## **Virginia Site Specific Application for Relying on**

## **Virginia Commonwealth University’s (VCU) IRB**

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| The purpose of ***this form is for organizations located in the Commonwealth of Virginia*** to provide the VCU IRB with sufficient information on local context and institutional policies to serve as the Single IRB of Record for the below-referenced multi-site study. The relying site should complete this form and provide it to the VCU PI for submission to the VCU IRB. The relying site should indicate N/A in response to any questions that do not apply to the type of study being conducted.This form should be uploaded by the VCU PI into the RAMS-IRB study for which the reliance is being requested. |
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| **Protocol Information** |
| **VCU IRB #:** |  |
| **Title of Protocol:**  |  |
| **VCU PI:**  |       |
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| **VCU IRB Information** |
| **FWA #** | 00005287 |
| **IRB Contact:** | Stacy West / irbreliance@vcu.edu (804) 827-1446 |
| **Signatory Official:** | Dr. P. Srirama Rao / psrao@vcu.edu / (804) 827-2262 |
| **Signatory Official Address:** | Vice President for Research and InnovationVirginia Commonwealth University800 E. Leigh St., Suite 3000PO Box 980568Richmond, VA 23298 |
| **Relying Site Information** |
| **Institution:** |  |
| **FWA #:** |  |
| **IRB Contact / Email / Phone:**  |       |
| **PI Name:** |       |
| **PI Title:** |       |
| **PI Address:** |       |
| **PI Phone:** |       |
| **PI Email:** |       |
|  |  |
| **Site Study Team Contact Name:** |       |
| **Study Team Contact Phone:** |       |
| **Study Team Contact Email:** |       |
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| **Organizational Questions** |
| 1.Is the Site AAHRPP accredited? [ ]  Yes [ ]  No2. Has the site elected on its FWA to apply federal regulations only to federally funded research? [ ]  Yes [ ]  NoPlease note that VCU has extended its assurance to all research regardless of funding and will report all instances of unanticipated problems involving risk to subjects or others, serious or continuing noncompliance, terminations, and suspensions of research.3. State any other names by which the organization is known or does business and any corporate affiliations it has with other organizations, such as a university or hospital network.     If the organization is or is part of a network or system, describe which entities or sites within the system will conduct the research and how regulatory oversight is provided or structured within the system with respect to those entities/sites.     Do those other entities/sites operate under their own independent FWA(s)? [ ]  Yes [ ]  NoIf yes, each of those entities/sites will need to complete this form.4. Are there any governmental inquiries or investigations over the past three years **that may be material to the activities that would be conducted under the proposed IRB Authorization Agreement** for this study? Include research compliance problems (e.g., OHRP or FDA inquiries or investigations and corrective actions). Provide the status of such matters, including how they were resolved if applicable. [ ]  Yes [ ]  No      |
| **Local Context Issues** |
| 1. Are there any local, community or cultural issues that may be different for your population of subjects that require consideration?      2. Do you expect a large percentage of the potential research population to speak languages other than English? If so, please describe:     3. Does your site approve of the use of short forms for non-English speaking individuals? [ ]  Yes [ ]  NoIf yes, are there any limitations on the use of short forms (i.e., minimal risk research, # of uses, requirement to translate consent following use)? [ ]  Yes [ ]  No4. Are there any special characteristics of your institution or community of which the VCU IRB should be made aware? [ ]  Yes [ ]  NoIf Yes, Describe.     6. Is there anything described in the protocol that would not fall within the policies and practices of your institution that the VCU IRB needs to be aware of?     **Study Recruitment**7. If applicable to the current study, please describe the recruitment procedures that will be utilized for this study at your site.      **Studies with Minors**8. If applicable to the current study, please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining assent of children for participation in research.      **Studies with the Cognitively impaired**9. If applicable to the current study, please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity.      **Privacy and Confidentiality** 10. Describe how privacy of participants and confidentiality of data will be maintained at your site for this study.       |
| **Site Specific Informed Consent Requirements** |
| [ ]  Site IRB office has approved the local consent form(s) being submitted by the site PI[ ]  Site prefers to provide required consent language here.[ ]  A consent form is not needed for this site’s involvement in the study.If the site prefers to provide required consent language, provide the following information that should be inserted into the consent approved for the site.1. Site approved statement regarding compensation in the event of a research related injury.

     1. Any additional required information that must be included in an informed consent form.

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| **HIPAA Requirements** |
| 1. Will VCU serve as the Privacy Board for your site for this research study? [ ]  Yes [ ]  No [ ]  N/APlease note that if Yes, the VCU IRB will assume responsibility for approving waivers of authorization, partial waivers of authorization, and Authorization language if included in informed consent documents. All other HIPAA compliance functions remain the responsibility of the site.2. Your site prefers (select one):[ ]  HIPAA Authorization language included in consent form[ ]  Stand Alone HIPAA Authorization1. Does your site require specific HIPAA Authorization language? [ ]  Yes [ ]  No

If Yes:[ ]  Required language has been provided in the site consent form provided to the VCU IRB, or[ ]  Required language is provided as an attachment to this form  |
| **Ancillary Reviews** |
| Each relying site is responsible for obtaining any required local institutional ancillary reviews that apply to the conduct of this research protocol. Please list any ancillary reviews that the VCU IRB will need to review and consider for this protocol. |
| **Conflict of Interest**Each site is responsible for reviewing the protocol and determining whether a conflict of interest exists in accordance with the site’s institutional policies. It is the relying site’s responsibility to manage or eliminate any conflict. If a conflict is deemed to exist, the conflict and the management plan must be disclosed to the VCU IRB. The VCU IRB will have the final determination whether it is appropriate for the VCU IRB to assume IRB review responsibilities given any disclosure and management plan. The VCU IRB reserves the authority to grant final approval to the management plan as it relates to the conduct of this human subjects research. |
| 1. Does the protocol present any potential conflicts of interest as defined in the relying Site’s institutional policies? [ ]  Yes [ ]  No If Yes:  2. Please fully describe the conflict:       1. Please attach or describe the Management Plan including any language that should be in the consent document.

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| **Education / Training** |
| 1. Describe the organization’s human subject protection training and education requirements for researchers and study staff. Please include initial as well as continuing education requirements.

     1. The organization verifies that all personnel engaged in this research have completed the organization’s required human subject protection training. [ ]  Yes [ ]  No

If No, please explain.     1. If the study is a clinical trial and/or sponsored by NIH, describe the organization’s Good Clinical Practice training and education requirements for researchers and study staff. Please include initial as well as continuing education requirements.

     1. If the study is a clinical trial and/or sponsored by NIH, the organization verifies that all personnel engaged in this research have completed the organization’s required Good Clinical Practice training. [ ]  Yes [ ]  No

If No, please explain.      |
| **Principal Investigator Qualifications** |
| Please provide the Principal Investigator’s Curriculum Vitae.1. The site verifies that the PI is appropriately qualified to conduct this study and holds all of the necessary credentials and permissions. [ ]  Yes [ ]  No
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| **Other Information** |
| Please provide any other information relevant to the conduct of this study that you think the VCU IRB may need to know in order to fulfill its role as the Single IRB of Record for this study:      |

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| **Signature of Site PI** | **Date** |
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|  |  |
| **Signature of Relying Site IRB Contact** | **Date** |

Please indicate which of the following documentation are being submitted with this site application.

[ ]  Relying site specific informed consent document(s)

[ ]  Relying site specific assent document(s)

[ ]  Relying site specific recruitment materials

[ ]  Relying site HIPAA Authorization form (separate from consent form)

[ ]  Relying site PI curriculum vitae

[ ]  Relying site COI management plan