

# VA New York Harbor Healthcare System Institutional Review Board Project Modification Form

<b>Principal Investigator (PI):</b>	
<b>Project Title and (if ongoing study) VA IRB Number:</b>	
<b>Contact Person:</b>	<b>E-mail:</b>
<b>Phone number:</b>	<b>Date Form Completed:</b>

In order for the IRB to fully evaluate a modification request, please provide a summary of all modifications and the required documents. Note that any modifications to a protocol cannot be implemented until after final IRB approval is received unless safety of participants are at risk, in which case the IRB should be informed accordingly.

Check all protocol modifications that apply:

- 1. Consent form and/or HIPAA authorization changes**  
**Version Number:                      and/or Version Date:**

*(Provide a clean copy of the revised consent form and/or HIPAA authorization, a description of the revisions and highlighted (tracked changes) revised consent form and/or HIPAA authorization)*

- 2. Protocol revision –**  
**Amendment/Version Number:                      and/or Version Date:**

*(If the PI or sponsor of the study (e.g. VA CSP, NIH, pharma) is requesting IRB approval of a modified protocol, check this box and any other relevant boxes below. Attach a description of the modification, the revised protocol, and, if required, a revised consent form (and check #1 above).)*

- 3. Inclusion / Exclusion Criteria Change** (provide a document explaining changes)

- 4. Investigator Brochure revision** (provide a document explaining changes)

- 5. Advertisement (s) / Recruitment Letter (s)** (include copies of all documents)

- 6. Add or remove personnel:** *(Attach a Change of Research Personnel Form, a revised Research Protocol Staff Report and, if applicable, a letter from Sponsor acknowledging change)*

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- 7. Change in Sponsor(s) or source of funding:** (*Attach revised consent form if applicable.*)

**Add Sponsor Name:**

**Delete Sponsor Name:**

- 8. Change the way vulnerable subjects are included in the study.** Submit *HSQ Appendix A – Recruitment of Vulnerable Subjects*

- 9. Change payment for participants.** Submit *HSQ Appendix B – Payment for Participation*

- 10. Change the way radiation is used in the study.** Submit *HSQ Appendix F – Use of Radiation*

- 11. Change a human biological specimens component.** Submit *HSQ Appendix G–1 Human Biological Specimens Questionnaire Specimen Analysis* or *HSQ Appendix G–2 Human Biological Specimens Questionnaire - Research involving Banked Specimens or the Banking of Specimens*

- 12. Change the manner in which the data are secured or to whom data are disclosed? (e.g., changed from paper to electronic format, from identified to de-identified format, etc.).**

Please describe and submit *Privacy and Data Security Plan*:

- 13. Change where the data are stored?**

Please describe and submit *Privacy and Data Security Plan*:

- 14. Change the utilization of VA NYHHS services (i.e., path and lab, pharmacy, imaging, etc.) not previously approved.**

Please describe:

- 15. Other** Please describe and attach any appropriate documentation:

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## Project Modification Form

Project modifications may be reviewed and approved by expedited procedures if the modification represents a minor change in previously-approved research during the period (of 1 year or less) for which approval is authorized. A minor change is one which makes no substantial alteration in the overall risk-benefit relationship for subjects.

Type of review requested:

- Full IRB, study does not meet criteria for expedited review.
- Expedited review. Please complete **Request for Expedited Review Form**