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| Protocol Closure Form  University of Virginia IRB for Health Sciences Research |

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| **INSTRUCTIONS AND INFORMATION**  **Do not submit this form** for projects determined to meet the criteria of: **coded, non-human subject research, exempt** **from federal regulations or non-engaged in human subject research.**  *The Protocol Closure Form should be submitted to the IRB-HSR for protocols when all the following apply:*   * + All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing)   + All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained)   + No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary)   + Analysis of subject identifiable data, records, specimens are complete (i.e., use or access to subject identifiable data is no longer necessary: this includes review of source documents by study sponsors) or UVA PI is leaving UVA. See question #6 for additional information. * **Forms should be submitted electronically to** [**IRBHSRcontinuations@virginia.edu**](mailto:IRBHSRcontinuations@virginia.edu) * The closure event will be documented in IRB Online. The Protocol Closure Form will be on file and available for download in IRB Pro. * Questions on this form pertain only to subjects enrolled under the UVA protocol (Not other sites) unless the IRB-HSR is the IRB of Record for all sites in the study. * For questions regarding how long one must keep records, see [Record Retention Requirements](https://recordsmanagement.virginia.edu/records-retention/overview)   *IMPORTANT:*   * If this study involved specimen banking and you intend to keep the specimens after this study is closed, you need to have a separate protocol called a “Database Protocol” to keep these specimens. If you do not have an IRB approved Database Protocol the specimens must be destroyed now. * If you will be using any of the data in future research, a “Database Protocol” may be required to store the data. See question #10 for additional information. * The data and specimens from this or multiple studies may be stored under a single “Database Protocol” with the IRB. |

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| IRB-HSR/UVA Study Tracking #: | PI Name: |
| Title: | |

**Do you confirm the PI is aware of this protocol closure and has reviewed and approved this report?**  Yes  No

**Submitted by:**

Name:       Email Address:

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| 1. | **Enrollment: Were any “subjects” enrolled?**  *Answer this question YES if anyone signed a consent form.*  *If you were only using data and or specimens without a consent form, answer this question YES if you used any data and/ or specimens for this study.* | Yes No |
|  | **IF YES,**   * Total number of subjects enrolled (signed consent)/# of specimens or # of charts reviewed under this UVA protocol   Have subjects completed required follow-up visits per protocol?  **If No**, have arrangements been made for these subjects to obtain follow-up at another institution?  *If no, make arrangements for follow-up, and then close the study.* | Yes No NA  Yes No |
|  | **SINCE THE LAST CONTINUATION, how many enrolled were adults and how many were children?\***  (\*children-less than 18 years of age at time they were enrolled) | **Adult**:  **Children:** |
|  | **IF NO,**  Did you have access to any health information to identify or contact potential subjects for this study (e.g. did you look at medical records and or talk to any potential subject for the purpose of enrolling in this study)?  *The IRB-HSR office uses this information only to determine how long we must keep records after this protocol is closed.* | Yes No |

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| 2. | **If this is sponsored trial, do you confirm you have had your study close out visit?** | Yes No  N/A |

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| 3. | **If UVA is the Data Coordinating Center or the IRB-HSR is the IRB of Record for all sites in the study do you confirm that all sites have closed this study?** | Yes No  N/A |

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| 4. | **Have you had an audit by an outside agency since the last review?**  **If Yes,** attach a copy of the audit findings and any corrective actions that have been implemented as a result of this audit.  *Note: Routine monitoring by the sponsor or their representative does not constitute an audit unless it generates an official written response from the sponsor.* | Yes No |

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| 5. | **Have you had any subjects withdraw or had any complaints since the last review?** If YES, summarize: **.** | Yes No |

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| 6. | **Briefly summarize any recent published literature regarding this study.**  *If there are no recent publications- state "NA- No recent publications.* |

