|  |  |  |  |
| --- | --- | --- | --- |
| **MODIFICATION REQUEST FORM** | | | |
| * **CHECK IRB Pro for current versions of ALL documents prior to making revisions.** * Send documents to the IRB-HSR using [**SUBMIT DOCUMENTS** button in **IRB PRO**](https://research.virginia.edu/irb-hsr/irb-pro) * Revisions need to be **tracked from the currently approved protocol/application/ consent(s)/supporting documents**. * [Definitions and Reporting guidelines for Modifications](https://research.virginia.edu/irb-hsr/modifications-amendmentsrevisions-currently-approved-research) * This **modification request form** must be submitted as a **word document.** | | | |
| IRB-HSR/UVA Study Tracking #:       PI Name:  **Submitted by:** **Date:**  **Do you confirm that the PI approves the changes being submitted?** **Yes**  **No** | | | |
| Minor Changes/Minimal Risk  **OR** | | | |
| Significant Changes/Greater than minimal risk (full board review required)   * Changes to Inclusion/Exclusion Criteria * Additional new risk(s) added * Changes to Study Design/study plan and/or statistical plan | | | |
|  | | | |
|  |  |  | **GENERAL** |
| 1. | Yes | No | **Are you changing the study status with this modification?**  ***If YES****, follow one of the following processes:*   * *If you are changing the status with a modification that requires additional changes, complete both the Modification Request Form AND the Status Change Form via IRB PRO-Submit Documents-Modifications* * *If you are only changing the status without other modifications, complete and submit ONLY the* [*Status Change Form*](https://research.virginia.edu/sites/vpr/files/2020-04/Status%20Change%20Form.doc) *via IRB PRO-Submit Documents-Continuations*. |
| 2. | Yes | No | **Has the funding for the study changed?**  ***If YES****, list new sponsor/funding source:*  *List funding sources being removed:*  *If new funding is from a grant, list IRB-HSR grant # (if applicable):*  *Do you certify that this study is consistent with the aims of the grant?*  ***Yes*** ***No*** |
| 3. | Yes | No | **Is this modification a response to requested revisions following a Post Approval Monitoring (PAM) audit?**  ***If YES****, include a COPY of the PAM report AND address ALL outstanding PAM issues with this modification.* |
|  |  |  | **STUDY PERSONNEL** |
| 4. | Yes | No | **Are you changing the PI on this study? NEW PI NAME:       UVA Computing ID:**  ***If YES****, include the following documents with this modification if UVA IRB-HSR is the IRB of Record:*   * *Modification request form (this form).* * *Current CITI training certificate of new PI and if Full Board study, GCP training certificate.* * *Revised IRB Protocol/Application/Non-UVA IRB Application with new PI background information.* * *Revised Consent documents with New PI contact information (only if UVA IRB is the IRB of Record).* * *If applicable, you may need to complete and submit the “*[*Change in PI Letter*](https://research.virginia.edu/sites/vpr/files/2022-08/ChangeinPILetter080822.docx)*” (only if UVA IRB is the IRB of Record and you are NOT reconsenting subjects).*   **Will the former PI remain on the study?**   Yes  No  ***If YES****, in what position: (indicate)*  Sub-Investigator  Study Coordinator  Other (role)  **Explain the reason for the PI change:**  **Do you confirm that the NEW PI has adequate resources (including space, equipment, and personnel) for conducting the study?**  Yes    **Do you confirm that the NEW PI has adequate financial resources (funding) to conduct this study?**   Yes  ***If YES,*** *provide details of current funding source(s):* |
| 5. | Yes | No | **Are you adding personnel who are NOT affiliated with UVA?**  ***If YES****, include the following documents with this modification:*   * *Submit a copy of their UVA CITI Basic Researcher Training documentation.* * *A signed* [*unaffiliated investigator agreement*](https://research.virginia.edu/sites/vpr/files/2020-04/Unaffiliated%20Investigator%20Agreement%204-27-20.doc). * *Complete the* [*Appendix: Non- UVA Personnel section*](https://www.irb.virginia.edu/Template_Sections/HIC_Application/personnel_non_uva_with_application_A.doc) and add *to the very end of the application or protocol.* |
|  |  |  | **SUBJECTS** |
