Adapted Tele-Behavioral Activation Targeted to Increase Physical Activity in Depression

NCT04990401

IRB Approved Date: 6/29/2023

Title of Study: Adapted Tele-Behavioral Activation Targeted to Increase Physical Activity in Depression

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

The purpose of this research study is to improve physical activity adherence among individuals with depressive symptoms by offering an adapted Behavioral Activation Teletherapy (BAT) intervention that emphasizes physical activity and exercise facilitated through teletherapy. This is a two-phase study. You are volunteering to participate in the second phase.

Participants will undergo a screening visit that includes completion of depression and physical activity surveys, vitals, and medical history. Following screening, participants will complete 10 sessions of behavioral activation- based therapy over a 10 - 14-week period to evaluate the feasibility, acceptability, and implementation of the BAT intervention. Participants will also complete weekly questionnaires remotely. In addition to the screening visit and 10 intervention sessions, participants will complete 1-month and 2-month post-intervention sessions. Each visit will take 1 – 1.5 hours. Participants are asked to complete and monitor their physical activity according to the guidance of the study clinician. Total study duration 5-6 months.

The greatest risks of this study include the possibility of injury during physical activity and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below. Please take your time to review this information carefully.

Information about this form

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Research Site
In-person visits (2) will take place at the Center for Depression Research and Clinical Care (CDRC) at UT Southwestern Medical. Participants also have the option to come to the CDRC for intervention sessions.

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Madhukar H. Trivedi, MD, Department of

Psychiatry at UT Southwestern Medical Center.

Funding
National Institute of Mental Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to UT Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

Depressive disorders are chronic, recurrent disorders with significant disease burden. There is a need for innovative interventions to reduce depression recurrence inherent in current treatments and improve the physical health of persons with depressive symptoms.

You are asked to participate in this research study of behavioral activation teletherapy targeted to increase physical activity in depressed individuals because you have met the initial prescreening criteria.

The researchers will evaluate the feasibility, acceptability, and implementation of the Behavioral Activation Teletherapy. After optimizing the BAT intervention in Phase 1 of the study, the researchers will evaluate the feasibility and acceptability of its delivery, test preliminary outcomes, and determine the minimum number of sessions needed to achieve remission.

A description of this research study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you met the initial prescreening criteria as a person with depression and have an interest in increasing physical activity. Additional screening procedures will be completed following the signing of this consent form to confirm your eligibility for the research study.

How many people are expected to take part in this study?
This study will enroll approximately 50 study participants between the ages of 18 and 64.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 13 visits (2 in-person visits and 11 remote visits) with the researchers or study staff.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain, and which procedures will not have to be repeated. All procedures conducted during this study are for research purposes only.

Screening Procedures (In-Person)
- *Clinician Interviews:* Interviews with study clinician will be conducted throughout the study to assess depressive symptoms, mood, and feelings.
- *Self-report questionnaires:* You will be given different questionnaires to answer questions about how you are feeling and your physical activity.
- *Vitals:* We will measure your height and weight.
- *Medical clearance for physical activity:* Your PCP, OB/GYN, or the study physician will need to review your medical history via the SCQ and your physical activity readiness prior to screening visit and sign the Medical

Eligibility checklist to approve continuation in the study. If you do not have a PCP or OB/GYN or cannot schedule a visit, the study physician will review the documents if you are medically cleared to continue.

- *Review of medications:* You will talk with the study staff about any medicines you take.
- *Fitbit:* You will be provided with a Fitbit after eligibility criteria has been reviewed. You will need to wear the Fitbit during the duration of the study in order for the site to monitor your physical activity. You will be provided with instruction on how to properly use this device.

This visit will take approximately 1 hour – 1.5 hours.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and other possible options.

Study Procedures - as a participant, you will undergo the following procedures:

Behavioral Activation Teletherapy (BAT)
If you are determined to be eligible for the study after the screening visit, you will be scheduled for ten BAT intervention sessions. The first 10 BAT sessions and 1-month follow-up post-intervention will be conducted remotely, and the final visit at 2-months post-intervention will be conducted in-person. You will be required to have a MyChart account with UT Southwestern Medical Center to complete the teletherapy sessions. The study staff will provide you with instructions on how to set up MyChart and will answer any questions you may have.

Audio-recording: Audio-recordings of the BAT sessions will be completed to ensure high quality of data and treatment administration. These recordings will not include any private health information and will be safely stored and transmitted to Dr. Trivedi to ensure privacy. You will not be able to continue in the research study if you do not consent to audio-recording of BAT sessions.

_____ I allow the research staff to audio-record my behavioral activation teletherapy sessions and stored for quality assurance.

First BAT Session (1 hour – 1.5 hours, Remote)
The first session will allow the study clinician to better understand your depressive symptoms and physical activity goals/challenges. In addition to the teletherapy session, you will also complete:

- *Self-report questionnaires:* Prior to BAT intervention, you will complete questionnaires remotely to answer questions about how you are feeling and your physical activity.
- *Review of medications:* You will talk with the study staff about any changes in the medications you take.
- *Participant Homework:* You will need to read psychoeducational handouts, provided by the study staff, about depression, physical activity, and Behavioral Activation over the next week. You will be instructed to complete a diary of all activities completed during the upcoming week; a worksheet to track your schedule/calendar will be provided by the study staff.

