REQUEST FOR CHANGE IN PROTOCOL AND/OR CONSENT

SECTION I

IRB#:

TITLE OF PROTOCOL:

PRINCIPAL INVESTIGATOR:

DEPARTMENT:

CAMPUS ADDRESS:

Phone/Email:

Instructions: Per requirements of 45 CFR 46.103(b)(4) and 21 CFR56.108(a)(3)(4), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subject or provide important information germane to informed consent. In this circumstance, the IRB must be notified immediately.

The following information must be provided to the IRB as per the specific instructions in each subpart. The information should be typed.

Attach a revised IRB Application (with changes highlighted or underlined). If no changes are made to the IRB Application, then attach a copy of the protocol abstract. *Note: the IRB files must contain a complete and accurate description of the research; therefore, as described in Section II, changes must be accompanied by a revised IRB Application.*

CERTIFICATION OF PRINCIPAL INVESTIGATOR

Signature certifies that the proposed changes are necessary for scientific or administrative reasons or to protect or reduce risks to human subjects of the research. The investigator understands that, if approved by the IRB these changes become a permanent change to the protocol, and that all subsequent changes require prospective IRB approval before initiation.

_____ _____

Signature of Investigator Date

SECTION II

1. **Are there changes in study title?** If yes, then complete the following:
    a. Provide the current title (before the change).
    b. Provide the new (proposed) title. (Note whether this is a an *addition* to the current title, or a *replacement* of the current title)
    c. If the change in study title is related to a new or additional grant submission, specify the new funding source and include a copy of the grant along with the request for change form.

2. **Are there changes in eligibility criteria?** If yes, then complete the following:

For *each* change in eligibility:

a. Describe the current eligibility criterion (before the change).
b. Describe the new (proposed) criterion.
c. Provide the rationale or justification for the change.
d. Will the change in eligibility affect the potential risks of the research (that is, will the new subject population experience increased or different risks)?
e. Will the change in eligibility affect the potential benefits of the research?

Note: Changes in eligibility must be accompanied by an amended IRB Application with revised Sections II.8 and/or 9, and other sections as appropriate.

3. **Are there changes in accrual?** If yes, then complete the following:

    a. What is the *new* maximum number of subjects (at Oakwood University IRB approved performance sites listed in Section I of the IRB application)? *Note: The IRB approves a maximum number of subjects to be enrolled. NOT the number of subjects who are actually evaluable for the aims of the research. "Enrolled" subjects are persons who have agreed to participate in the research and have signed the consent form.*

    b. What is the statistical or other justification for the new maximum accrual requested?

Note: Changes in accrual must be accompanied by an amended IRB Application with a revised Section II.3 and other sections as appropriate.

4. **Are there changes in methods or procedures which affect human subjects?** If yes, then complete the following:

    For *each* change in methods or procedures (interventions):

    a. Describe the current method or procedure (before the change).
    b. Describe the new (proposed) method or procedure.

c. Provide the rationale or justification for the change.
d. Will the change in methods or procedures affect the potential risks of the research (that is, will subjects experience increased or different risks)?
e. Will the change in methods or procedures affect the potential benefits of the research?
f. Will the change require already enrolled subjects to be re-consented? If re-consent is required then describe the process of re-consent in Section II.9 below. If re-consent will not be required then provide rationale.

Note: Changes in methods and procedures must be accompanied by an amended IRB Application with a revised Section II.10 and other sections as appropriate.

5. Are there administrative and other changes which do not affect human subjects/

If yes, attach a list of the changes, including, as appropriate, justification for changes. Note: Copies of a revised protocol or amendment and cover letter from the study sponsor may be submitted in lieu of this list.

6. Are there changes in consent form risk statements which are not described above? If yes, then complete the following:

For each change related to addition or modification of risk statements:

a. Describe the current risk statement (before the change).
b. Describe the new (proposed) risk statement.
c. Provide the rationale or justification for the change.
d. Was the new or modified risk the result of one or more adverse events reported to the IRB? If so, describe the events(s).
e. Will the change require already enrolled subjects to be re-consented? If re-consent is required then describe the process of re-consent in Section II.8 below. If re-consent will not be required then provide rationale.

Note: Changes in risk statement must be accompanied by an amended IRB Application with a revised section II.12 and other sections as appropriate.

Note: Copies of revised consent/assent forms must be submitted with the changes highlighted or underlined.

7. Are there other changes in consent forms not described above? If yes, attach a list of the changes, including, as appropriate, justification for changes. Note: Copies of revised consent/assent forms must be submitted with the changes highlighted or underlined.

8. Are there changes in study personnel? If yes, then complete the following:
   a. List study personnel to be added. Classify any additional personnel as investigator, participating personnel, or administrative or data management personnel.

b. List study personnel to be deleted.

Note: Changes in methods and procedures must be accompanied by an amended IRB Application with a revised Section II (for Behavioral and Social Science Research) as appropriate.

Note Copies of revised consent/assent forms must be submitted with the names of any added personnel highlighted.

Note: All personnel added to the protocol must be trained prior to approval of the change.

9. Process of Re-Consent/Assent.

Note: Significant new finding (for example, previously unknown side effects) developed during the course of the research or information concerning changes in protocol that may related to the subject's willingness to continue participating must be provided to the subject [45CFR46.116.b(5) and 21CFR50.116.b(5)]. In this section, the investigator must describe the process of re-consent. Copies of revised consent and assent forms and/or amendments to the consent form must be submitted, with the changes highlighted or underlined.

a. Describe the process of obtaining re-consent from already enrolled subjects.
b. What is the location where re-consent will be negotiated, and how is the environment conducive to discussion and thoughtful consideration?
c. How much time will be allotted to the process of re-consent?
d. If children or adolescents are subjects of the research, how will the process of re-assent be structured for those subjects?

Materials to be submitted (as applicable):

1. **One original and one copy of this form.**
2. **Revised IRB Application (with changes highlighted or underlined) including protocol abstract, or if no revisions are made, a copy of the protocol abstract alone.**
3. **One copy of the revised consent form with changes highlighted or underlined.**
4. **Two copies of the revised consent form without highlighting or underlining. Originals should be suitable for reproduction (printed single sided using a 12 point font). Upon IRB approval, this form will be stamped with the date of the next valid approval period.**
5. **If applicable, one copy of any correspondence from the sponsor related to this change, including amendments, revised protocols and revised investigator brochures.**