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| **NON-UVA IRB MODIFICATION REQUEST FORM** |
|  **STUDY INFORMATION** |
| **IRB-HSR Tracking #:** Click or tap here to enter text.**PI Name:**Click or tap here to enter text. | **Submitter Name:** Click or tap here to enter text.**Date Completed:** Click or tap here to enter text. |

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| **Changes made in response to an audit:** |
|  | [ ]  Yes | [ ]  No | **Is this modification a response to requested revisions following an audit?** **If YES**, include a copy of the audit report with this submission.Summarize ALL outstanding issues:Click or tap here to enter text.Summarize the issues *addressed in this modification*:Click or tap here to enter text. |
| **Changes made to the UVA study PI:** |
|  | [ ]  Yes | [ ]  No | **Are you changing the study PI at UVA?** **If YES**, **submit the following documents:** * **New PI’s current HSR CITI Basic Researcher training certificate.**
	+ Include the new PI’s GCP training certificate if required by the Sponsor of if the study is more than minimal risk.
* **Revised Non-UVA IRB Application with new Investigator Experience Section.**

Provide the **new PI’s** **name and credentials**:Click or tap here to enter text.Provide the **new PI’s computing ID**:Click or tap here to enter text.Explain **the reason** for the PI change:Click or tap here to enter text.**Do you confirm that the NEW PI has adequate material resources (including space, equipment, and personnel) for conducting the study?** [ ]  ***YES****, I affirm that the new PI has adequate material resources to conduct this study.***Do you confirm that the NEW PI has adequate financial resources (funding) to conduct the study?**[ ]  ***YES****, I affirm that the new PI has adequate financial resources to conduct this study.*Provide details about the current funding sources:Click or tap here to enter text.**Will the former PI remain on the study?**  [ ]  Yes [ ]  No**If YES**, indicate their new position (e.g., sub-investigator, study coordinator):Click or tap here to enter text. |
| **Changes made to the Non-UVA IRB Application:** |
|  | [ ]  Yes | [ ]  No | **Are you revising the Non-UVA IRB Application for either:** 1. Compensation/Recruitment?
2. Recruitment updates that require a new HIPAA waiver? \*
3. Changes related to the Data Security Plan

**If YES, complete the following:** * **Submit a TRACKED CHANGES copy of the revised Non-UVA Application.**
* **Fill in the text box below:**

Provide a bullet list of the changes with the rationale for the changes being made:Click or tap here to enter text.\* Only answer yes to item 2 if UVA serves as the HIPAA Privacy Board **and** you intend to add “Contacting potential participants by a person who is not a member of their healthcare team” as a method of recruitment. |
| **Changes made to the Data Security Plan:** |
|  | [ ]  Yes | [ ]  No | **Do you have changes to how data is collected, transferred, or stored that impact the Data Security Plan (DSP)?** **If yes, complete the following:** * Submit a TRACKED CHANGES copy of the revised DSP.
* Fill in the text box below:

Provide a bullet list of the changes with the rationale for the changes being made: Click or tap here to enter text.**If the changes to the DSP have an impact on the Non-UVA IRB Application, modify it to account for the change and submit the tracked changes version for our review (Question 3).**  |