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| **REQUEST FOR MODIFICATION APPROVAL FORM** | | |
| * All documents associated with your modification are to be sent to:[irbhsr-mods@virginia.edu](mailto:irbhsr-mods@virginia.edu) for a mandatory pre-review. * Revisions need to be **tracked from the currently approved protocol/application/ consent(s)**. **CHECK IRB Pro for current versions of documents prior to making revisions.** * Pre-reviews are typically conducted within 10 business days. * To modify the document or use the links, you must first **unprotect** the document. * [Definitions and Reporting guidelines for Modifications](https://research.virginia.edu/irb-hsr/modifications-amendmentsrevisions-currently-approved-research) | | |
| IRB-HSR or UVA Study Tracking #: | | PI Name: |
| ***Check one:*** | Minor Changes/Minimal Risk | |
| Significant Changes/Greater than minimal risk (full board review required)   * Changes to Inclusion/Exclusion Criteria * Additional new risks added * Changes to Study Design * Changes to Statistical Plan * Changes to study plan (e.g. extended duration of treatment) | | |
| Modification to Exempt Determination Application-Email to IRBHSR@virginia.edu | | |

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| 1. | | Yes | No | | N/A | Does this modification include revisions to make the IRB-HSR the single IRB of record?  (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 plan, statistical section.  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.  *Yes  No* | |
| 2. | | Yes | No | | N/A | 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.* | |
| 3. | | Yes | No | | N/A | Does this modification affect institutions relying 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)*    **NOTE: If modification affects UVA and ALL relying sites check HERE:** | |
| 4. | | Yes | No | | N/A | Does this modification ONLY include the addition of a **Revised Investigator Brochure**?  ***If YES,*** *d*oes the PI and/or Sponsor confirm there are no updates required to the protocol or the consent documents per the revised Investigator’s Brochure?  *Yes  No*  ***If yes****, include a copy of the following documents with the modification submission:*   1. *Summary of Changes* 2. *Tracked version of the updated IB* 3. *Clean Version of the updated IB* | |
| **Summarize & provide a rationale for the revisions:**  *If there is a sponsor’s protocol summary of changes, you must still list the key revisions. Attach the sponsor’s protocol summary of changes when you submit your other documents for pre-review.*  ***Note: answer N/A if yes to #4 above*** | | | | | | | |
| 5. | | Yes | No | |  | Does this modification include 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) *and answer Yes to box#7.* | |
| 6. | | Yes | No | |  | Does this modification add new personnel who are not affiliated with UVA?  ***If YES****, submit a copy of their training in Human Subject Research Protection, a signed* [*unaffiliated investigator agreement*](https://research.virginia.edu/sites/vpr/files/2020-04/Unaffiliated%20Investigator%20Agreement%204-27-20.doc) *and modify the protocol to add or update the:* [*Appendix: Non- UVA Personnel section*](https://www.irb.virginia.edu/Template_Sections/HIC_Application/personnel_non_uva_with_application_A.doc)*.* | |
| 7. | | Yes | No | |  | Do changes require revisions to the **IRB-HSR Application or Protocol**?  ***If YES****, submit a copy of the revised IRB-HSR Application or protocol*  *Note: Turn track changes on, revise date and make all applicable revisions* | |
| 8. | | Yes | No | | N/A | Do changes require revisions to the **consent form(s)**?  ***If YES****, include one copy of the consent(s) with changes tracked.*  *Note: Turn track changes on, revise version date and complete all applicable revisions* | |
| 9. | | Yes | No | | N/A | Do changes require an **additional consent form or a consent addendum**?  ***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. | |
| 10. | | Yes | No | | Have subjects **enrolled** in this study?  ***If YES****, does the modification affect subjects currently enrolled, being treated, or in follow-up including their willingness to continue in the study?*  *Yes*  *No*  *If YES, how you will notify subjects of the changes(s) and what is the timing for this notification to subjects: (Note: Based on nature of additional risks for example, should subjects be informed of this new information immediately; if not, why not?*  *If NO, describe why the modification will not affect subjects previously enrolled.* | | |
| 11. | | Yes | No | | Has the **funding** for the protocol changed?  ***If YES****, list new sponsor:*  *If new funding is from a grant, list IRB-HSR grant # (if applicable):*  *Do you certify that this protocol is consistent with the aims of the grant?*   *Yes  No* | | |