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| 7. | **Why is this study being closed? (*check one*)**  Database protocol- data/specimens no longer needed and have been destroyed or de-identified per HIPAA regulations.  Contract never finalized  Data analysis complete  Protocol has an outside sponsor, queries completed, sponsor has closed this site  No funding, time, personnel to do the study  Other; *Explain*:  PI moving to another institution. I confirm I am aware of the following:   1. I should use the Exit Checklist found on IRB-HSR website at https://provost.virginia.edu/system/files/documents/Faculty-Departure-Checklist-2015\_508.pdf 2. I should follow info on Information Technology Services website at http://its.virginia.edu/guides/chklist.html 3. 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. 4. No data/health information or specimens may be taken from UVA without a signedTransfer 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. 5. 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 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.** 6. A HIPAA Data Use Agreement will be incorporated into the Data 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 IS Decision Support office ( [researchdata@hscmail.mcc.virginia.edu](mailto:researchdata@hscmail.mcc.virginia.edu)) . They will review it to confirm it meets the criteria of a Limited Data Set under HIPAA regulations. The IS Decision Support office will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the Data Transfer Agreement being signed. 7. If I have health information that is de-identified\*\* under HIPAA I will submit the file to the IS Decision Support office ( [researchdata@hscmail.mcc.virginia.edu](mailto:researchdata@hscmail.mcc.virginia.edu)) . They will review it to confirm it meets the criteria of de-identified under HIPAA regulations. The IS Decision Support office will provide OSP/ SOM Grants and Contracts office with this confirmation prior to the Data 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 IS Decision Support office for their review.*** |

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| 8. | **Did this study involve a gadolinium enhanced MRI/MRA?**  **If Yes**, did any of the subjects receive the MRI/MRA after July of 2005?  **If Yes**, have these subjects been given the information regarding the risk of NSF with gadolinium-enhanced MRI/MRA in either the consent or the consent addendum?  ***If No,*** *contact the IRB-HSR office regarding steps that must be taken before this study can be closed.* | | Yes No  Yes No  N/A  Yes No  N/A |
| 9. | Did the results support or disprove your original hypotheses? Comments (*You may provide any additional information to further explain the box checked to the right*.) | NA- No subjects enrolled  NA- Database protocol  *Do not check if protocol has a hypothesis.*  NA- Study not yet complete- transferring to new institution  NA- Study not completed.  Results supported the hypothesis  Results did not support the hypothesis  Results are not conclusive  Sponsor continues with analysis and results are not available at this time. *This response is only applicable if the study has a sponsor outside of UVA.* | |
| 10. | **What will be done with the data from this study after it is closed? *Choose all applicable options***  No data from this study will be used in future research.  Data will be stored per sponsor’s requirements *(if applicable*), [IRB-HSR Record Retention Requirements](https://recordsmanagement.virginia.edu/records-retention/overview) and [UVA Records Management Policies.](https://recordsmanagement.virginia.edu/)  Data from this study will be used in future research.  Data will be stored per sponsor’s requirements *(if applicable*), [IRB-HSR Record Retention Requirements](https://recordsmanagement.virginia.edu/records-retention/overview) and [UVA Records Management Policies.](https://recordsmanagement.virginia.edu/records-retention/overview)  Data from this study that has NOT been de-identified will be retained under Database Protocol IRB-HSR #       for use in future research. (requires that the initial study obtained consent for future research, the database study will obtain consent or the database study and subsequent research will be conducted under a Waiver of Consent/ HIPAA Authorization)  OR  Data from this study that has been de-identified (contains no HIPAA identifiers) will be retained and used for future research. No consent is required and no additional IRB approval is required. See [Determination of Human Subject Research Form.](https://research.virginia.edu/sites/vpr/files/2020-04/Determination_of_Human_Subjects_Research%204-7-20_0.doc)  For Database Protocols ONLY: All data has been destroyed or de-identified per HIPAA regulations (e.g. no HIPAA identifiers kept).  *Do not check this option if the protocol has a hypothesis. Check one of the other options.*  Copies of data will be taken with PI to new institution- see information above in # 7. | | |

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| 11. | **What will be done with any specimens collected during this study?**  ***Choose one option below:***  NA- no specimens collected  Specimens will be kept long term with HIPAA identifiers at UVA under a database protocol IRB-HSR #      .  *This closure form cannot be processed until you provide the IRB-HSR number.*  Specimens will be stored long term at new institution of PI. They will not be moved until a Transfer Agreement is signed.  All specimens have been sent to sponsor per protocol  Specimens have been destroyed or de-identified (No HIPAA identifiers kept)  **Additional Comments** |