

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

**Annual Renewal Application Form**

PROTOCOL #:

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| Federal regulations require annual renewal of research based on risk level. Please review your most recent OHRA action letters to determine whether annual renewal is required. Please check the OHRA submission system for expiration dates.  Research that requires Convened/Full Annual Renewal is due 6 weeks prior to expiration.  Research that qualifies for Expedited Annual Renewal is due at least 2 weeks prior to expiration.  Incomplete submissions will be returned for edits regardless of expiration date.  **DOCUMENTS REQUIRED FOR ANNUAL RENEWAL - Please provide one copy of the following:**   * + Completed Annual Renewal Form   + A detailed Progress Report document (See below for details on each section required in progress report)   + The currently approved protocol document   + Currently approved versions of Informed Consent Forms (unless enrollment is permanently closed, or no informed consent forms are required or used in the research). These versions should not include any tracked changes.   + Documentation representing the study monitoring activities from the past year (see study monitoring section of form)   For Biomedical Research Only:   * Currently approved Investigators Brochures and/or Package Inserts for all study drugs/devices   **Progress Report -** include the following information:   1. 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) 2. All submissions require a narrative summary of the study activities that occurred during the approval year, including notable comments, notable participant experiences, any delays in study activities, and expected activities for the coming year. Please do not re-iterate the enrollment numbers provided in this form unless a specific clarification is needed. 3. All submissions require a summary of any planned/outstanding amendments that will be submitted to the OHRA for review including the planned timeline for submission and the impact the modifications have for enrolled participants, as applicable. 4. All submissions require a report regarding the status of the approved participant engagement plan (as it relates to the status of the research and enrollment status). 5. ***If approval expired or will expire****:* No research-related activities may occur after the protocol expiration date. If the study has expired or will expire while waiting for OHRA review, the following information should be included in your progress report:  * Please describe any study activities that have occurred during the lapse in approval * Provide an explanation for what led to the delayed submission of the Renewal * Provide a corrective action plan to avoid expiration in the future * If this is not the first time that the study has expired, comment on whether the existing corrective action plan needs to be corrected * If your research is greater than minimal risk and activities need to occur during the lapse for the benefit or safety of participants, a separate exception must be approved (please contact the OHRA for assistance). |

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| 1. **PARTICIPANT ENROLLMENT REPORTING - (Items A – J**)   *Please be mindful that enrolling beyond the approved target is considered a deviation. If you have enrolled participants beyond your target and plan to continue consenting participants, please submit a modification to revise your enrollment target and plan.* | |
| 1. Target Enrollment: *(Please list the maximum number of participants approved to be consented. If no maximum was set, please enter “No Target Set.”)* |  |
| ***CONSENTED PARTICIPANTS BREAKDOWN:*** *(Even if participants do not sign their name to a form, they are considered consented if a process was completed to gain their permission to voluntarily participate)* | |
| 1. Number of participants consented since the last Continuing Review: |  |
| 1. Number of participants consented since the initiation of the study: |  |

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| ***PARTICIPANT STATUS BREAKDOWN:*** *Do not account for individual participants in multiple categories. D+ E+ F + G = C. Provide any required clarification in your progress report.* | |
| 1. Number of participants actively participating in study procedures**:** |  |
| 1. Number of participants only in follow up procedures**:** |  |
| 1. Number of participants who completed all required procedures since enrollment began (*no further study related contact required*): |  |
| 1. Are there any participants who provided consent that are no longer participating  (no further study related contact required) for reasons other than completion? | **YES NO** |
| **\*If YES***: Please provide a summarized list below of participants that did not complete the study but have ended participation since enrollment began. Include the reasons other than completion and the number of inactive participants in each category. (Categories to consider: determined ineligible after consent, lost to follow up, voluntary withdrawal, withdrawal by the PI, disease progression, adverse event, etc.)* | |

