Appendix I

Form 7

CENTRA HEALTH-- Institutional Review Board

HIPAA AUTHORIZATION

Version 1, 23JUN2015

You must have each participant sign this form if your study will use Protected Health Information (PHI) [e.g., existing data, records or specimens (including electronic information from a clinical database)].

Instructions for Submitting

Include a sample of your form with your submission.

Submission Instructions
This form is in Word format.

- For each number, italicized text/bullets that are not applicable to your study should be deleted.
- Save the form and send with application.

Address for all Applications and Other Correspondence

irb@centrahealth.com electronically or

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

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

Principal Investigator:

Phone number:

Research Staff needing access to protected health information:
[As approved by IRB in Application Section A]

Study Title:

During the research study, your doctors, their staff, their agents and hospital personnel (collectively called the "Researchers") will be collecting health information about you that is called "protected health information" or "PHI." PHI is protected under a federal privacy law called the Health Insurance Portability and Accountability Act (HIPAA) (45 C.F.R. Parts 160 and 164). By signing this form, you are giving your written permission for the Researchers, as well as the study Sponsor ***[INSERT SPONSOR NAME]*** and the Sponsor's agents and contractors (collectively called the "Sponsor Group") to use and disclose (share) your PHI for the purposes described below:

1. These are the types of your PHI that may be used and shared in the study:
    - *[State PHI elements that will be used and shared, e.g., name, gender, initials, address, telephone number, date of birth, dates of hospitalization, social security number and insurance information;*
    - *All information in your medical record, the results of physical exams and tests, your medical history and other data collected during the study;*
    - *Insurance reimbursement information (e.g., bills for hospital care, physicians services, laboratory tests, diagnostic procedures, drugs, etc.); and*
    - *Information contained in your medical records prepared by other healthcare providers from whom you have sought medical care while taking part in the study.]*

2. The Researchers may:
    - *[State how Researchers will use and disclose PHI, e.g., Receive, use and share your PHI to conduct the study;*
    - *Share your PHI with the Sponsor Group;*
    - *Share your PHI, as required by law, and with representatives of government organizations, review boards, including the [Insert Institution Name] IRB, and*

others who are required to watch over the safety and effectiveness of medical products or the conduct of medical research; and

- *Remove from your health information your name, and to the extent feasible, other information that could be used to identify you.]*

3. The Sponsor Group may:
    - *[State how Sponsors will use and disclose PHI, e.g., Receive, use and share your PHI to conduct the study and as required by law;*
    - *Use and share your PHI as described in the Informed Consent form and in this Authorization;*
    - *Use and share your insurance information (e.g., hospital and doctor bills, bills for laboratory test, diagnostic procedures, drugs, etc.) for reimbursement purposes;*
    - *Share your PHI with representatives of US and foreign government agencies, review boards and others who watch over the safety and effectiveness of medical products and research activities;*
    - *Use and share your PHI for internal reference, for comparison with other data, to help design subsequent trials, and in regulatory papers submitted to United States and foreign regulatory agencies for later developed products; and*
    - *Remove from your health information, your name, and to the extent feasible, other information that could be used to identify you.]*

4. Please note:
    - After your PHI is given to someone other than the Researchers, federal privacy laws might not protect the PHI from further use or disclosure. However, the Researchers and Sponsor Group will protect your PHI by using and disclosing it only as permitted by you in this Authorization.
    - You do not have to sign this Authorization, but if you do not, you will not be able to be in the study if the study involves treatment.
    - Your medical treatment, payment for services, enrollment and eligibility for benefits will not be based on whether or not you sign this Authorization.
    - This Authorization has not expiration (ending) date.

      By signing this consent form, you authorize the use and disclosure of health information about you as described above. You have the right to revoke this authorization, in writing, at any time by sending written notification to ***[insert name and address]***. If your revoke your authorization for use and disclosure of health information for research purposes, you will be discontinued from the research. However, the principal investigator, hospital, sponsor and its

researchers may still use and disclose health information that has already been obtained as permitted in this authorization to maintain the reliability of the research.

- If you withdraw this Authorization, your PHI that has already been shared may continue to be used and shared to maintain the integrity of the research.
- While the Study is taking place, you will not be allowed to see your health information that is created or collected during the study. After the study is finished; however, you may see this information if you ask your doctor, in writing.
- The results of the study may be published in scientific journals or presented at medical meetings, but your name and identify will not be disclosed in them.

PATIENT'S HIPAA AUTHORIZATION

By signing this Authorization form, I give my written permission for my Protected Health Information to be used and collected as described in this form. I have been given a copy of this signed Authorization.

_____/ _____
Signature of Patient Date

_____
Printed Name of Participant

OR

_____/ _____
Signature of Legal Authorized Representative & their relationship Date

_____
Printed name of Legal Authorized Representative & their relationship