Form 4

CENTRA HEALTH-- Institutional Review Board

REPORTS OF APPROVED HUMAN SUBJECTS RESEARCH

Version 4 17MAR2020

This application is to report correspondence or progress to a currently approved study. Ie: report is requested more frequent than annually.

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 as a pdf via email to irb@centrahealth.com.

Address for all Applications and Other Correspondence

irb@centrahealth.com electronically

CENTRA HEALTH Institutional Review Board
REPORT OF APPROVED HUMAN SUBJECTS RESEARCH
Version 4 17MAR2020

Centra IRB Received (date):

Action:

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

Title of Study:

Continuing Review

1. Number of local subjects accrued since last report and total.

2. Summary of any unanticipated problems.

3. Summary of adverse events. Did they occur at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and the investigator brochure?

4. Summary of circumstances that lead to the withdrawal of any local subjects.

5. Summary of any local complaints about the research.

6. Summary of any new literature that is relevant to the research.

7. Review of any amendments or modifications to the research since the last report, any modifications to the protocol previously approved.

8. Copies of any revised consent documents since the last local review.

9. Summary of currently available study-wide adverse events and/or interim findings and monitoring entity's assessment of the information reviewed.

10. Other: _____

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:

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