text. |
| **Are there sources of support that are unique to your site?** | YES [ ]  NO [ ]  **If YES**, check all sources of support (pending or awarded) and indicate the source name: [ ]  Monetary[ ]  Material or Equipment (e.g., drugs or devices)[ ]  None of the above**Source(s):**Click or tap here to enter text. |

**Section 3: The Conduct of This Study at VCU**

|  |  |
| --- | --- |
| **Please select the activities that will be performed at VCU and/or performed by VCU’s employees. (select all that apply)** | ☐ Recruitment☐ Enrollment☐ Obtaining consent☐ Data collection☐ Implementing/administering research intervention☐ Identifiable data/sample analysis☐ De-identified (coded) data/sample analysis☐ Anonymous data/sample analysis☐ Registry/repository creation or maintenance☐ Manuscript or presentation preparation[ ]  Funding Only[ ]  Other: Click or tap here to enter text.  |
| **Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?** | YES [ ]  NO [ ]  **If YES,**please describe the differences and specify whether you have attached any site-specific recruitment materials for IRB review:Click or tap here to enter text.  |
| **Please review the protocol and template consent form and verify that there are sufficient resources available at your site to carry out the research as planned, including study team members with prior clinical trial experience.** *If any changes are required to the study plan related to the resources available at your site, please outline the required changes.* | YES [ ]  NO [ ]  *Please note: The answer to this must be YES prior to submission.*Changes required: Click or tap here to enter text. |
| **Are there any different requirements for how data will be accessed and/or stored at your site from those described in the protocol or associated documents based on local requirements or state laws?** | YES [ ]  NO [ ]  N/A to this study’s conduct at VCU [ ]   |
| **Are you proposing any variation from the currently approved consent process and/or process for documentation of consent at your site?** | YES [ ]  NO [ ]  **If YES,** please describe the differences: Click or tap here to enter text. |
| 1. **Are there any other different requirements for how the protocol will be implemented and/or conducted at VCU based on local requirements or state laws?**
 | YES [ ]  NO [ ] **If YES**, explain: Click or tap here to enter text. |
| 1. **Please provide a brief description of your institution’s human subjects protection training requirements for researchers and study staff.**
 | Training: Click or tap here to enter text. |
| 1. **If your institution has a post-approval monitoring program or other regulatory oversight for ongoing research, please provide a description of the monitoring program.**
 | Monitoring: Click or tap here to enter text. |
| **Please review the protocol and template consent 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 must be taken to address these concerns.** | [ ]  None[ ]  Characteristics/concerns have been identified. Explain: Click or tap here to enter text. |
| **It is possible that the External IRB may have additional questions about your local community. Please include the best contact for additional questions about local site information.** | Local Site Contact Name: Click or tap here to enter text.Email Address: Click or tap here to enter text.Phone #: Click or tap here to enter text. |

**Section 4: Board-Specified Study-Specific Questions**

|  |  |
| --- | --- |
| **4a. Please select the populations that will be enrolled at the relying site. (select all that apply)** | ☐ Children☐ Wards of the state☐ Neonates☐ Pregnant women or fetuses☐ Prisoners☐ Adults with impaired decision-making capacity☐ Individuals with limited English proficiency☐ Employees of relying site☐ Students of relying site☐ Active military personnel[ ]  Other: Click or tap here to enter text. |

 *[See Appendix A for common Study-Specific Questions that may be added.]*

|  |  |
| --- | --- |
| **4b.** Click or tap here to enter text. | Click or tap here to enter text. |
| **4c.** Click or tap here to enter text. | Click or tap here to enter text. |
| **4d.** Click or tap here to enter text. | Click or tap here to enter text. |

**Signatures/Attestations**

[USE FOR SMART AGREEMENT]

By signing below, the signatories affirm that they have reviewed the SMART IRB Agreement, Letter of Indemnification and the responsibilities of relying institutions and attest that the information fulfills the relying institutions responsibilities for the provision of local context information.

As specified in the Agreement, Relying Institution is solely responsible for consulting with its own legal counsel to determine whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation and any HIPAA documentation), meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance. Relying Institution is solely responsible for identifying all ancillary reviews required by applicable regulation or policy in the Reliance Application and must notify Reviewing IRB of the outcome of such reviews prior to final protocol approval.

[USE FOR NON-SMART AGREEMENT]

By signing below, the signatories affirm that they have reviewed the agreement and attest that the information fulfills the relying institutions responsibilities for the provision of local context information.

