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| **PERSONNEL CHANGE FORM** |
| **INSTRUCTIONS and INFORMATION: [See:](https://research.virginia.edu/irb-hsr/who-needs-be-listed-protocol-do-all-researchers-including-collaborators-need-be-listed-0)** [Who needs to be listed on the protocol?](https://research.virginia.edu/irb-hsr/who-needs-be-listed-protocol-do-all-researchers-including-collaborators-need-be-listed-0)* If NO revisions are needed to the protocol and/or consent(s), e-mail completed form to: IRBHSRadmin@virginia.edu. **Label EACH form with “Personnel Change Form\_DATE”**
* All study Personnel must have current human subject’s protection training[**(CITI)**](https://research.virginia.edu/irb-hsr/citi-training)**.**
* This form is NOT required if the individual being added works under the HIPAA covered entity and has NO access to identifiable information.
* **Do NOT submit this form for non-human subject determinations or non-engaged applications if personnel to be added are within the UVA HIPAA covered entity.**
* If applicable, check with sponsor re: which individuals listed on a 1572 form, Delegation of Duties Log must also be listed on the protocol.
* Personnel outside of UVA who will not have access to subjects or identifiable data do NOT need to be added to the personnel list of this protocol, however the study team must obtain a Non-funded Agreement from OSP or the SOM Office of Grants and Contracts prior to sharing the data/ specimens.
* Do not list Non-UVA faculty, staff, and/or students if **ALL** of the following apply:
	+ the individual is the PI at another site or is under the oversight of a PI at another site with which you have a contract,
	+ the study will be approved by their own IRB, ethics board etc. AND
	+ their institution has a Federal Wide Assurance (FWA) number.

**\*\*If Study involves a change of PI, or addition of Non UVA Personnel, submit this Personnel Change form** *to:* *irbhsr-mods@virginia.edu* along with a completed [Modification Request Form](https://research.virginia.edu/sites/vpr/files/2020-10/Modification%20Request%20Form_10-01-20.docx). |

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| **SECTION I: List IRB-HSR#’s/ UVA Study Tracking#/Non-UVA Tracking#** |

[ ]  **IRB-HSR#**

[ ]  **UVA Tracking#**

[ ]  ***Non-UVA IRB is serving as the IRB of record***

 ***(eg. WIRB, Advarra, outside academic) [Tracking #]***

**Does this Personnel Change require any additional changes to the study and/or consent OR a change in PI?** [ ]  YES [ ]  NO

 If yes, Submit this **Personnel Change form** along with the [**Modification request Form**](https://research.virginia.edu/sites/vpr/files/2020-10/Modification%20Request%20Form_10-01-20.docx) to: irbhsr-mods@virginia.edu

**DO you confirm the person submitting this Personnel Change form is a CURRENT member of the study team?** [ ]  YES

**Note:** *This form MUST be completed by a person(s) who is already listed with the IRB-HSR on this protocol.*

**Do you confirm the PI is aware of this change?** [ ]  Yes [ ]  No

 **SECTION II: DELETIONS (add more rows as necessary)**

*NOTE: All individuals leaving UVA are strongly encouraged to use the* [*Exit Checklist*](https://provost.virginia.edu/system/files/documents/Faculty-Departure-Checklist-2015_508.pdf) *A person is considered to have left UVA if the person is transitioning to Emeritus Status, is no longer in a paid position at UVA or a student, resident or fellow who has completed their training. If a person who is leaving UVA will continue to work on a study, the protocol must be modified, and a Material Transfer Agreement signed prior to sharing any data with the departing researcher.*

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| **Last Name**       | **First Name**       | **M. Int**         | **UVA ID**       | **Position#**       |
|  |  |  |  |  |
| **Last Name**       | **First Name**       | **M. Int**  | **UVA ID**       | **Position#**       |
| **Last Name**       | **First Name**       | **M. Int**        | **UVA ID**        | **Position#**       |

***NOTE:*** *Only the PI, Study Coordinator I, II, IRB Coordinator and Department Contact will receive emails including continuation status reports from the IRB-HSR.*

**Which position do you want them DELETED from? [ADD POSITION # ABOVE]**

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| --- | --- |
| 1. Study Coordinator I
 | **6.** Study Coordinator II |
| 1. Study Coordinator I (to be removed as contact for website advertisement)
 | **7.** Study Coordinator II (to be removed as contact for website advertisement) |
| 1. Additional Study Coordinator
 | **8.** Sub-investigator |
| 1. IRB Coordinator
 | **9.** Department Contact |
| 1. Principal Investigator
 | **10. \*see below\*** |

