REQUEST FOR RENEWAL/UPDATE OF IRB APPROVAL **Form 2A** OR STUDY CLOSURE **Form 2B**

Version 9 17MAR2020

This application is to seek renewal or to report closure of a human subjects research project that has been approved by the IRB. All studies require continuing IRB review at intervals appropriate to the degree of risk, but at least once per year. Conducting human subject research without current IRB approval is a violation of federal and institutional regulations. *If IRB approval of a project expires prior to the renewal of approval by the IRB, it is considered a lapsed study and all research-related procedures must halt, except where doing so would jeopardize the welfare of the human subjects.*

If the study involving Human Subjects Research has ended:

- Complete and submit only the progress report (i.e., *Conflict of Interest page is inapplicable*).

If the research is continuing:

- Include the items identified in the checklist, next page.

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 IRB Received (date):

Action:

If the research is continuing:

- Check the relevant items.

Check	Item
□	1. This form (renewal/update or closure).
□	2. Any items specifically requested in questions # 4 through 9 (in that order).
□	3. This application should be updated to include any modifications since the study was initially approved or last renewed. **If there are any new modifications included with this renewal, highlight the proposed modifications by underlining.**
□	4. Clean copies of all consent document(s) to be used in the upcoming approval period, for stamping, if applicable. ICF are only required if there are changes to the ICF.

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

Title of Study:

Principal Investigator: **Study Coordinator:**

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. In a few sentences, describe the past year's work, and describe what you plan for the upcoming year, including data analysis, if relevant.

2. Number of subjects involved through direct contact or use of their data (Note: **b+d** should not be larger than **a**)

a. Total local projected number as approved by IRB:
b. Total number of subjects involved to date locally (for clinical trials include "screen failures"):

c. Number of subjects added since last renewal locally:
d. Number to be included in upcoming year locally:
e. Total enrollment for the study:

Answer the following questions based on information since initial approval or last renewal. Only include subjects covered by this IRB.

3. Have there been any modifications approved since the last review? If your IRB application has not already been updated to reflect these changes, do so now and attach any revised documents, including application and/or consent documents. (Not required for updates.)	__ yes __ no
4. Have any local subjects withdrawn voluntarily or been withdrawn from the study? **If yes, explain**; give number and reasons for withdrawals.	__ yes __ no
5. Have there been any complaints about the research from local subjects or others? **If yes, explain**	__ yes __ no
6. Have there been any findings (e.g., publications, new information) that alter the risk/benefit ratio or otherwise impact the study? **If yes, explain, including whether these new findings are relevant to participants' willingness to continue**.	__ yes __ no
7. Have there been any relevant multi-center reports? **If yes, provide a copy of the report**.	__ yes __ no
8. Does this study have a Data and Safety Monitoring Committee (DSMC or DSMB)? **If yes, provide a report** from the DSMC.	__ yes __ no
9. Have there been local unanticipated problems or serious adverse events that have not previously been submitted to the IRB? **If yes, include all appropriate copies**. If copies have been sent to the IRB in the past, please note the date(s) of the letter to the IRB.	__ yes __ no
10. Has this study been audited by external sponsor or monitor since approved or last renewed? **If yes, include a copy** of the audit report.	__ yes __ no
11. Are you requesting any changes to the study or consent documents? **If yes, include the form** requesting *Modification of Approved Human Subjects Research* and underline the proposed change in the updated application and/or consent documents. (Not required for updates.)	__ yes __ no
12. Studies that involve surveying employees require Human Resource approval which must be obtained prior to application submission to the IRB. The contact for the Human Resource Department is HR Director at 434-200-5342.	

Action requested by Principal Investigator (choose only one):

Renew approval:

__ Study has always involved *only* analysis of existing data or specimens. Continue as approved.

Study involves(ed) direct interaction/intervention or contact with subjects:

__ Continue as approved: Enrollment of new subjects continues.

__ Enrollment of new subjects closed; interaction/intervention with previously enrolled subjects continues.

__ Direct interaction with subjects completed but subsequent monitoring or follow up continues.

__ Subjects' involvement completed but renewal is requested for data analysis.

Closure of Study:

__ Research completed: Identifiable data or human biological specimens are stored according to plan already approved by the IRB.

__ Research completed: All data or human biological specimens are deidentified.

__ Lack of funding or other *(specify):*

_____ _____

Signature of Principal Investigator Date

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

(Not applicable if Closure)

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.

A.3.1. 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	__ yes	__ no

gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? Explain: _____ _____ _____		
(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
A.3.2. 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
A.3.3. 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.