As specified in the Agreement, Relying Institution is solely responsible for consulting with its own legal counsel to determine whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation and any HIPAA documentation), meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance. Relying Institution is solely responsible for identifying all ancillary reviews required by applicable regulation or policy in the Reliance Application and must notify Reviewing IRB of the outcome of such reviews prior to final protocol approval.

|  |  |
| --- | --- |
|  Lead Site Investigator Signature: | Institutional Contact [e.g., HRPP Lead] Signature: Role/Title: Click or tap here to enter text. |
| Print Full Name: Click or tap here to enter text. | Print Full Name: Click or tap here to enter text. |
| Contact Phone #: Click or tap here to enter text.Email: Click or tap here to enter text. | Contact Phone #: Click or tap here to enter text. Email: Click or tap here to enter text. |
| Date of Signature: Click or tap here to enter text. | Date of Signature: Click or tap here to enter text. |

*Disclaimer: VCU applies the 45 CFR 46, Subpart A, Protections of Human Subjects Regulation*

*to all non-exempt human subject research regardless of the study funding source.*

**Appendix A: Supplemental Questions Added on a Study-Specific Basis [as applicable]**

|  |  |
| --- | --- |
| *[Add if sites are being added AFTER COVID]***Please select one [or more] of the following options as they relate to COVID restrictions on research activities at your site:** | [ ]  I confirm that there are no COVID-related restrictions that would limit my site’s ability to begin research. [ ]  My site is not currently permitting this type of research to start. [ ]  My site has restrictions on specific research activities as described below:Click or tap here to enter text.  |
| *[Add if study is approved for enrollment of adults lacking capacity to consent]***Please identify any relevant state law or local policy requirements pertaining who may serve as a legally authorized representatives (LARs) providing informed consent for subjects lacking the capacity to consent. Please confirm that you will adhere to these requirements.** | Click or tap here to enter text. |
| *[Add if study is approved for enrollment of adults lacking capacity to consent]***Please identify any relevant state law or local policy requirements for assessing the capacity to consent (and/or determining whether an individual lacks capacity) and describe how capacity to consent will be assessed.** | Click or tap here to enter text. |
| *[Add if study is approved for enrollment of adults lacking capacity to consent]***Please provide a description of any site-specific requirements regarding re-consent when using a legally authorized representative (LAR). If re-consent is required per local law or institutional policy, please be specific as to whether the re-consent must be conducted in writing. Please provide a link to any applicable local laws or institutional policies related to re-consent.** | Click or tap here to enter text. |
| *[Add if study includes protocolized drugs/devices]* **Does your site have an ancillary committee/reviewer that has reviewed and approved your plan for drug/device management (e.g., storage, dispensation and/or handling)?**  | YES [ ]  NO [ ]  **If NO,** please describe your institution’s plan for the storage, dispensing and monitoring of the study drug/device:Click or tap here to enter text. |
| *[Add if study is using traditional/high-efficacy drugs]***Are any of the approved drugs in either the first-line (traditional) therapies or second-line (higher-efficacy) therapies not considered a standard of care option at your site?** | YES [ ]  NO [ ]  **If YES**, please explain and explain how this will be addressed at your site:Click or tap here to enter text. |
| *[Add if VCU requires physician consent]***Does your site have a specific requirement for who may obtain informed consent for this research?** | YES [ ]  NO [ ]  **If YES**, please describe the requirement and how you will address it:Click or tap here to enter text. |

|  |  |
| --- | --- |
| *[Add if study is approved for enrollment of non-English speakers]***This study is approved for enrollment of non-English speakers. Which of the following applies to your site?** | [ ]  We plan to target non-English speakers.*Please note: If you plan to target non-English speakers, you are required to use a translated consent form. Please provide translated site-specific consent information sheet(s) after the English version has been approved.*[ ]  We do not plan to target, but may enroll a non-English speaker.[ ]   We will not enroll non-English speakers. |
| *[Add if study is approved for enrollment of non-English speakers and adjust the options based on whether the study allows for a short form process]* **If your site will not target, but may enroll a non-English speaker, please select one of the following options:** | ☐ We plan to use our site-approved short form. ☐ We plan to use the VCU IRB short form.☐ My site does not allow use of a short form. We plan to use a translated consent form. *Please provide translated site-specific consent information sheet(s) after the English version has been sIRB-approved.*☐ N/A – we will not target non-English speakers as indicated above. |

