LOCAL CONTEXT INFORMATION / HIPAA FOR INFORMED CONSENT DOCUMENT

Add applicable sites:
University of Texas Health Science Center at San Antonio (UT Health San Antonio)
University Health

How you may be contacted throughout the Study?
[Include statement if visits include email communication with subjects and not covered in the consent document]
The research team would like to communicate with you regarding your research visits via email, which uses an "encrypted" method for secure transmission. When one of the research team sends you an email, you will receive an email that says "[SECURE MESSAGE]" from a research team member with a link to open the message. When you click on the link it will take you to a secure website where you can read the message and reply after successful authentication. If you are not able to receive email, you may not be eligible to participate in the study.

[Include statement if study will use texting to communicate with subjects and not covered in the consent document]
The research team would like to communicate with you regarding your participation via text message. These messages may include information related to your participation in the study and payment information, if applicable. In order to do this, we will share your name and phone number with *UT Health San Antonio's secure texting platforms*. Standard text messaging rates will apply if you do choose to receive the text messages.
If you are not able to receive texts, you may not be eligible to participate in the study.

[Include statement if visits include telemedicine and not covered in the consent document]
Telemedicine/Telehealth Visits
Include consent form wording from Telemedicine/Telehealth Medical Service State Regulatory Requirements guidance document when not covered in consent form document.

What if a research-related injury occurs? *DO NOT replace industry sponsor wording when the sponsor is responsible for research-related injury. Research-related injury cannot be billed to insurance, consistent with the contract.*
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

***If** there are procedures that are occurring at non-affiliated off-site locations, add:*
What if an injury occurs off-site?
I UNDERSTAND AND AGREE THAT I MAY BE REQUIRED TO SIGN A RELEASE AND WAIVER WITH THE [insert name of facility] ("PREMISES") WHERE THE RESEARCH ACTIVITY WILL TAKE PLACE. UT HEALTH SAN ANTONIO DOES NOT OWN, OPERATE, CONTROL, OR MAINTAIN ANY OF THE PREMISES WHERE THE RESEARCH ACTIVITY PERFORMED FOR THE STUDY SHALL TAKE PLACE. UT HEALTH SAN ANTONIO HAS NO LEGAL AUTHORITY TO DIRECT THE PREMISES AND UT HEALTH SAN ANTONIO AND THE PREMISES ARE SEPARATE LEGAL ENTITIES.

Payments – Will there be any payments for participation?
If payment is being paid by a ClinCard add:
The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each [modify as appropriate – i.e., study visit]. Your name, address and date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

*Insert the following **only** if the payments will exceed $600 per subject*

If you are paid, the money you receive may be taxable. When the total payment is $600 or more in one calendar year, the institution must report the amount to the IRS. The IRS considers it earned income and treats it like any other income.
***AND** include if ClinCard is not being utilized:*
Your name, address and date of birth and social security number will be shared with the IRS for the purposes of compensation processing. This information will only be used for the administration of the compensation and will be kept strictly confidential.

***AND** If payment is being paid by a check issued by UTHSCSA, add:*
Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt and you may not receive a check.

After the paragraph giving the External IRB information, insert the following:
The University of Texas Health Science Center at San Antonio is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

HIPAA Authorization wording - Include all sections that are not part of the informed consent document:
Information about how this study will use your Protected Health Information (PHI)
Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study. In carrying out this research, the health information we will see and use about you will include: *[modify the below information as appropriate for your study include any "sensitive" information, such as HIV status, illegal drug use, pregnancy testing, genetic testing, mental health information]*

- your medical history and blood work,
- pathology, imaging and radiology reports and results of medical tests,
- information from interviews or from questionnaires,
- demographic information like your age, marital status, the type of work you do and the years of education you have completed,
- contact information such as your name, phone number, and/or email address.

We will get this information by [specify how the PHI will be gathered for your particular study. For example: by asking you, asking your doctor, by looking at your chart at (the name of health care facility)].

