Appendix E

Form 3

CENTRA HEALTH-- Institutional Review Board

MODIFICATION OF APPROVED HUMAN SUBJECTS RESEARCH

Version 6, November 15, 2016

This application is to seek approval for a modification to a currently approved study. Any proposed changes to previously approved human subjects research must be reviewed and approved by the IRB prior to implementation. This includes modifications to the study, inclusion or exclusion criteria, recruitment methods, research personnel, or *any* new or revised study materials. If the modifications reported relate to or implicate a Related Party, Financial Interest or potential Conflict of Interest, the Conflict of Interest Questions and Certification attached here must be completed. Approval is required for all modifications whether initiated by the investigator or external sponsor. **This form should not be used to report violations and deviations.**

Instructions for Submitting

Include with your submission the items indicated in the list on the next page, where applicable.

Submission Instructions

This form is in Word format.

- Click into the highlighted area ( ) requesting an answer and type your answers into the form.
- Save the form.
- Send the application and all other pertinent documentation (ie protocol, informed consent, etc.) electronically via email to irb@centrahealth.com.

Address for all Applications and Other Correspondence

irb@centrahealth.com electronically or

Centra Health IRB
Administration
1901 Tate Springs Road
Lynchburg, VA 24501

CENTRA HEALTH Institutional Review Board
MODIFICATION OF APPROVED HUMAN SUBJECTS RESEARCH
Version 6, November 16,2016

Centra IRB
Received (date):

Action:

Include the items indicated, where applicable:

- *Check* the relevant items below and include one copy of all checked items 1-5 in the order listed.
- Also include one additional collated set of copies (sorted in the order listed) for items 1 and 2.

→ **Applications will be returned if these instructions are not followed.**

Check	Item	Total No. of Copies
□	1. A concise summary of the requested modification using this form. List and describe each proposed change to aid in IRB review. Add pages as necessary. Provide a concise summary of changes when submitting an updated Investigator Brochure or Master Protocol.	1
□	2. New or revised consent forms, questionnaires, surveys, recruitment materials, advertisements, etc. One copy should have changes highlighted by underlining, and the other clean copy will be used for stamping.	1 highlighted 1 clean
□	3. If you have made substantive changes to the study design or procedures, submit a revised full IRB application with changes highlighted by underlining. If you are making changes only to the first page, just submit that page.	1
□	4. The sponsor's document describing the amendment, if any.	1
□	5. If adding personnel, include name, location (Centra Health or specific outside location), role, and email address for each person who should receive electronic copies of IRB correspondence to PI.	1

IRB study #: IRB of Record: _____ **Date:**

Title of Study:

Principal Investigator: **Study Coordinator:** (if applicable)

For industry sponsored research (if applicable):

Sponsor's master protocol version #: Version date:
Investigator Brochure version #: Version date:
IND (Investigational New Drug) #: IDE (Investigational Device Exemption #:

Any other details you need documented on IRB approval:

1. **List and describe each proposed change:**

2. **Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?** ___yes ___no
   If yes, explain, including whether these events or findings are relevant to participants' willingness to continue.

3. **Do any of the proposed changes increase risk?** ___yes ___no If yes, explain.

_____ _____
Signature of Principal Investigator Date
Typing me name on the line above constitutes an electronic signature.

Centra Institutional Review Board
Conflict of Interest Questions and Certification

The following questions apply to **all IRB Principal Investigators and/or Study Doctors and Study Coordinators** engaged in the design, conduct, or reporting results of this project **and/or Related Party.**

Definitions:

Related Party is the Principal Investigator's and/or Study Doctor and Study Coordinator's spouse, domestic partner, or dependent children, siblings, parents or equivalents by marriage, or other individuals residing in the PI/Study Coordinator's household.

Financial Interest: Anything of monetary value received from a financially interested company, including but not limited to: director's fees; consulting fees; honoraria; gifts; other emoluments or "in kind" compensation such as travel and entertainment (including those from a third party if the original source is a financially interested company), for any services not directly related to the reasonable costs of conducting the research as specified in the research agreement; equity interest (*e.g.*, stocks, stock options, convertible notes, other ownership interests); and intellectual property rights (*e.g.*, license fees, current and future royalties from patents and copyrights).
The term "Financial Interest" does not include:

i. Salary or other remuneration received from [Hospital];

ii. Holdings in mutual funds;

iii. De minimus gifts whose aggregate value does not exceed $100 per annum; or reasonable business expenses, including travel and meals provided in the regular course of business.

Conflict of Interest: means any situation or circumstance in which an IRB Member or a Related Party has a financial, personal, or other interest (including, but not limited to, an Individual Interest, Financial Interest, or Institutional Interest) which conflicts with, compromises, or has the appearance of conflicting with or compromising the individual's independent judgment and objectively rendering the member incapable of making an unbiased and objective decision regarding the research.

1. Currently or during the term of this research study, does any member of the research team or a Related Party have or expect to have:		
(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? Explain: _____ _____ _____	__ yes	__ no
(b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no
(c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? Explain: _____ _____ _____	__ yes	__ no

(d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no
2. Has Centra Health or has Centra Health-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team? Explain: _____ _____ _____	__ yes	__ no
3. Has Centra Health or has a Centra Health-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project? Explain: _____ _____ _____	__ yes	__ no

If the answer to ANY of the questions above is *yes*, list name(s) of all research team members for whom any answer to the questions above is *yes*:

_____

<u>Certification by Principal Investigator/Study Doctor/Study Coordinator</u>. By submitting this IRB application, I (the PI/Study Doctor/Study Coordinator) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every Centra Health employee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered "yes" to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential Conflicts of Interest that exist in relation to my study are reported as required by IRB policy.

_____ _____

Signature of Principal Investigator Date

Typing my name on the line above constitutes an electronic signature.

_____ _____

Signature of Study Coordinator Date

Typing my name on the line above constitutes an electronic signature.