HIPAA Language for Non Sponsored Studies

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see you personal health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in the Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor/investigator and staff will use your medical records and information created or collected during the study to conduct the study.

- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities (e.g. the Food and Drug Administration) [list any other groups or organizations that may have access to PHI] and the Rochester Regional Health Clinical Investigation Committee overseeing this study at RRH.

- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.

- Your original medical records, which may contain information that directly identifies you, may be reviewed by regulatory authorities and the Rochester Regional Health Clinical Investigation Committee overseeing this study at RRH. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.

- Your medical records and study data may be held and processed on computers.

- If research related procedures are performed within the Rochester Regional Health (RRH)(i.e. laboratory tests, imaging studies and clinical procedures) the results will be placed in your Electronic Medical Record (EMR). Once placed in

your EMR, results are accessible to appropriate RRH staff who are not part of the research team.

Your personal health information may no longer be protected by the HIPAA privacy rule once it is disclosed by your study doctor/investigator to other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor/investigator or RRH. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

Your authorization for the use and disclosures described in this Data Privacy Statement does not have an expiration date.