| 12. | | Yes | No | | N/A | Does the modification require **PRC approval***? Answer N/A if this trial is not related to cancer research.*   * *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.* | |
| 13. | | Yes | No | | N/A | 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).* | |
| 14. | | Yes | No | | Is the **title** of the study being revised?  ***If YES****, ensure* ***ALL*** *documents (e.g. protocol/consent, data security plan, IRB application) headers are updated to reflect the new title.* | | |
| 15. | | Yes | No | | Are you requesting the **sponsor’s protocol #** field in IRB online be updated?  ***If YES****, list new number:* | | |
| 16. | | Yes | No | | Is this modification a response to requested revisions following a Post Approval Monitoring **(PAM) audit**?  ***If YES****, address any outstanding PAM issues with this modification and include a copy of the PAM report with your modification submission for reference.* | | |
| 17. | | Yes | No | | Were any changes requested by the IRB following a Full Board Modification or a Full Board Continuation Review? | | |
| 18. | | Yes | No | | Are you changing the **study status** with this modification?  ***If YES****, complete and submit a* [*Status Change Form*](https://research.virginia.edu/sites/vpr/files/2020-04/Status%20Change%20Form.doc) *with this submission.* | | |
| 19. | | 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. | | |
| 20. | | Yes | No | | Are you revising the UVA **enrollment # OR if the UVA IRB is serving as the IRB of record, revising the overall enrollment #**?  ***If yes***, complete the [Enrollment Change Form](https://research.virginia.edu/sites/vpr/files/2020-04/Enrollment%20Change%20Form%204-23-20_0.doc) and submit this form along with the updated IRB protocol and/or consent(s) (if applicable) | | |
| 21. | | Yes | No | | Do you need to add or significantly alter 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 your IRB protocol or application and/or consent. | | |
|  | |  |  | | * Participation of Children * Clinical Data Repository * Impaired decision-making capacity * Compensation and/or Reimbursement * Drugs and Biologics * Gadolinium-enhanced MRI * Genetic Research | | * Non- UVA Personnel or UVA Personnel not under the HIPAA Covered Entity * Testing for HLA Status * Research with Prisoners * Specimen Banking * Video/Audiotaping and/or Photography * Waiver of Documentation of Consent (verbal consent) |
| 22. | | Yes | No | | Do you need to change/expand the **recruitment** methods, or any process related to **pre-screening**?  If yes, use IRB online and click on the “Modification Templates” tab. View the current Recruitment template for your study type against the Recruitment template in your approved protocol or IRB application. If your study contains an outdated recruitment section, you will need to complete the current one UNLESS you are only making a very minor change. Recruitment and pre-screening revisions need to be submitted for pre-review along with any other revisions that may have been made.  NOTE: If the modification affects the content of an advertisement/recruitment material that has been previously approved, revise the advertisement/recruitment material and submit it to the IRB ([IRBHSRads@virginia.edu](mailto:IRBHSRads@virginia.edu)) for a separate IRB-HSR approval event. | | |
| 23. | | Yes | No | | Do you need to add or significantly alter anything related to an investigational study device?  ***If yes***, use IRB online and click on the “Modification Templates” tab. Click on “Device Questions from Protocol Builder” and answer the questions.   * E-mail the completed device questions document to Medard Ng. If you have an IRB protocol, also attach the currently approved protocol. In the subject line of the e-mail write “Device questions for review”. * You will be provided with the template sections that need to be completed. | | |
| 24. | Yes | | | No | Will this modification include changes to how data is collected, transferred and stored?  ***If Yes***, revise the Data Security Plan and submit to the IRB-HSR. The IRB-HSR staff will send to InfoSec if their review is required. | | |
| 25. | 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. | | |
| 26. | Yes | | | No | Will this modification include the addition/revision of a **stand-alone sub-study protocol** under the same IRB-HSR# as the main/parent study? | | |
| 27. | Yes | | | No | Will this modification involve adding data/specimens collected from a previous study to a database? See [Keeping data/specimens for future research](https://research.virginia.edu/irb-health-sciences-research-hsr/submissions-hsr/responsibilities-principal-investigators-0/what-do) | | |

**Submitted by:** **Date:**

**Do you confirm that the PI approves the changes submitted?**  **Yes**  **N**