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| **10. [ ]  Principal Investigator: Leaving UVA**I confirm that the PI being removed is aware of the following:1. I should use the [Exit Checklist.](https://provost.virginia.edu/system/files/documents/Faculty-Departure-Checklist-2015_508.pdf)
2. Original study files are considered institutional records and may not be transferred. I am to notify my department administration regarding where the originals will be kept at UVA.
3. No data/health information or specimens may be taken from UVA without a signed Material Transfer Agreement (MTA) between OSP/SOM Grants and Contracts Office and the new institution. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVA. It will also approve which HIPAA identifiers may be taken outside of UVA with the health information or specimens.
4. I must have IRB or Privacy Board approval from my new institution for any research data / identifiable\*\* protected health information or specimens I plan to transfer. Once I have IRB or Privacy Board approva,l I will submit this document to the School of Medicine Grants and Contracts Office or to the Office of Sponsored Programs (OSP) if I am not in the School of Medicine. Nothing will be transferred until the MTA is signed by both parties. During transfer, any electronic data with identifiable protected health information (PHI) will be encrypted and any non electronic PHI/ specimens will be securely maintained against theft or loss. **NOTE: Any identifiable health information or specimens collected without consent will NOT be allowed to leave UVA.**
5. A HIPAA Data Use Agreement will be incorporated into the Material Transfer Agreement to cover any health information I am taking with me that meet the criteria of a Limited Data Set\*\* under HIPAA regulations. If I am taking a Limited Data Set with me, I may not also take a key to the code that would allow me to re-identify the subject. If I have a limited data set to transfer, I will submit it to the Clinical Data Repository (CDR). They will review it to confirm it meets the criteria of a Limited Data Set under HIPAA regulations. The CDR will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the Material Transfer Agreement being signed.
6. If I have health information that is de-identified\*\* under HIPAA I will submit the file to the Clinical Data Repository (CDR). They will review it to confirm it meets the criteria of de-identified under HIPAA regulations. The CDR will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the Material Transfer Agreement being signed.

***\*\* If you are unsure if the health information in your files is identifiable, limited data set or de-identified- submit the file to the CDR for their review.***  |

**If any deleted personnel are a contact for an online ad for UVA Health System, list name and contact information of new contact for online Advertisement:** [ ]  N/A Yes,

**Do you confirm that personnel remaining on this study have the expertise to conduct this study?** [ ]  Yes [ ]  No

**SECTION III: ADDITIONS: (add more rows as necessary)**

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| **UVA ID**       | **Last Name**       | **First Name**       | **M. Int:**       | **Box #**       | **Position#**       |
| Phone#       | UVA Email       | School       | Dept       | DIV       |
|  |  |  |  |  |  |
| **UVA ID**       | **Last Name**       | **First Name**       | **M. Int:**       | **Box #**       | **Position#**      |
| Tel #       | UVA Email       | School       | Dept       | DIV       |
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\* ***Only one person is allowed in positions other than sub-investigator or additional study coordinator. If you add new personnel to a position for which someone is already listed, the person currently in the position will automatically be removed! Only those individuals listed as PI, Study Coordinator I or II, IRB Coordinator or Department Contact will receive emails including continuation status reports.***

**Which position do you want them ADDED to? [ADD POSITION # ABOVE]**

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| 1. Study Coordinator I
 | **6.** Study Coordinator II Add as new contact for website advertisement. Only one SC allowed as contact for website advertisement*Add as new contact for website advertisement. NOTE: Only one SC allowed as contact for website advertisement* |
| 1. Study Coordinator I Add as new contact for website advertisement. Only one SC allowed as contact for website advertisement. *Note to staff- update contact in IRB Online and in text of website advertisement.*
 | **7.** Study Coordinator II (to be removed as contact for website advertisement) |
| 1. Additional Study Coordinator
 | **8.** Sub-investigator |
| 1. IRB Coordinator
 | **9.** Department Contact*Note: this person may not have access to subjects or their identifiable data. If this person requires such access they should be added in a different position.* |
| 1. Principal Investigator: **Submit Personnel Change form to** irbhsr-mods@virginia.edu

*Note: ONLY individuals who are paid by UVA or who are Emeritus and have a research appointment (paid or unpaid) may serve as a PI. Visiting professors, Morrison’s and students may NOT serve as PI.* *Students may be allowed to be the PI on Exempt Applications. Contact the IRB-HSR staff to discuss this option.*  |

