**Amendment Form**

Instructions: Please include tracked change copies as well clean copies for any of the items in which changes are needed. If there are changes in the investigators and/or staff please include a signed copy of their CV/resume, license and certificate of human subjects training. Any changes **may not** be implemented prior to receiving IRB approval.

Forward one complete electronic copy to [christine.fornwalt@meritushealth.com](mailto:christine.fornwalt@meritushealth.com) and one hard copy to the Office for the Human Subject Protection RW Suite 229, Room 2224. For questions, please contact the Office for Human Subject Protection at 301-790-8825.

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| PI Name: Click here to enter text. | IRB#: Click here to enter text. |
| Study Title: Click here to enter text. | |

Choose all that apply regarding changes.

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| --- | --- |
| Estimated Number of Subjects | Research Objectives |
| Inclusion/Exclusion criteria | Procedures |
| Study population | Study Drug |
| Consent Form | Medical Device |
| Investigator Brochure | Questionnaires |
| Recruitment/Advertisements |  |

See page 2 for required details.

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| 1. Title Change?  Yes  No If yes, please name: Click here to enter text. |
| 2. Is there a change in Principal Investigator or study staff?  Yes  No  If yes, please name: Click here to enter text. |
| 3. Check one:  This amendment does not increase risk to participants  This amendment may or will increase risk to participants |
| 4. Does this amendment required changes to the Informed Consent Document(s)?  Yes  No |
| 5. In your professional opinion, does this amendment involve information that might  relate to a participant’s willingness to continue to take part in the research?  Yes  No |
| 6. Is this amendment request due to an unanticipated problem or adverse events?  Yes  No |

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| **REQUIRED:** Please attach the sponsor’s summary of changes. If you do not have a summary of changes, please complete the section below. For each proposed change to each document(s), describe the currently approved section of the protocol, questionnaire, consent, etc. and then summarize the proposed change, addition, etc. Multiple changes within one document can be listed under one proposed revision section using bullets. Include a justification for the modification request.  Example:  Currently Approved: Consent form:   * Principal Investigator – Dr. Orange; * Visit 3 - A 20 ml Blood draw.   Proposed Revision: Consent Form   * Principal Investigator to be Dr. Purple. Dr. Orange is retiring. * Visit 6 – A 10 m blood draw will be done. A 20 ml draw is no longer required. |

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| 1. | Currently Approved: | Click here to enter text. |
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| Proposed Revision: | Click here to enter text. |
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| 2. | Currently Approved: | Click here to enter text. |
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| Proposed Revision: | Click here to enter text. |
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| 3. | Currently Approved: | Click here to enter text. |
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| Proposed Revision: | Click here to enter text. |
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| 5. | Currently Approved: | Click here to enter text. |
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| Proposed Revision: | Click here to enter text. |

PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Reviewer’s comments: Click or tap here to enter text.

Reviewer’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_