|  |  |
| --- | --- |
| *[Add if study is approved for enrollment of pregnant women]* **Will your site require pregnancy testing to verify eligibility for study participation?** | YES [ ]  NO [ ]  **If YES**, please include any language in your site-specific consent template. |
| *[Add if the protocol identifies plans for sharing data outside of the covered entity]* **Does your institution have any policies related to data security?** | YES [ ]  NO [ ]  **If YES**, please describe:Click or tap here to enter text. |
| *[Add if the protocol identifies plans for sharing data outside of the covered entity]* **Please confirm that the plans for data sharing as outlined in the protocol comply with your institutional requirements. If additional requirements [e.g., agreements, data security provisions, etc.] are required for your site, please provide a summary of these requirements with your response.** | Click or tap here to enter text. |
| *[Add if emancipated minors may be enrolled; males and females less than 18 who can consent for themselves as permitted by law.]* **Please identify any state law or local policy requirements pertaining to when a minor is emancipated and other requirements/conditions under which a minor can provide consent.** | Click or tap here to enter text. |
| *[Add if mandatory reporting is required]* **Please provide your institutional or state requirements for HIV testing and STI reporting and also provide the specific required consent language related to these requirements.** | Click or tap here to enter text. |
| *[Add if the Board* ***REQUIRES*** *physician consent]* **Please confirm that a physician will carry out the consent process for your site and name the physicians approved to consent for this study.** | Click or tap here to enter text. |
| *[Add if the Board indicates specific requirements for who may obtain consent for studies involving termination of pregnancy]* **Please describe your site’s plan to ensure that the individual(s) involved in obtaining consent for the study are distinct from any individual(s) involved in discussions regarding options for termination of the pregnancy.** | Click or tap here to enter text. |
| *[Add if the Board indicates specific requirements for who may determine viability of a neonate]***Please describe your site’s plan to ensure no member of the study team will play a role in determining the viability of the neonate.** | Click or tap here to enter text. |

**Appendix B: Annotated Bibliography of Virginia Law-Human Research**

Title 12. Health. Agency 5. Department of Health. Chapter 20. Regulations for the Conduct of Human Research.

**§ 12VAC5-20-40. Policy.**

<https://law.lis.virginia.gov/admincode/title12/agency5/chapter20/section40/>

Title 12. Health. Agency 5. Department of Health. Chapter 20. Regulations for the Conduct of Human Research.

**§ 12VAC5-20-100. Informed consent.**

<https://law.lis.virginia.gov/admincode/title12/agency5/chapter20/section100/>

Title 12. Health. Agency 5. Department of Health. Chapter 20. Regulations for the Conduct of Human Research.

**§ 12VAC5-20-110. Categories of human research exempt from regulation.**

<https://law.lis.virginia.gov/admincode/title12/agency5/chapter20/section110/>

Title 12. Health. Agency 5. Department of Health. Chapter 550. Board of Health Regulations Governing Vital Records. Part XII. Inspection of Records and Disclosure of Information.

**§ 12VAC5-550-480. Research requests.**

<https://law.lis.virginia.gov/admincode/title12/agency5/chapter550/section480/>

Title 12. Health. Agency. 35. Department of Behavioral Health and Developmental Services. Chapter 115. Regulations to Assure the Rights of Individuals Receiving Services from Provider Licenses, Funded, or Operated by the Department of Behavioral Health and Developmental Services. Part IV. Substitute Decision Making.

**§12VAC35-115-145. Determination of capacity to give consent or authorization.**

<https://law.lis.virginia.gov/admincode/title12/agency35/chapter115/section145/>

Title 22. Social Services. Agency 30. Department For Aging and Rehabilitative Services. Chapter 40. Protections of Participants in Human Research.

**§ 22VAC30-40-70. Elements of the HRRC's review process.**

<https://law.lis.virginia.gov/admincode/title22/agency30/chapter40/section70/>

Title 22. Social Services. Agency 30. Department For Aging And Rehabilitative Services. Chapter 40. Protections of Participants in Human Research.

**§ 22VAC30-40-80. Kinds of research exempt from committee review.**

<https://law.lis.virginia.gov/admincode/title22/agency30/chapter40/section80/>

Title 22. Social Services. Agency 30. Department For Aging And Rehabilitative Services. Chapter 40. Protections of Participants in Human Research.

**§ 22VAC30-40-90. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.**

<https://law.lis.virginia.gov/admincode/title22/agency30/chapter40/section90/>

Title 22. Social Services. Agency 30. Department For Aging And Rehabilitative Services. Chapter 40. Protections of Participants in Human Research.