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| **Additional Criteria for Added Personnel** |
| **Do you confirm that this person(s) has current training in Human Subject Research Protection?** *If an individual is not an employee of UVA, you may attach proof of Human Subject Research Protection training from their home institution.* | [ ]  Yes [ ]  No |
| **Does the person(s) being added, their spouse, or dependent children, have a significant financial interest (SFI) that reasonably could be considered related to the scope of this protocol?** *If YES, a modification must be submitted with this personnel change to:**irbhsr-mods@virginia.edu***Has the COI Committee provided a COI Management Plan?** *If yes, include the Plan with the modification submission.*  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Will the person(s) being added have access to patients in the UVA Health System or their identifiable health information?**  | [ ]  Yes [ ]  No |
| **Is this person(s) a student outside of the UVA HIPAA Covered Entity (e.g. not a medical, nursing student)?** **If YES, will the student work on this project within the UVA HIPAA Covered Entity?** **If YES, have they completed the medical center orientation or the most recent annual retraining?** *If No, person must obtain approval as a volunteer*  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Is this person(s) a student within the UVA HIPAA Covered Entity (e.g. UVA Nursing or Medical Student) OR a non-UVA student who is employed by UVA Health?***If YES, no additional requirements are needed.* **If NO, is this person a UVA student who will receive class credit for working on this research?**  **If YES, will the student work on this project within the UVA HIPAA Covered Entity?** **If YES, have they completed the medical center orientation or the most recent annual retraining?****If this person has not completed the medical center orientation, do you confirm that you have obtained approval from the VPR office for this person to work on the research?** *To obtain approval complete the* [*Volunteer in Research Form- Non SOM*](https://research.virginia.edu/media/5021) | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Is this person a Professor Emeritus with a research appointment?** *If YES, attach departmental appointment letter.* *IMPORTANT: This letter is different from the letter acknowledging Emeritus Status***If this person IS NOT a student or Professor Emeritus is this person in a paid position at UVA?****The following personnel types are considered to NOT be in a paid position at UVA:**UVA Encompass Health (formerly UVA HealthSouth), Culpeper Community Hospital or nutrition services employees, Visiting Professor **If NO, do you confirm that you have obtained approval from SOM for this person to work on the research?** *To obtain approval complete the* [*SOM Volunteer in Research Form*](https://med.virginia.edu/office-for-research/wp-content/uploads/sites/279/2019/07/volunteers-in-research-labs-form-071119B.pdf) ***If NO:*** *A signed HIPAA Authorization must be obtained from any UVA patient who is observed receiving medical evaluation/treatment for the purpose of research, by any individual who is not a volunteer approved by the School of Medicine, a student or employee of the UVA HIPAA covered entity. The HIPAA Authorization form may be obtained from the UVA Health System.*  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Does this study involve the use of a laser outside of clinical care?** (for questions contact the Clinical Staff Office)**If YES, will this person be applying laser energy to the subject?** **If YES, has this person been granted privileges in the use of this specific laser? (must be yes)** | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Do all personnel being added fit into one of the following criteria?** * Individuals are not working in the HIPAA Covered Entity and will have no access to health information from the HIPAA Covered Entity.
* Volunteers approved through the School of Medicine and working in the HIPAA Covered Entity
* Non-SOM volunteers approved through the VPR office
* UVA faculty, Professor Emeritus with research appointment (paid or unpaid), employees or students of the UVA HIPAA covered entity\*

*\*The UVA HIPAA covered entity is composed of the UVA VP Office of Research, the Health System, School of Medicine including the Sheila C. Johnson Center & the Exercise and Sports Injury Laboratory and the Exercise Physiology Core Laboratory, School of Nursing, Morrison’s Nutrition Services, Center for Survey Research.****If NO, the personnel change must be submitted as a Modification.*** ***Send the following documents to*** *irbhsr-mods@virginia.edu* *for pre-review.* * + Personnel Change Form
	+ [Unaffiliated Investigator's Agreement](https://research.virginia.edu/sites/vpr/files/2019-08/Unaffiliated_Investigator_Agreement.doc) signed by each person listed on the study who is not affiliated with UVA and a current completion form for Human Subject Protection Training.
	+ Study- with the “Non-UVA Personnel” section in the current study inserted and or revised.

*NOTE: If the subjects are NOT signing a consent form to participate in this study, the study team will also be required to Track this disclosure in EPIC.*  | [ ]  Yes [ ]  No |

**IRB-HSR is the IRB of record for this study**

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| **This Personnel Change form is approved by the IRB-HSR as a Modification and is available in IRB PRO****IRB Staff Name:       Date:** |

**IRB-HSR is *NOT* the IRB of record for this study**

**This Personnel Change form has been received by the IRB-HSR and is available in IRB Pro.**

[**Receipt Acknowledgment Standing Letter**](https://research.virginia.edu/sites/vpr/files/2019-10/Receipt%20Acknowledgement%20Standing%20Letter.docx)