| 6. | Yes | No | **Are you revising the UVA** **enrollment # OR if the UVA IRB is serving as the IRB of record for a multisite study, revising the overall enrollment #? *NOTE: If applicable, update the IRB protocol/application and/or consent(s).***  ***If YES****, please complete the questions listed below.*   1. Current # of subjects enrolled: 2. UVA approved enrollment number:       UVA revised enrollment number: 3. What is the reason for increasing or decreasing enrollment at UVA or Relying sites? 4. Is the UVA site revising the statistical analysis of the protocol? **Yes**  **No**   **If YES**, please explain: |
| 7. | Yes | No | **Are you including the addition of prisoners as research subjects?**  *If currently approved to enroll prisoners, include a copy of the* [*“Consent Addendum-Prisoner Subjects Population.”*](https://research.virginia.edu/sites/vpr/files/2019-08/consent_addendum_prisoner.doc)  ***NOTE: For studies regulated by the Department of Defense***  *When a prisoner becomes a participant, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB Chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB’s approval to change the research protocol. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.* |
|  |  |  | **STUDY DOCUMENTS** |
| 8. | Yes | No | **Are you revising the IRB Application, Protocol, OR any surveys/questionnaires, or supporting documents?**  ***If YES****, submit a copy of the revised IRB-HSR Application or protocol, survey/questionnaires, or supporting documents (e.g., Manual of operations).* ***Turn track changes ON****, revise the date, and make all applicable revisions.*   1. *Attach the sponsor’s protocol summary of changes, if applicable.* 2. *\*\*\*Include detailed* ***bulleted list and rationale*** *for the revisions.*   ***If there is a sponsor’s protocol summary of changes, you must still list the key revisions. .***   1. *List and provide sponsor, DSMB, and/or regulatory agency letters, if applicable*   **ADD BULLETED LIST and RATIONALE:** |
| 9. | Yes | No | **Are you adding an IND or IDE to a UVA investigator-initiated trial?**  ***If YES****, obtain and submit a School of Medicine Clinical Trials Office (SOM CTO) review letter to the IRB with your modification request.* |
| 10. | Yes | No | **Are you adding data/specimens collected from a previous study to a database?**  ***If YES****, add the Plan for protecting data/specimens to the IRB Application, if applicable.* See [Keeping data/specimens for future research](https://research.virginia.edu/irb-health-sciences-research-hsr/submissions-hsr/responsibilities-principal-investigators-0/what-do) |
| 11. | Yes | No | **Are you adding or significantly altering any of the following sections of the protocol/application/consent?**  ***If YES****, use IRB online and click on the* ***“Modification Templates****” link to add the appropriate template sections(s) to the IRB protocol or application and/or consent.*   * *Participation of Children* * *Impaired decision-making capacity* * *Drugs, Biologics, or Devices* * *Gadolinium-enhanced MRI* * *Genetic Research* * *Testing for HLA Status* * *Research with Prisoners* * *Specimen Banking* * *Video/Audiotaping and/or Photography* * *Waiver of Documentation of Consent (verbal consent)* |
| 12. | Yes | No | **Are you submitting recruitment material that is intended for the prospective subjects that is either new or a modification to already approved material)?**  ***If YES****, EITHER submit a copy of the revised recruitment material tracking the changes OR submit the NEW (not previously approved) Recruitment material to be used.*  **LIST ITEMS:**  *For revised recruitment material, outline the requested revisions below.* |
| 13. | Yes | No | **Are you requesting either In-person Electronic Consenting OR Remote Electronic Consenting (e-Consenting)? For additional guidance see: [HERE](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html)** ***If YES***, *please contact the IRB HSR directly regarding required template for your IRB application. The type of template will be determined by the age of your application and/or protocol.*  Once template is acquired, **turn track changes ON**, revise the date, and make all applicable revisions.  ***NOTE:*** *Please complete the questions listed below.*   1. *Include a detailed* ***rationale*** *for this request:*      1. *If applicable, did the study team receive Sponsor approval for e-consent?* **Yes**  **No**  **N/A**  * ***If YES****, please submit a copy of the approval documentation (i.e., email correspondence).* |