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| ***EQUITABLE PARTICIPANT SELECTION:*** This section should include all participants since enrollment began: *NOTE: Many funded studies require collecting and reporting this information. If your study is funded by an entity that requires tracking/reporting of this information, please complete the following sections.* | |
| 1. Is information from OR about participant gender and/or sex being collected?   **YES,** *please provide the information you have collected for* *all participants since enrollment began.*  **NO,***please leave sections blank or place N/A in the associated boxes.* | |
| Sex assigned at birth | Gender identity provided by the participants |
| Male: | Men: |
| Female: | Women: |
| Intersex: | Another identity: |
| Unknown: | Unknown: |
| 1. Is information about participants’ race/ethnicity collected?   **YES,** *please provide the information you have collected for* *all participants since enrollment began.*  **NO,***please leave sections blank or place N/A in the associated boxes.* | |
| **Ethnicity:** | |
| Hispanic or Latino: | |
| **Race:** | |
| American Indian or Alaskan Native: | |
| Asian: | |
| Black or African American: | |
| Native Hawaiian or Pacific Islander: | |
| White: | |
| Unknown or Not Reported: | |

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| 1. ***VULNERABLE POPULATIONS THAT REQUIRE SPECIAL CONSIDERATIONS:*** | |
| **Has your study enrolled:** | |
| **Pregnant Women?** | **YES NO** |
| **Prisoners?** | **YES NO** |
| **Children (aged 17 or younger)?** | **YES NO** |
| *Please Note: If your study has enrolled any of the above populations and the inclusion of these populations was not previously approved, a separate deviation report must be submitted to the OHRA for review/consideration.* | |

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| 1. **Study Monitoring / Quality Control / Issues Identification and Reporting**   It is the expectation of the OHRA that all research protocols will include a plan for site monitoring and quality control to identify, document and report issues that occur during research. Studies that require annual renewal should review their records and update the OHRA about these activities. |
| 1**.** Please confirm whether all issues that occurred have been individually assessed by the PI (or delegated co-I) to determine whether they require OHRA reporting.  **YES NO**  **\*If NO:** please explain in your progress report |
| 2. Did you submit any Issues Reports to the OHRA in the past year?  **YES NO**  **\*If YES,** please be sure your progress report provides a summary assessment of the collective impact of these issues that occurred and provide any new information about those issues if applicable. You do not have to re-submit the same report forms. |
| 3**.** Did any issues occur that were not reported to the OHRA?  **YES NO** |
| 4. Please provide documentation/records of the quality control and monitoring activities from the past year.  Documentation may include logs, checklists, audit reports, etc. The monitoring documentation should identify issues and be clear that OHRA criteria for reporting have been assessed including adverse impact on; participants’ rights, welfare/safety (including any potential or actual harm), participant willingness to participate and the overall scientific integrity of the study. Records should indicate any related corrective and preventative actions that were taken. |

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| 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. | | **N/A**  (no products or agents being administered) |
| 1. Have there been any updates related to the products administered on this trial in the past year? This may include but is not limited to: revised package inserts, revised investigator brochures, product recalls or bans, new product manufacturer, etc. | | **YES NO** |
| * 1. If Yes, please confirm that all updates have been submitted to the OHRA appropriately, or indicate that an amendment is soon forthcoming: | | |
| 1. Is this study conducted under an IND or IDE ***where the IND or IDE Sponsor is a researcher within UHG?*** | **YES : answer 2a**  **NO** (i.e., Sponsor is external to the UHG; the study has an IND/IDE Exemption, etc.) | |
| * 1. Has the protocol, Sponsor, PI, or any sub-investigators been inspected by the FDA or other health authority?   **NO**  **YES:** Was an FDA Form 483 or other inspection report issued? **YES NO** | | |

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| 1. **Safety Monitoring**   Please refer to the safety monitoring provisions outlined in your protocol prior to responding to the following questions. | |
| 1. Does the protocol identify an external group, entity, or individual that will periodically assess safety data (e.g., independent Data Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC), or other safety monitoring entity, independent medical monitor, etc.) | **YES:** answer 1a  **NO:** stop |
| 1. Does the entity/individual issue reports to the site? (refer to protocol and/or charter, if applicable) | **YES:** answer 1b  **NO:** stop |
| 1. Please clarify the status of the expected safety monitoring reports:   All reports have already been submitted to the OHRA in real-time.  Reports are attached with this submission. Please explain any reasons for delay in your progress report.  Reports are unavailable. Please specify reason for unavailability and expected date of receipt in your progress report. | |

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| 1. **Risk-Benefit Assessment** | |
| Is there any **new** information to report that would **alter** the previous determination that risks to participants are minimized AND risks to participants are reasonable in relation to anticipated benefits, if any? | **YES NO** |
| **\*If YES:** Please describe the new information the OHRA should consider that may alter the previous determinations for these two approval criteria: | |