

HIPAA ADDENDUM

To the Patient Informed Consent Document

Authorization to Use, Create, and Disclose Protected Health Information

Protocol Title:

There is a requirement under U.S. federal law called the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 160 & 164) that requires protection of your health and medical information so that it is kept private and confidential to the greatest extent possible. Protected health information includes information that identifies you (for example, your name, date of birth, social security number, etc.) and clinical data. As a research study participant, it is necessary to collect clinical data and information that identifies you. Clinical data includes, but is not limited to: your medical history, laboratory and medical imaging test results, blood or tissue sample results, physical examination findings, and information about the course of your health condition.

As a study subject, if you sign this form you authorize access to your protected health information by the following agents:

- ◆ The Principal Investigator of the study, ***[Principal Investigator's Name]***
- ◆ The research staff at ***[Institutions Name, if more than one institution is involved list all institutions names.]***
- ◆ St. Luke's Health System Institutional Review Board that governs this research study.
- ◆ Representatives of ***[Sponsor's Name and any data coordinating / research administration facilities they may use to conduct the study.]***
- ◆ Representatives from the United States and foreign health authorities.

These parties may review your protected health information to confirm information about you as related to your participation in this study.

Once your information is disclosed to the study, ***[Sponsor's Name and any data coordinating / research administration facilities they may use to conduct the study.]***, the IRB or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by US federal privacy regulations. The laws of your state may provide further protection. While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the study is completed. You have the right to see a copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

Authorization for access to your protected health information has no expiration date. You may revoke (take back) your authorization of future access to your protected health information at any time, but it must be done in writing to ***[Principal Investigator's Name and address]***.

Data collected prior to your revocation will still be used or accessed by the parties listed on this form from that point forward. **If you revoke access to your protected health information by the parties listed on this form, then you may not continue in this study.**

Printed Name of Study Subject or Legally Authorized Representative

Signature of Study Subject or Legally Authorized Representative

Date Signed

If the subject's representative signed on behalf of the subject, include a description here regarding that individual's authority to act on behalf of the study subject.

Printed Name of Person Who Conducted the Informed Consent Discussion

Signature of Person Who Conducted the Informed Consent Discussion

Date Signed