| 14. | Yes | No | **Are you revising the Data Security Plan (DSP)? [i.e., how data is collected, transferred, or stored].**  ***Turn track changes ON****, revise the date and make all applicable revisions.*  ***If YES****, include detailed* ***bulleted list and rationale:*** |
|  |  |  | **CONSENT** |
| 15. | Yes | No | **Are subjects** **currently enrolled in the study?**  *See additional information on* [*Reconsenting Requirements*](https://research.virginia.edu/irb-hsr/re-consenting-requirements)  ***NOTE:*** *Please answer the questions below regarding RECONSENT:*   1. ***If RECONSENTING****,* ***include how you will notify subjects of the changes(s) and what is the timing for this notification:*** *(Note: Based on nature of additional risks for example, should subjects be informed of this new information immediately; if not, why not?):* 2. ***If NOT RECONSENTING, provide justification as to why not:*** |
| 16. | Yes | No | **Are you revising the consent form(s)**?  ***If YES****, submit a copy of the revised IRB-HSR consent form.* ***Turn track changes ON****, revise the date and make all applicable revisions.*   1. *Attach the sponsor’s tracked and/or clean revised model consent, if applicable.* 2. *\*\*\*Include detailed* ***bulleted list and rationale*** *for the revisions.*   ***If there is a sponsor’s protocol summary of changes, you must still list the key revisions.***  **ADD BULLETED LIST and RATIONALE:** |
| 17. | Yes | No | **Does the modification require an additional consent form or a consent addendum?**  **You are required to use the UVA IRB** [**Consent addendum Template**](https://research.virginia.edu/sites/vpr/files/2020-08/Consent%20Addendum%208-21-20.doc)  *If applicable, attach the sponsor’s tracked and/or clean revised model consent or addendum.*  *Name of Additional Consent or Addendum:* |
| 18. | Yes | No | **Does this modification include submission of a translated consent document or any other translated supporting documents?**  ***If YES,*** *please complete the questions listed below.*   1. Are any additional revisions required to the *ENGLISH* version of the document? **Yes**  **No**  * ***If YES,*** *those revisions must be approved by the IRB-HSR BEFORE you can submit a modification to add a translated version.*  1. Is the translated document presented in a way that ensures IRB-HSR staff to be able to accurately match it to the corresponding IRB approved *ENGLISH* counterpart? **Yes**  **No**     * ***Suggestion****: The footer of the translated document could include the version date of the corresponding IRB approved ENGLISH counterpart and date of translation.* 2. Is a Certificate of Translation included? **Yes**  **No**     * ***If YES,*** *does it contain the following information:*       + *UVA IRB Tracking Number*      + *Study Title*      + *Name of the documents that are being translated (i.e., consent form, subject material, etc.) along with the version date of the corresponding IRB approved ENGLISH counterpart.*      + *Date of translation*      + *Statement that the translator is qualified.*   **EDUCATIONAL RESOURCE FOR SIGNATURE LINES:**   |  |  | | --- | --- | | ***INDIVIDUAL*** | ***WHICH FORM TO SIGN?*** | | *Subject/Surrogate* | *Translated Short Form OR Fully Translated Consent Form* | | *Interpreter* | * *Translated Short Form AND English Version of Full Consent*   *OR*   * *Translated Full Consent* | | *Person Obtaining Consent* | *English Version of Full Consent* | | *Parent/Guardian* | *Applicable form in language they understand (sign one of the following)*   * *English Version of Full Consent* * *Translated Full Consent* * *Translated Short Form* | |
| 19. | Yes | No | **Does this modification include** **submission of UVA IRB-HSR Short Forms**?***If YES,*** *submit a copy of the revised* [*IRB-HSR short form*](https://research.virginia.edu/compliance-and-integrity/compliance-programs/human-subject-research/irb-health-sciences-research-25)*.* ***Turn track changes ON****, revise the version date, and make all applicable revisions. Include a detailed* ***bulleted list and rationale for this request.*** **ADD BULLETED LIST and RATIONALE:** |
