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| REQUEST FOR MODIFICATION APPROVAL FORM | | |
| * An Administrative IRB-HSR **pre-review** is MANDATORY for all modifications. * Documents associated with your modification are to be sent to:[irbhsr-mods@virginia.edu](mailto:irbhsr-mods@virginia.edu) * Revisions need to be **tracked from the currently approved protocol/application/ consent(s)**. Accept all previous changes and delete all old comments. ONLY current revisions should be present when documents are sent for pre-review. * An IRB Application does NOT need to be signed, except with a change in PI. * Pre-reviews are typically conducted within 10 business days. If you do not hear back from someone at the IRB within this timeframe, e-mail Medard Ng at [htn3u@virginia.edu](mailto:htn3u@virginia.edu) or Andrea Ruhsam at [alr8q@virginia.edu](mailto:alr8q@virginia.edu) * If you wish to modify this 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) | | |

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| 1. | | Yes | No | | N/A | | Does this study modification include institutions relying on the UVA IRB as the sIRB of record?  ***If yes, which relying sites are affected by this modification?*** | |
| 2. | | Summarize and provide a rationale for the change(s)  *If there is a sponsor’s summary of changes, you must still list the key revisions. Attach the sponsor’s summary when you submit your other documents for pre-review. If there are changes only specific to an individual relying site, please add that information here. (e.g. PI change at Site A only)* | | | | | | |
| 3. | | Yes | No | |  | | Does this modification include the addition of prisoners as research subjects?  *If now enrolling 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.* | |
| 4. | | 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 and modify the protocol to add or update the: Appendix: Non- UVA Personnel section. For additional guidance see # 20 below.* | |
| 5. | | 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 with changes tracked****.*** | |
| 6. | | Yes | No | | N/A | | Do changes require revisions to the **consent form(s)**?  ***If YES****, e-mail one copy of the consent(s) with changes tracked.* | |
| 7. | | 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. | |
| 8. | | 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, describe how you will notify them of the changes(s):*  *If NO, describe why the modification will not affect subjects previously enrolled.* | | | |
| 9. | | 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):*  *If new funding is from a grant, do you certify that this protocol is consistent with the aims of the grant?*   *Yes  No* | | | |
| 10. | | 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.* | |
| 11. | | Yes | No | | N/A | | Does the modifications require **Human Investigations Involving Radiology Exposure (HIRE) Committee approval***?*   * *Please complete all necessary forms per current HIRE procedure* [*http://www.medicine.virginia.edu/clinical/departments/radiology/physics/hire-committee.html*](http://www.medicine.virginia.edu/clinical/departments/radiology/physics/hire-committee.html) * *If HIRE approval is needed, it must be obtained* ***PRIOR*** *to submission to the IRB.* | |
| 12. | | Yes | No | | Was the **title** of the study revised?  ***If YES****, make sure the protocol/consent headers were updated to reflect the new title.* | | | |
| 13. | | Yes | No | | Are you requesting the **sponsor’s protocol #** field in IRB online be updated?  ***If YES****, list new number:* | | | |
| 14. | | Yes | No | | Were any modification changes requested 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.* | | | |
| 15. | | Yes | No | | Were any changes requested by the IRB following a Full Board Modification or a Full Board Continuation Review? | | | |
| 16. | | 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.* | | | |
| 17. | | Yes | No | | Are you adding an **IND or IDE** to a UVA investigator-initiated trial?  ***If yes***, you need to obtain and submit a School of Medicine Clinical Trials Office (SOM CTO) review letter to the IRB with your modification request. | | | |
| 18. | | Yes | No | | Are you becoming the **overall PI** of a multi-site study?  ***If yes***, you need to obtain and submit a School of Medicine Clinical Trials Office (SOM CTO) review letter to the IRB. | | | |
| 19. | | Yes | No | | Are you revising the UVA **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 (if applicable) | | | |
| 20. | | Yes | No | | Do you need to add or significantly alter any of the following sections of the Protocol/application/consent? | | | |
|  | |  |  | | * Participation of Children * Clinical Data Repository * Cognitive Impairment * 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) |
| ***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. | | | |
| 21. | | Yes | No | | Do you need to change/expand the **recruitment** methods, or anything related to **pre-screening**?  ***If Yes****,*   * Go into IRB online and click on the “Modification Templates” link. View the current Recruitment template for your study type against the Recruitment template in your approved protocol or 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. | | | |
| 22. | | Yes | No | | Do you need to add or significantly alter anything related to a study device?  ***If Yes****,*   * Go into 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. | | | |
| 23. | Yes | | | No | | If you are updating the consent, were non-medical terms used, and is the consent written at an 8th grade or lower reading level? | | |
| 24. | Yes | | | No | | Will this modification affect the content of an advertisement that has been previously approved?  ***If Yes,*** revise the advertisement and submit it to the IRB ([IRBHSRads@virginia.edu](mailto:IRBHSRads@virginia.edu)) for approval. | | |
| 25. | 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. | | |
| 26. | Yes | | | No | | Does this change create a significant financial conflict of interest? If yes, attach the COI Management Plan approved by the Conflict of Interest committee. | | |
| 27. | Yes | | | No | | Will this modification include the addition/revision of a standalone sub-study protocol under the same IRB-HSR# as the main/parent study? *Refer to the IRB Website to determine which submission method is appropriate for this substudy*  Are you submitting a separate study submission? | | |

**Additional Comments:**

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

**Do you confirm that the PI approves the changes submitted?**  **Yes**  **No**

**Questions? Contact the** [**IRB-HSR Staff**](https://research.virginia.edu/irb-hsr/staff-directory-0) **assigned to Modifications.**