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| **Grant: Just In Time Information** |

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| **INSTRUCTIONS AND INFORMATION*** This form is to be submitted for a new grant proposal that will fund a new protocol that has not yet been approved by the IRB-HSR.
* Submit this completed form to the IRB-HSR at IRBHSR@virginia.edu when you have reason to believe your grant application/ proposal will be funded.
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| **Grant Title:**       |
| 1. | **Name of Sponsor/Funding Agency :**      Address:      City:       State:       Zip:      Phone:       Fax:       |
| 2. | **Will this grant proposal require a Certification from UVA for submission to NIH GWAS (Genome Wide Association Study) data repository (dbGaP)?**  | [ ]  Yes [ ]  No  |
| **IF YES**, complete and submit the [Genomic Data Sharing Submission Certification Form](https://research.virginia.edu/sites/vpr/files/2020-04/Genomic%20Data%20Sharing%20Submission%20Certification%20Request%20Form%204-23-20.doc)  with this form.  |
| **IF YES**, *If GWAS certification is required, the consent(s) used to collect the data must have already been approved by the IRB or be submitted to the IRB with this application.*  |
| 3. | **Do you certify the following:** * **All protocols to be funded by this grant will be consistent with the aims of this grant. [ ]** Yes **[ ]** No

**An IRB approval of all protocols to be funded by this grant will be obtained prior to the initiation of the human subject research?** **[ ]** Yes **[ ]** No |
| 4. | **To avoid any conflict of interest are any** [**IRB-HSR members**](https://research.virginia.edu/irb-hsr/board-membership-lists) **listed on the grant? If yes,** list names       | **[ ]** Yes **[ ]** No |

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| Principal Investigator of New Grant |
| First name:       | Last name:       | Degree:       |
| Phone:       | E-mail:       | Messenger Mail:       |
| Department:       | Division:       |
| Name of employer:      *Also attach the completed and signed Appendix A if the PI is not employed by UVA:* |

**Submitted by:**        **Date:**

**By entering your name above, you confirm the Principal Investigator of this planned grant has reviewed this information, attests to its accuracy and provides all certifications required on this form.**

**Appendix A: *ONLY required if Grant is being submitted by a non- UVA institution.***

 IRB Reliance Agreement for Grant

This agreement authorizes **Click here to enter Name of Relying Institution** to rely on the **University of Virginia IRB for Health Sciences Research (IRB-HSR)** for the review of the grant noted below.

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**University of Virginia (Reviewing IRB)**

**OHRP Federal Wide Assurance (FWA) #:** 00006183

**UVA IRB-HSR#/Tracking # of Reliance Agreement:** Click here to enter text.

**Click here to enter Name of Relying Institution** **(Relying Institution)**

**OHRP Federal Wide Assurance (FWA)** #:Click here to enter FWA #.

The Officials signing below agree that:

1) All human subject work will be done at the University of Virginia.

2) No HIPAA identifiers will be released to Relying Institution

3) Representatives of Relying Institution will also not have access to HIPAA identifiers during a monitoring visit.

4) Relying Institution confirms a written contract, negotiated through the UVA Grants and Contracts Office or the Office of Sponsored Programs, will be signed prior to any subject enrollment in a protocol under the oversight of the UVA IRB-HSR.

5) Relying Institution may rely on the University of Virginia IRB-HSR for education and review and continuing oversight of the human subject’s research described below:

**This agreement is limited to the following specific project:**

**Title of Grant:**

Name of Principal Investigator (Grant):

Sponsor or Funding Agency:       Award Number, if any:

Name/Email of UVA Grants & Contracts/ OSP personnel:       Email:

(whom you have submitted the Grant Proposal)

**Title of Research Protocol (if approved by UVA IRB-HSR)**

Name of Principal Investigator (Protocol):

IRB-HSR # /UVA Study Tracking #

**The following terms are agreed upon by all parties and attested to by signature below:**

1. The review performed by the University of Virginia will meet the human subject protection requirements of the Relying Institution’s OHRP-approved FWA.
2. The UVA IRB-HSR will follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution.
3. Relevant minutes of UVA IRB-HSR meetings will be made available to the Relying Institution upon request.
4. The Relying Institution remains responsible for ensuring compliance with their IRB’s determinations and with the Terms of its OHRP-approved FWA.

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The Officials signing below agree that **Click here to enter Name of Relying Institution** may rely on the **University of Virginia IRB for Health Sciences Research** under the terms of this agreement.

* This Agreement will become effective upon the date of the last signature below. The Agreement will remain in effect until such time that any institution provides a 30-day written notice of amendment or termination to the other institution.
* This document must be kept on file at both institutions and provided to the Department of Health and Human Services Office of Human Research Protections, upon request.

**University of Virginia Signatory Official**

*I agree and accept the responsibilities under this agreement as outlined above:*

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| **FWA Institutional Official (or designee) Signature:** |  | **Date**: |  |
| **Name**: |  Melur K. Ramasubramanian, PhD |  **Title:** | Vice President for Research |
| **Address**: | PO Box 400301136 Hospital Drive Charlottesville, VA 22904 |  **Phone**: | 434-924-8494 |

**University of Virginia Principal Investigator**

*I agree and accept the responsibilities under this agreement as outlined above:*

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| **PI Signature:** |  |  | **Date:** |  |
| **Name:** | Click here to enter text. | **Title:** | Click here to enter text. |
| **Address:** | Click here to enter text. | **Phone:** | Click here to enter text. |

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**Click here to enter Name of Relying Institution Signatory Official**

*I agree and accept the responsibilities under this agreement as outlined above:*

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| --- | --- | --- | --- | --- |
| **FWA Institutional Official (or designee) Signature:** |  |  | **Date**: |  |
| **Name:** | Click here to enter text. | **Title:** | Click here to enter text. |
| **Address:** | Click here to enter text. | **Phone:** | Click here to enter text. |
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