JEFFERSON—Office of Human Research

# **AMENDMENT TO RESEARCH PROTOCOL**

**Version Date – FOR OHR USE: 8/23/19**

**(Form Must be Typewritten)**

Do Not Use this Form When Submitting Revisions Requested by the Board. Submit Board Revisions Under Separate Cover.

**IRB Control #:** **Department:**

**SPONSORED PROGRAMS ACCOUNT NUMBER: 080- \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI:**

**Study Title:**

**Funding Source**:

**Is OHR-9 (continuing review) being submitted simultaneously with this amendment? YES \_\_\_ NO \_\_\_**

**This amendment contains:**

**PLEASE NOTE: For both full and expedited reviews, please submit the required documents electronically using the Portal. In addition, for full reviews, 3 collated packets of hardcopies are also required.**

|  |  |
| --- | --- |
| [ ] **Revisions to consent form only** – Required Documents:   * *OHR-12* * *Revised consent form with revisions in track changes* * *Current stamped consent form* * *Current approved OHR-2* * *If amendment includes revisions to the risk section of the consent form, include itemization of revisions from investigator brochure or memo from the sponsor or PI providing rationale for the revisions.* * *One clean copy of the consent form for stamping*   [ ] **Revisions to protocol only** – Required Documents*:*   * *OHR-12* * *Sponsor or investigator itemization of revisions* * *If externally funded - relevant pages of sponsor protocol and OHR-2 with revisions in track changes* * *If department funded - OHR-2 with revisions in track changes* * *Current stamped consent form* * *One clean copy of revised sponsor protocol and/or OHR-2*   [ ] **Revisions to protocol and consent form** – All of the documents listed above for revisions to the consent form and protocol are required.  [ ] **Other** (e.g., advertising, supplementary materials, etc.) – Required Documents:   * *OHR-12* * *Advertising, supplementary materials, etc.* | **FOR IRB USE ONLY**  **[ ] Full Review**  **[ ] Expedited Review**  **[ ] Substantive**  **[ ] Non-Substantive**  **[ ] Review Not Required** |

**In general, all amendments to minimal risk research and minor changes in greater than minimal risk research can be reviewed as expedited. Examples of expedited amendments are: advertising, informational materials, grammar/syntax corrections to protocol and/or consent form.**

**DIRECTIONS:**

* **Summarize key points of the amendment separating major and minor changes.**
* **Examples of major changes: Risks, objectives, procedures, data analysis.**
* **Examples of minor changes: Formatting, consistency, grammar, spelling.**
* **Address the main changes affecting the subjects, the protocol, and the consent form(s) and provide rationale for the main changes (e.g., dose-limiting toxicities, suspension of enrollment for interim analysis, etc.).**
* **Include ANY change involving risk.**
* **If available, attach amendment synopsis from the sponsor.**

**FAILURE TO FOLLOW THE ABOVE DIRECTIONS WILL RESULT IN DELAYED APPROVAL.**

**NOTE: Even if there is a sponsor provided detailed list of changes, please provide a SUMMARY of the changes below (the key reasons for the amendment).**

**Major Changes:**

**Minor Changes:**

***If this amendment involves only the addition of advertising or recruitment materials, or grammar/syntax corrections to the consent form or protocol, you may skip to the signature section below. For all other amendments, you must complete the following section.***

1. Current expiration date: **OR**

NA. Study no longer requires continuing review [per 45 CFR 46.109(f)(9)]

NA. Study is exempt.

1. IRB-approved enrollment per year: .
2. IRB-approved total enrollment for study: .
3. Number of subjects enrolled to date: .

*[Note: for the purposes of the OHR-12, “subjects enrolled” is defined as subjects who have successfully screened and been randomized or allocated or begun study procedures.]*

* 1. Number of subjects currently receiving study intervention: .
  2. Number of subjects on follow-up not receiving intervention: .
  3. Number of subjects completed study (no longer being followed): .
  4. Number of:
     1. Lost to Follow Up: \_\_\_\_\_
     2. Withdrawals: \_\_\_\_\_ Specify Reason:
     3. Deaths: \_\_\_\_\_ Specify Cause and if Related to Study:

1. In your opinion, does this amendment add increased risk to the study? \_\_\_Yes \_\_\_No

Please explain:

6. Is this amendment the result of an unanticipated problem involving risk to subjects or others (including adverse events): \_\_\_No OR \_\_\_ Yes. Specify institution where event occurred:

For amendments relating to new risk information, please attach all relevant information that would allow the Board to assess the risk data (e.g., SAE and UAP reports from eSAEy and eazUP, Medwatch reports, correspondence from sponsor, DSMB reports, FDA letters, data from previous studies, publications, etc.).

**Current Study Status:**

\_\_\_ Enrollment is active.

\_\_\_ Enrollment is closed. Subjects currently receiving study treatment.

\_\_\_ Enrollment is closed. Subjects not receiving study treatment. Study is in follow-up.

\_\_\_ Other – Specify:

**Re-Consent Determination (Complete if consent form has been revised):**

To maintain our primary objective of human subject protection, the following subjects will be re-consented in order to provide information, which may relate to the subjects’ willingness to continue participation:

**All subjects who received study intervention**

**All active subjects (not subjects 30 days\* post last treatment, in follow-up, withdrawn, or off study)**

**All active subjects including subjects 30 days\* post last treatment (not subjects in follow-up, withdrawn, or off study)**

**All active subjects including subjects 30 days\* post last treatment and in follow-up (not subjects withdrawn or off study)**

**Subjects will not be re-consented**

**Subjects will not be re-consented, but will be informed of the change(s)**

**The change to the consent form would require re-consent, but there are no subjects enrolled to be re-consented**

**Other (Specify):**

**\*Unless protocol indicates another time period. Specify:**

**Specify the reason/clarification for this determination if not described above in the summary of changes:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name** of Person Completing This Report Date Telephone/fax/e-mail

**Signature** of Principal Investigator Date Telephone/fax/e-mail