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| **VCU IRB study personnel roster**  (for Expedited and Full Board Research) | | | |
| **Principal Investigator:** |  | **vcu email:** |  |
| **Research Coordinator:** |  | **vcu email:** |  |
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| **STUDY PERSONNEL ROSTER INSTRUCTIONS:**  **▪ Definitions and detailed instructions for form completion and submission are located at the end of this form. Please review the instructions carefully before completing, revising, or submitting this form.** | | | | | | | | | | |
| **STUDY PERSONNEL ROSTER** | | | | | | | | | | |
|  | **First Name** | **Last Name** | **COI Investigator\*\*** | | **Non-VCU Affiliate - COI Policy Adherence (See Instructions)\*\*\*** | | **Role in Study -** (entry should match information on *Study Personnel Information and Change Form*) | | **Date Addition Proposed to IRB:** | **Date Removal Proposed to IRB:** |
|  |  |  | ***YES*** | ***NO*** | ***VCU Policy*** | ***Non-VCU Affiliate’s Institutional Policy*** |  | |  |  |
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**Roster Version Date:**  (*Insert updated version date)*

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| **STUDY PERSONNEL ROSTER – CONTINUATION PAGE (if needed)** | | | | | | | | | | |
|  | **First Name** | **Last Name** | **COI Investigator\*\*** | | **Non-VCU Affiliate - COI Policy Adherence (See Instructions)\*\*\*** | | **Role in Study -** (entry should match information on *Study Personnel Information and Change Form*) | | **Date Addition Proposed to IRB:** | **Date Removal Proposed to IRB:** |
| ***YES*** | ***NO*** | ***VCU Policy*** | ***Non-VCU Affiliate’s Institutional Policy*** |
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| **STUDY PERSONNEL ROSTER INSTRUCTIONS**  *(The following instructions do not need to be submitted to the IRB)*  ***GENERAL INSTRUCTIONS***   * The Personnel Roster is to list all VCU project personnel who are *engaged*\* in this research protocol (including the Principal Investigator), as well as all non-VCU affiliated individuals (affiliated with another institution/site) and Independent investigators (those with no institutional affiliation) who are also *engaged* but do **not** have IRB approval for this protocol from their own institution. For those non-VCU individuals who are affiliated with another institution/site but do not have IRB approval from their own institution, an IRB Authorization Agreement must be put in place if the study involves a **DIRECT FEDERAL AWARD** to VCU (or application for such) (see the VCU IRB Written Policies and Procedures (WPPs), #XVII-6; *Involving Non-VCU Institutions in VCU Human Subjects Research* at <http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm>). For independent investigators (not affiliated with VCU or another institution), an Independent Investigator Agreement must be put in place if the study involves a **DIRECT FEDERAL AWARD** to VCU (or application for such) (see WPP # XVII-15; *Involving Independent Investigators in VCU Human Research* at <http://www.research.vcu.edu/irb/wpp/flash/XVII-15.htm>). All non-VCU affiliates and Independent Investigators on the Personnel Roster must also meet the VCU IRB education requirements. If either Agreement is required, complete the appropriate template Agreement and include it with the IRB submission. * The Personnel Roster is to be kept current throughout the approval period with the IRB, and retained within the investigator’s study documentation. This roster is intended to serve as an ongoing list of all personnel currently engaged in the project, as well as those who have been, but are no longer, involved. A *Personnel Information and Change Form* is also required for each project personnel added to the study. If additional rows are needed on the Personnel Roster, please contact [ORSP@vcu.edu](mailto:ORSP@vcu.edu). * ***COI Investigator*\*\*** Designation and Requirements   + The VCU PI must designate in the *COI Investigator* column whether each individual is a *COI Investigator\*\** (see Definitions below).   + VCU Affiliate designated as a *COI Investigator*     - All reported financial interests (FI) and research relatedness, if relevant, must be up to date in the Activity and Interest Reporting System (AIRS).   + Non-VCU Affiliate designated as a *COI Investigator* –     - \*\*\* *Non-VCU Affiliate – COI Policy Adherence* column - The non-VCU institution/site must elect to adhere to one of the following Conflict of Interest policies that comply with 45 CFR Part 50, Subpart F, and must note the selection by checking the appropriate box in the *Non-VCU Affiliate – COI Policy Adherence* column of the Personnel Roster:       * **VCU Policy** – Non-VCU affiliate’s institution does not have an active and/or enforced conflict of interest policy and agrees to abide by Virginia Commonwealth University’s policy, Conflict of Interests in Research, located online at <http://www.assurance.vcu.edu/Policy%20Library/Conflict%20of%20Interests%20in%20Research%20-%20INTERIM.pdf>.       * **Non-VCU Affiliate’s Institutional Policy** - Non-VCU affiliate’s institution has an active and enforced conflict of interest policy that is consistent with the provision of 42 CFR Part 50, Subpart F “Responsibility of Applicants for Promoting Objectivity in Research”, and the non-VCU affiliate agrees to abide by this policy.     - If the institution elects to abide by the **VCU Policy**, the VCU PI and PI Department must ensure that all such *COI Investigators* are entered into the VCU Affiliate database. Instructions for creating affiliate relationships can be found here: <http://www.hr.vcu.edu/pdf_docs/AffiliateUserGuide.pdf>. Once the names have been entered and a VCU eID is issued for each, the individuals should be instructed to log in to the VCU eRA Activities and Interests Reporting System (AIRS) to complete training and enter their financial interests.   + Independent Investigator designated as a *COI Investigator* –     - The independent investigator must agree to abide by Virginia Commonwealth University’s policy, Conflict of Interests in Research, located online at <http://www.assurance.vcu.edu/Policy%20Library/Conflict%20of%20Interests%20in%20Research%20-%20INTERIM.pdf>. The VCU PI and PI Department must ensure that such *COI Investigators* who are independent investigators are entered into the VCU Affiliate database. Instructions for creating affiliate relationships can be found here: <http://www.hr.vcu.edu/pdf_docs/AffiliateUserGuide.pdf>. Once the names have been entered and a VCU eID is issued for each, the individuals should be instructed to log in to the VCU eRA Activities and Interests Reporting System (AIRS) to complete training and enter their financial interests.   + IRB approval cannot be granted until financial interest reports and a COI review are completed for all designated *COI Investigators*.   ***DEFINITIONS:***   * ***\*Engaged***- Any individual who interacts or intervenes with research participants, has access to identifiable private information about participants, and/or obtains the informed consent of research participants. (See OHRP’s guidance on “Engagement of Institutions in Research” at <http://www.hhs.gov/ohrp/policy/engage08.html>). * ***\*\*COI Investigator***– Any individual, regardless of title, role or position, who is **responsible** for the design, conduct, or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigator or subrecipient investigator, medical investigator, collaborator, consultant, student, trainee, or research coordinator. Exceptions include students or other personnel whose research activities are directly supervised. By considering an individual’s degree of independence relative to the research, the PI on the protocol designates those who meet the definition of COI Investigator.   ***SUBMISSION INSTRUCTIONS***  **Initial Review Submission:**   * At the time of Initial Review, submit **4 copies** of the following to ORSP, attached to the *Initial Review Submission Form* and accompanying documents:   + *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer)   + *VCU IRB Study Personnel Information and Change Forms* for all *engaged* project personnel   **Existing Studies Only (Phase-in of *COI Investigator* designation):**   * **NOTE:** Beginning with Continuing Review submissions received **on or after 10/1/12**, investigators must convert the existing Personnel Roster to the updated format which includes a *COI Investigator* designation (updated form contains an *IRB Template Rev. Date* header of 9/1/12 or later) and submit with the continuing review. The continuing review will not be approved until an updated *Personnel Roster* containing *COI Investigator* designations is on file and financial interest reports and COI reviews are completed for all designated *COI Investigators*. * If the list of personnel varies from the previously approved Personnel Roster (adding or removing personnel), also follow instructions below under *Adding or Removing Personnel.* * At the time of Continuing Review (during phase-in and subsequent continuing reviews), submit **4 copies** of the following to ORSP, attached to the Continuing Review Submission Form and accompanying documents:   + *VCU IRB Study Personnel Roster* listing all project personnel (footer version date should be updated to reflect changes)   **Adding or Removing Personnel:**   * All changes in research personnel must first be submitted to, and approved by, the IRB. * To add or remove personnel (including a change to the Principal Investigator and/or Medically Responsible Investigator), revise the *VCU IRB Study* *Personnel Roster* to note personnel who are being added and/or removed. Include an updated version date in footer. When removing personnel from a study, **do not** delete name(s) from this roster, but enter the date of removal in the appropriate column. * When updating the roster to add or remove personnel, also submit the appropriate *VCU IRB Study* *Personnel Information and Change Form(s)*. * A change to the Principal Investigator also requires (in addition to the Personnel documents noted above) submission of a *Change in Research Submission Form* and applicable amended documents (i.e. Protocol/Research Plan, ICF, etc). * For changes that involve Non-VCU sites – In addition to the *VCU IRB Study* *Personnel Roster* and *VCU IRB Study* *Personnel Information and Change Form*, personnel changes that involve non-VCU sites must also be addressed within the protocol/research plan (Section XIV. *Involvement of Non-VCU Institutions/Sites*). Changes to the protocol/research plan are to be submitted via a *Change in Research Submission Form*, along with any other applicable document(s). * If adding Independent Investigators, follow instructions for the addition of Independent Investigators available at http://www.research.vcu.edu/forms/vcuirb.htm. * To make changes to study personnel, submit **4 copies** of the following to ORSP:   + Revised *VCU IRB Study* *Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer). Also provide the most recent IRB-approved Personnel Roster.   + *VCU IRB Study* *Personnel Information and Change Form*(s), noting personnel who are being added and/or removed.   + Curriculum Vitae for addition of Principal Investigator, Medically Responsible Investigator, and/or Trainee (Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if trainee project).   + Additional applicable documents, as noted above, and per instructions |