Include whenever a study involves 1) Web Universal Resource Locators (URLs) or Internet Protocol (IP) address numbers (e.g. Use of geolocation apps or devices or use of social media to track participants; or 2) Biometric Identifiers, including finger and voice prints or full face photographic images and any comparable images
During this study, we may request that you [describe activity eg, use app, etc] to help us collect information about you. The information we collect may include data that would include identifiers such as [modify as appropriate for your study] your URL or IP addresses, biometric identifiers which means a retina or iris scan, fingerprint, voiceprint, or record of hand or face geometry. This information will be used to [describe how the study will use the information (eg, track frequent places you visit, etc)].

We anticipate collecting this type of data XX times during your participation in this study. [If there are specific times that this information will be collected; describe that here] You may forget that you are being tracked, and the "device/app" may

record your visits to private locations. You will be able to disable or temporarily pause location tracking whenever you wish, however, doing so may compromise the study results.

Please indicate your willingness to [use this device/app], however, if you choose not to allow us to collect data from you using this device/app, you will not be able to participate in this study.

□ Yes
□ No

How will your PHI be shared?

Because it is research, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in conducting and overseeing this research study including:

***If** applicable, add/edit the following:*

- The sponsor of the study, [name the company], and the entities that they use to monitor, administer, or conduct the research
- The company funding the study;
- University approved texting platform
- The company [name the company] that makes the study drug/device;
- [if the study involves a drug or device regulated by the FDA regardless of whether test article is already approved, add:] The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research;
- The following collaborators at other institutions that are involved with the study: [insert name and institution – these are collaborators at institutions not affiliated with UTHSCSA IRB];
- [For studies with a DSMB/DSMC] The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason;
- The members of the local research team;
- Mobile application company or device manufacturer chosen for this research study may have access to your information and use it in other ways. There is also the chance that depending on the agreement the research team and the mobile application company established, the mobile application company may own some or all of your information
- Law enforcement agencies
- The Institutional Review Board and the Compliance Office of UT Health San Antonio, and other groups that oversee how research studies are carried out; and
- The Research offices at [select all appropriate, delete others:] UT Health San Antonio, South Texas Veterans Health Care System (STVHCS), University Health, Southwest Foundation for Biomedical Research, Southwest Research Institute, Christus Santa Rosa Health Care.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in this research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here. [This is a required element. If you believe it does not apply to your study, submit a request for an alteration of authorization using Form J.]

If the study involves obtaining genetic information include the following:

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside [name the study site or sites] for review or testing. We will use appropriate information security safeguards that meet applicable state and/or federal laws, rules, regulations designed to protect your data when it is being collected, stored and transmitted. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Include, as applicable:
We can provide some recommended tools and practices to prevent online tracking mechanisms and improve your online privacy. For practices, first check your web browser's privacy settings to enable "Do Not Track" and/or "Private Browsing." Please note such settings will not make you entirely anonymous, however, as your Internet Service Provider (ISP) or employer network can still track what pages you visit. For recommendations on how to improve online privacy go to: privacyrights.org.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you must provide this in writing and send your letter to [Insert name and complete mailing address of the person to whom a request to revoke must be sent]. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Include, if applicable You must revoke permissions or uninstall any mobile device applications for this study to stop sharing PHI.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. *[Explain any limitations that might affect the subjects' access to their PHI, for example: You will only have access to your PHI until [insert date or event]. OR, if the nature of the study makes it necessary or preferable to temporarily suspend access, explain this by adding: Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.*

How long will your PHI be used?
Choose one of the following, indicating when PHI will no longer be used. This element is required by HIPAA regulations to be in an authorization.

End of the study
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

***OR**, on a specific date*
By signing this form, you agree to let us use and disclose your health information for purposes of the study until (insert a specific date). This permission to use your personal health information expires on this date.

***OR**, for repositories*
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. There is no expiration date because repositories by their nature are intended to use stored materials continually. We do not know how long it will take us to finish doing all of the analyses and we will need to use your health information for as long as it takes.

NOTE: Effective 2/23/23, witness signature is no longer an institutional requirement.