**§ 22VAC30-40-100. Informed consent.**

<https://law.lis.virginia.gov/admincode/title22/agency30/chapter40/section100/>

Title 23.1. Institutions of Higher Education; Other Educational and Cultural Institutions. Subtitle I. General Provisions. Chapter 1. Definitions and General Provisions. Article 2. General Provisions.

**§ 23.1-107. Private institutions of higher education; human research review committees.**

<https://law.lis.virginia.gov/vacode/title23.1/chapter1/section23.1-107/>

Title 32.1. Health. Chapter 1. Administration Generally. Article 3. Department of Health and State Health Commissioner.

**§ 32.1-23. Publication of information.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter1/section32.1-23/>

Title 32.1. Health. Chapter 5. Regulation of Medical Care Facilities and Services. Article 1. Hospital and Nursing Licensure and Inspection.

**§ 32.1-127.1:03. Health records privacy.**

[https://law.lis.virginia.gov/vacode/title32.1/chapter5/section32.1-127.1:03/](https://law.lis.virginia.gov/vacode/title32.1/chapter5/section32.1-127.1%3A03/)

Title 32.1. Health. Chapter 5. Regulation of Medical Care Facilities and Services. Article 1. Hospital and Nursing Licensure and Inspection.

**§ 32.1-127. Regulations.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5/section32.1-127/>

Title 32.1. Health. Chapter 5.1. Human Research.

**§ 32.1-162.16. Definitions.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.16/>

Title 32.1. Health. Chapter 5.1. Human Research.

**§ 32.1-162.17. Exemptions.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.17/>

Title 32.1. Health. Chapter 5.1. Human Research.

**§ 32.1-162.18. Informed consent.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.18/>

Title 32.1. Health. Chapter 5.1. Human Research.

**§ 32.1-162.19. Human research review committees.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.19/>

Title 32.1. Health. Chapter 5.1. Human Research.

**§ 32.1-162.20. Applicability of federal policies.**

<https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.20/>

Title 53.1. Prisons and Other Methods of Correction. Chapter 2. Correctional Facilities. Article 2. Treatment and Privileges of Prisoners.

**§53.1-36. Prisoners may assist in medical research programs.**

<https://law.lis.virginia.gov/vacode/title53.1/chapter2/section53.1-36/>

Title 59.1. Trade and Commerce. Chapter 42.1. Uniform Electronic Transactions Act.

**§ 59.1-485. Legal recognition of electronic records, electronic signatures, and electronic contracts.**

<https://law.lis.virginia.gov/vacode/title59.1/chapter42.1/section59.1-485/>

Title 59.1. Trade and Commerce. Chapter 53. Consumer Data Protection Act.

**§ 59.1-582. (Effective January 1, 2023) Limitations.**

<https://law.lis.virginia.gov/vacode/title59.1/chapter53/section59.1-582/>

Additional Resources:

● [Commonwealth of Virginia Human Research Review Committee (HRRC)](https://www.dars.virginia.gov/hrrc/)

● [Commonwealth of Virginia Laws Relevant to Human Subjects Research and Informed Consent](https://www.dss.virginia.gov/files/about/irb/procedures_sections/irb_operations/Virginia_Laws_Human_Subjects_Research.pdf)

● [Commonwealth of Virginia The Research Informed Consent and HIPAA Authorization Process](https://www.va.gov/files/2022-04/Informed_consent_process.pdf)

**Appendix C: PI’s Post-Approval Responsibilities**

* Once approved as a site by the external IRB, update the study record in RAMS-IRB to provide the **current expiration date of research and upload the approval letter**.
* Keep a regulatory binder and maintain an active record of all submissions to the IRB of record.
* Submit any modifications to the VCU HRPP through RAMS-IRB that require local review. Examples of such changes include:
	+ Personnel changes
	+ Changes of PI
	+ Changes in conflicts of interest
	+ Changes for which there is a specific institutional policy/state law requirement (e.g., review by an ancillary committee)
	+ Changes to the consent form that require amendment to the sponsor protocol (e.g., Economic Considerations, In Case of Injury language sections in the consent form)
* Update the study record in RAMS-IRB with the new expiration date and approval of continuing review as issued by the external IRB.
* Promptly report to the VCU HRPP any determinations of serious or continuing noncompliance or Unanticipated Problems that may Involve Risks to Subjects or Others (UPIRSOs) that the external IRB made for the VCU site.
* Promptly report to the VCU HRPP any notifications of suspension or termination that you receive for the study from the external IRB.
* Update RAMS-IRB when the study was completed and closed by the IRB of record.