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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).** |