**Institutional Review Board**

**CHANGE REQUEST FORM**

*Human Research & Compliance* |LOMA LINDA UNIVERSITY HEALTH | Office of Research Affairs

24887 Taylor Street, Suite 202 Loma Linda, CA 92350 *(909) 558-4531 (voice) /e-mail: irb@llu.edu*

Principal Investigator:

Department:

Protocol Title:

IRB #: Approval End Date:

Current Stipulations:

1. **This Change Request is a result of: (check all that apply)**

Initiated by Sponsor.

Initiated by local (LLU) Investigator.

Protocol change was necessary to eliminate apparent immediate hazards to subject(s).

1. **Protocol Change(s):**
2. Briefly summarize this Change Report, using the preferred wording to appear in the IRB's approval letter.  
   (This is also the only description appearing in future protocol profiles.)

Does this change require notification only and does NOT require confirmation of IRB approval?

No; fill out the rest of this form.

Yes;

b. Classification of significant change(s):

SAFETY

1a. List any change(s) in monitoring (number each change):

1b. If any item(s) listed above DECREASE monitoring, explain why subject safety will NOT be adversely affected.

PROCEDURES

2a. List any change(s) in subject-related intervention (number each change):

2b. What is the scientific justification for item(s) above, and explain how risk to subjects is affected:

SUBJECTS

3a. List any change(s) that remove exclusion criteria or broaden inclusion criteria (number each change):

3b. Justify any item(s) above that remove safety exclusion or modifies fairness in subject selection:

ADMINISTRATIVE

4a. Change study title of IRB approval to the following:

4b. If study personnel will be changed, use the “Request to Change IRB Study Personnel” form.

1. If an updated Investigator's Brochure or Supplement accompanies this Change Request, choose one of the following options:

Attach a Summary of specific changes addressed in the Investigator's brochure.

Principal Investigator will review Investigator's brochure and attest to nonsubstantive content of changes.

1. **Change(s) in informed consent:**
2. Does the Change Request affect the process of obtaining informed consent?  
    No

Yes, describe:

1. Does the Change Request affect the IRB-approved Informed Consent Document (ICD)?  
    No

Yes, *submit revised ICD with changes highlighted for IRB review/approval, and clean copy for the IRB authorization stamp.*

1. Does the Change Request involve re-consenting subject(s) already enrolled?

No, provide a brief rationale:       *If rationale includes reference to existing IRB-approved consent document, check here*  and attach highlighted section of consent.

Yes, describe how this will occur:       If a new consent document will be used, check here  and attach for IRB review/approval.

1. **CHECKLIST OF ITEMS TO INCLUDE:**

Revised consent document is attached, with a copy highlighting requested changes.

Bottom of Form

1. **PI’s ATTESTATION:**

I accept responsibility for the factual content of this report and am available for discussion if additional questions are raised.

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Signature of Principal Investigator Date

**OFFICE USE ONLY**

**IRB ACKNOWLEDGEMENT and REPORT TO PRINCIPAL INVESTIGATOR.**

Change Report is accepted as submitted. Summary will appear in the Research Report for this study at the conclusion of this study’s approval period.

Further information required, as follows:

PI needs consultation with IRB chair.

Amendment requires full board review.

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Signature of IRB Representative Date

Version date10/14/2020