|  |  |  | **INVESTIGATOR BROCHURE** |
| 20. | Yes | No | **Does this modification ONLY include the addition of a Revised Investigator Brochure(s) (IB)?**  ***If YES,*** *does the PI and/or Sponsor confirm there are NO updates required to the protocol or the consent documents per the revised IB?*  ***Yes******No***  ***If YES****, include a copy of the following documents with the modification submission:*   * *Provide the PI and/or Sponsor confirmation to document this request.* * *Summary of Changes.* * *Clean and tracked versions of the updated IB.*   **NOTE:** If you are submitting more than one IB, then please list each one below: |
| 21. | Yes | No | **Does this modification include the addition of Revised Investigator Brochure(s) (IB) that requires updates to the protocol and/or the consent documents per the revised IB?**  ***If YES****, include a copy of the following documents with the modification submission:*   * *Summary of Changes.* * *Clean and tracked versions of the updated IB.* * *Clean and tracked versions of the revised consent form.* * *Clean and tracked versions of the revised protocol.*   ***NOTE:*** *Please answer the questions below regarding NEW Or REVISED RISKS associated with the IB.*   1. *Clearly outline all* ***new*** *risk language:*      1. *Clearly outline all* ***removed*** *risk language:*      1. *Clearly outline any* ***editorial changes*** *to the risk language:*      1. *Additional Comments:*     ***NOTE:*** *If you are submitting more than one IB, then please list each one below. If necessary, copy and paste the four questions outlined above and answer for each IB accordingly.* |
|  |  |  | **SINGLE IRB (sIRB)** |
| 22. | Yes    Yes | No      No | **Does this modification include revisions to appoint the IRB-HSR the single IRB of record (sIRB)?**  **(i.e., UVA IRB-HSR will be serving as the reviewing IRB for non- UVA sites)?**  ***If YES****, the protocol must be written to address overall enrollment #’s, data safety and monitoring, and statistical analysis. A multisite protocol must be created to be adhered to by all Relying sites.*  *See* [*HERE*](https://research.virginia.edu/irb-hsr/reliance-irb-hsr-serve-single-irb-sirb-record) *for additional information regarding UVA study team responsibilities and issues to consider when the UVA study team is the lead site.*  **Is the UVA PI becoming the overall PI of a multi-site study?**  ***If YES, obtain and submit a School of Medicine Clinical Trials Office (SOM CTO) review letter to the IRB.*** |
| 23. | Yes | No | **Does this modification include the addition of a relying site that will rely on the IRB-HSR as the reviewing IRB?**  ***If YES****, will the relying site enroll study subjects and require a site-specific consent(s)/assent(s) document?* ***Yes******No***  ***If YES****, include tracked changes versions of the applicable consent/assent documents with this modification.* |
| 24. | Yes | No | **Does this modification** **affect institutions already approved to rely on the UVA IRB as the sIRB of record**?  ***If YES,*** *which Relying site(s) are affected by this modification?*    *Add site specific information here. (e.g., PI change at Site A only)* |
|  |  |  | **ANCILLARY REVIEWS** |
| 25. | Yes | No | **Does the modification require review by the Protocol Review Committee (PRC) Cancer Center?**  *If you are unsure if your study requires PRC approval, check your initial PRC approval form, or contact the PRC Coordinator. If PRC approval is needed, it must be obtained* ***PRIOR*** *to submission to the IRB-HSR.* |
| 26. | Yes | No | **Does the modification require Human Investigations Involving Radiology Exposure (HIRE) Committee approval?**   * *Please complete all necessary forms per current* [*HIRE procedure*](https://med.virginia.edu/radiology/resources/staff-resources/medical-physics-support/human-investigations-involving-radiology-exposure-hire-committee/).   ***If YES****, HIRE approval must accompany this modification request along with any other documents that were updated (e.g., application/ protocol/ consent).* |
| 27. | Yes | No | **Does this modification create a NEW significant financial conflict of interest?**  ***If YES****, attach the COI Management Plan approved by the Conflict-of-Interest committee.* |