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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)* **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 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.
* 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.
* If adding a person, please include UVA ID using all capital letters to eliminate data entry errors.
* 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, addition of Non-UVA Personnel, addition of an Emeritus Professor or addition of an individual who will apply a laser to a human subject 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***

 ***(e.g. WCG, 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 l Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. The 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 approval 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 transfer agreement 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 in an identifiable manner.**
5. A HIPAA Data Use Agreement will be incorporated into thel 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 Enterprise Data Warehouse (EDW) ). They will review it to confirm it meets the criteria of a Limited Data Set under HIPAA regulations. The EDW will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the Transfer Agreement being signed.
6. If I have health information that is de-identified\*\* under HIPAA I will submit the file to the EDW). They will review it to confirm it meets the criteria of de-identified under HIPAA regulations. The EDW will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the 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 EDW for their review.***  |

**If any deleted personnel are a contact for an online ad for UVA Health , 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 (ALL CAPS)**       | **Last Name**       | **First Name**       | **M. Int:**       | **Box #**       | **Position#**       |
| Phone#       | UVA Email       | School       | Dept       | DIV       |
|  |  |  |  |  |  |
| **UVA ID (ALL CAPS)**        | **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 must submit 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 to the application and (if applicable) consent form must be submitted with this personnel change form to:**irbhsr-mods@virginia.edu***Has the COI Committee provided a COI Management Plan?** *If yes, include the Plan with this submission.*  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Will the person(s) being added have access to patients in UVA Health or their identifiable health information?** **If Yes, does the person(s) being added fit into at least one of the following roles?*** UVA student in the School of Medicine (SOM) or School of Nursing (SON)
* Approved volunteer through the School of Medicine
* Professor Emeritus with a paid or unpaid appointment in the SOM or SON
* Employee of UVA Health\*,

**\*The following personnel types are considered to NOT be an employee of UVA Health:**UVA Encompass Health (formerly UVA HealthSouth), Culpeper Community Hospital or nutrition services employees, Visiting Professor ***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 an individual not in a role noted above. The HIPAA Authorization form may be obtained from UVA Health.*  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Do any of the individuals be added meet the criteria of a “volunteer” as defined in the** [**UVA Policy: HRM-001 Authorization and Engagement of Volunteers**](https://uvapolicy.virginia.edu/policy/HRM-001)**?****If YES, do you confirm you will follow the** [UVA Policy: HRM-001 Authorization and Engagement of Volunteers](https://uvapolicy.virginia.edu/policy/HRM-001)**?****Will any of the volunteers observe or assist in research within the UVA School of Medicine (SOM)?****If YES, do you confirm you will follow the** [**SOM Policy, Volunteers in Research**](https://med.virginia.edu/policies/volunteers-in-research/)**?**  | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| **Are any of the person(s) being added a Professor Emeritus with a research appointment?**  *If YES, a modification to the Study Application must be submitted with this personnel change form to:**irbhsr-mods@virginia.edu* *and include the departmental appointment letter.**IMPORTANT: This letter is different from the letter acknowledging Emeritus Status and is usually valid for one year.*  | [ ]  Yes [ ]  No |
| **Does this study involve the use of a laser applied to a subject 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 person(s) being added fit into one of the following criteria?** * **UVA faculty, employees or students**
* **Volunteers approved through the School of Medicine**
* **Volunteers working outside of the School of Medicine and approved per the UVA Policy:** [**Authorization and Engagement of Volunteers (HRM001)**](https://uvapolicy.virginia.edu/policy/HRM-001#Volunteers_in_Research)
* **UVA Professor Emeritus with research appointment (paid or unpaid)**
 | [ ]  Yes [ ]  No |
| **Do you confirm that:*** **this is not a change in PI**
* **no person(s) being added have a financial conflict of interest**
* **no person being added is a Professor Emeritus**
* **the study does not involve the use of laser outside of clinical care.**

**If NO, this personnel change must be submitted as a Modification.** **Send the following documents to** **irbhsr-mods@virginia.edu** **for pre-review.** * + **Personnel Change Form (this 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 Application with the “Non-UVA Personnel” section inserted or revised.**
 | [ ]  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)