

HIPAA COMPLIANCE INFORMATION

Protocol Title:

Principal Investigator:

ADDENDUM TO INFORM CONSENT FORM FOR PARTICIPATING IN A HUMAN RESEARCH STUDY

(HIPAA AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION IN RESEARCH)

The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research. This form and the attached research consent form need to be kept together.

Purpose of this form:

You have been asked to take part in a research study. The consent form for this study describes your participation, and that information still applies. This addendum is required by the federal “Health Insurance Portability and Accountability Act” (HIPAA). The purpose is to get your permission (authorization) to use health information about you that is created by or used in connection with the research. If you are signing on behalf of someone other than yourself, this permission applies to that person’s health records.

Authorization to Use Health Information:

The investigators named above and their assistants will be allowed to see and to use your health information for this research study. We may share your health information with people at the hospital or Health Science Center who help with the research. We may share your information with other researchers outside of the Health Science Center [and John Peter Smith Health Network/insert any other participating institution \(if applicable\)](#) or with labs running additional tests. We may also share your information with people outside of the Health Science Center [and John Peter Smith Health Network/insert other participating institution \(if applicable\)](#) who are in charge of the research, pay for or work with us on the research, or by the U.S. Food and Drug Administration (FDA), in order to check for quality, safety or effectiveness. Some of these people make sure we do the research properly. The “confidentiality” section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the Health Science Center [and John Peter Smith Health Network/insert other participating institution \(if applicable\)](#) must obey may not protect your health information.

Page 1 of ____

Initials of Participant _____

Date _____

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. The information we might use or disclose includes:

List the personal health information or identifiers that will be collected specific to this study. *HIPAA requires a “specific and meaningful description” of the information. Information given can be written out or in bullet form. The description should be as specific as possible but should also be broad enough to cover ALL information that you think you will need during this study. Examples might include:*

[... supporting information from your entire medical record, results of lab tests, x-rays or other images, information from follow-up visits, billing and other financial records, diagnostic codes...]

For you to be in this research, we need your permission to collect and share this information.

Term of Authorization:

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information...*indicate how long subject’s information will be held OR if time frame for keeping record is uncertain insert “as long as necessary”...*, in case we need to look at it again. We will protect the information and keep it confidential.

Refusal to Sign/Right to Revoke:

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher listed on the attached consent form.

Insert Principal Investigator’s name and address

The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Questions regarding your privacy rights:

Any questions? Please ask Principal Investigator's Name, the principal investigator, by calling phone number. You can also call the Institutional Review Board, University of North Texas Health Science Center at Fort Worth, at 817-735-0409 with questions about the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

By signing this form, I am giving permission for the personal health information about _____ (print your name) to be collected and used as described above by the researchers and staff for the research study described in this form and the attached consent form. I will be given a copy of this authorization form after I have signed it.

Name of Participant (print)	Signature	Date
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Name of Person Conducting Informed Consent Discussion (print)	Signature	Date
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