

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

 **Amendment Application Form**

PROTOCOL #:

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| Federal regulations require IRB approval before implementing proposed changes, including any alteration in content or form to the protocol, consent form or supportive materials (Investigator’s Brochure, questionnaires, surveys, recruitment materials, study personnel list, etc…)**DOCUMENTS REQUIRED FOR AMENDMENT APPROVAL: Please provide one copy of the following:*** Completed Amendment Form
* Summary of changes that outlines all changes and provides rationale for each revision
* Applicable source documentation for the changes
* Tracked changes versions of all amended documents
* Clean versions of all amended documents
* Any new documentation that has not yet been submitted for OHRA approval
* All OHRA submissions must include a complete list of documents being submitted for review. Each listed item must include the name of the document, version identifier and date (e.g., Study Protocol version 7, dated 9/26/2017) Please include this in your summary of changes.
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| 1. **The purpose of this amendment is to:** *(please select all that apply)*
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| [ ] Update Personnel- *if this is the ONLY change being submitted; please only check this box, skip to the personnel change section, and continue completing the form. All personnel changes must also be made in the Face sheet of your OHRA application.*[ ] Submit revisions to / addition of study documents and/or procedures [ ] Provide regulatory documentation that does not alter study activity (e.g., administrative updates)[ ] Respond to stipulations from a previous review *(please provide original submission date or confirmation code in summary of changes)* |
| 1. **Research Involving Products/Agents**

*For studies administering the following as part of research procedures: drugs, devices, biologics, foods, food additives, cosmetics, investigational in vitro diagnostics or lab developed tests, vitamins, supplements, etc.*  | [ ] **NA**(*no products or agents**being administered*) |
| Does the Amendment involve changes to the investigational product or its management (e.g., new product being added, changes to dosing, administration, design, formulation, preparation, etc.)?**\*If yes, this should be thoroughly explained in the summary of changes** | [ ] YES [ ] NO |

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| 1. **Current status of study:** *(please check only one)*
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| [ ] Study has not begun(*no participants consented*) | [ ] Open to enrollment | [ ] Closed to enrollment |

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| 1. **Current enrollment:** please note the total in part 1 below should be the sum of 2, 3, & 4.
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| 1.Total number of participants consented since the study began:  |       |
| 2.Number of currently active participants:  |       |
| 3.Number of participants currently in follow up (if applicable):  |       |
| 4. Number of completed participants *(please include screen failures, withdrawals, etc. in this section):*  |       |

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| 1. **Changes to the consent form and re-consent plan:**
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| Does the current Amendment change the content of the consent form?  | [ ] YES [ ] NO |
| **\*If YES*,*** *please indicate the re-consent plan:*[ ] N/A- no participants enrolled[ ] Our site plans to re-consent all participants (active, follow-up, and completed)[ ] Our site plans to re-consent only a select number of participants. Please explain below.[ ] Our site does not plan to obtain re-consent |
| Please provide rationale for the chosen re-consent plan in the box below. Please be sure to consider how these changes impact the subjects who have consented to participate so far. |
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| 1. **Alteration of the risk/benefit profile of study:**
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| Please comment on whether any elements of the amendment pose any new or increased risk to participants.  |
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| 1. **Changes to personnel: Please check all that apply below**

Any changes shown here should also be made in the personnel listing in the Face sheet of your OHRA application. The OHRA requires documentation of completed CITI training for all personnel; please include reports for each person added to the protocol. |
| [ ] **No changes to personnel**[ ] **Removing personnel**—please list in summary of changes document and indicate whether any study documents require revision (Emergency Contacts in ICF, recruitment contacts, etc…)[ ] **Updating CITI training for existing personnel**—please list in summary of changes that accompanies this Amendment and provide renewed CITI training reports/certificates[ ] **Adding new personnel**—please include the name, affiliation, and role in the study for all staff being added in your summary of changes document that accompanies this Amendment.**If a change of PI is being submitted, a letter indicating transfer and acceptance of PI responsibilities is required with signatures from both the former and current PI.** |
| **Are there any newly-identified or changes to previous reported significant financial interests related to these personnel changes?**  | [ ] YES [ ] NO |
| *If yes: please ensure any new conflicts or changes to existing conflicts are documented on the Face sheet page of the OHRA application and reported to the UHG Compliance & Ethics Office.* |
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