BAT Sessions 2-10 (1 hour – 1.5 hours, Remote)
Sessions 2-10 will include meeting with the study clinician, reviewing homework/physical activity from the previous week, and depression symptoms. In addition to the teletherapy session, you will also complete:

- *Self-report questionnaires:* Prior to BAT intervention, you will complete questionnaires remotely to answer questions about how you are feeling and your physical activity.
- *Review of medications:* You will talk with the study staff about any changes in the medications you take.
- *Participant Homework:* You will complete BA activities discussed in session. You will continue to keep a diary of all activities completed during the upcoming week. Session 7 will also include reading a handout on relapse prevention.

One- and Two-Month Follow-Up Visits (1 hour – 1.5 hours, Remote)
Sessions 2-10 will include meeting with the study clinician, reviewing homework/physical activity from the previous week, and depression symptoms. In addition to the teletherapy session, you will also complete:

- *Self-report questionnaires:* Prior to BAT intervention, you will complete questionnaires remotely to answer questions about how you are feeling and your physical activity.
- *Review of medications:* You will talk with the study staff about any changes in the medications you take.

Fitbit and Fitabase (worn throughout study participation, beginning Week 0)
A Fitbit will be provided to you for the duration of the study to monitor your physical activity. You will need to have a smartphone so that the data can be synced with your phone and uploaded to Fitabase, a secure site where your physical activity data will be stored. Your PHI will be de-identified so that none of your personal information will be uploaded/saved to the website. The Fitbit will track your physical activity, which includes steps, activity intensity, METs (metabolic equivalent of task), energy expenditure, floors, sleep, and heart rate. The research team will ensure you have instruction to properly set-up the device. Please let the research team know if you have any questions. The Fitbit device will be dispensed at the end of screening visits after eligibility is confirmed and you will be allowed to keep the Fitbit after your study participation has ended.

Schedule of Assessments and Procedures

	Screening[a]	Core Intervention Weeks[i]								Booster	Booster	Post Study[b]	Post Study[b]
Visit/Session		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Week	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**11[c]**	**15**	**19[d]**
Pre-screen battery													
Inclusion/Exclusion Criteria Reviewed	X												
Demographics	X												
Physical Activity Readiness Questionnaire (PARQ)	X												
Medical Eligibility Checklist Form	X												
Self-Administered Comorbidity Questionnaire (SCQ)	X												
Concomitant Meds	X	X	X	X	X	X	X	X	X	X	X	X	X
MINI - Suicide, Psychosis and Mania/Hypomania modules	X												

Visit/Session		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Week	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**11[c]**	**15**	**19[d]**
Primary Outcomes													
PHQ-9[gh]	X	X	X	X	X	X	X	X	X	X	X	X	X
Fitabase/Fitbit[g]	X	X	X	X	X	X	X	X	X	X	X	X	X
International Physical Activity Questionnaire-Short Form (IPAQ-SF)		X			X				X				
Physical Activity Vital Signs (PAVS)[g]	X	X	X	X	X	X	X	X	X	X	X	X	X
Intervention													

BAT Form for Session Completion		X	X	X	X	X	X	X	X	X	X		
Weekly Activity Sheet		X	X	X	X	X	X	X	X	X	X		
Post-initial session questionnaire[e]		X											
Mid-point session questionnaire[e]					X								
Final Sessioln Feedback[ejk]													(X)
Mediating Variables[f]													
Positive and Negative Affect Schedule (PANAS)		X			X				X				
Dimensional Anhedonia Rating Scale (DARS)		X			X				X				
Multidimensional Fatigue Inventory (MFI-20)		X			X				X				
Rosenberg Self-Esteem Scale (RSES)		X			X				X				
Inventory of Depressive Symptomatology (IDS-SR)		X			X				X				
Emotion Regulation Questionnaire (ERQ)		X			X				X				
Covariates													
Generalized Anxiety Disorder Scale (GAD-7)[gh]	X	X	X	X	X	X	X	X	X	X	X	X	X
BMI (height/weight)	X												
Patient Adherence Questionnaire (PAQ)[g]	X	X	X	X	X	X	X	X	X	X	X	X	X
Safety and Tolerability													
Serious Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X
Adverse Event Reporting		X	X	X	X	X	X	X	X	X	X	X	X
Validity													
Behavioral Activation for Depression - Short Form[gh] (BAD-SF)		X	X	X	X	X	X	X	X	X	X	X	X

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

Risks from the research

The investigators have designed this study to learn how well the new intervention compares to commonly accepted treatment(s) for depression. There is a risk that the effectiveness and/or safety of BAT to increase physical activity may not be as good as the most commonly accepted treatments for depression. The BAT to increase physical

activity may not help treat your depression or it may make your condition worse.

Risks from the specific research procedures (interventions or procedures)
There are potential risks to taking part in this research study.

Potential psychological stress. The assessments and the intervention itself may cause unpleasant feelings or fatigue. During BAT sessions, you may experience emotional discomfort and sadness when discussing life events or material that might temporarily enhance a negative mood and discomfort at sharing personal information with someone that you do not know very well. You will be closely monitored by experienced research personnel and will be offered opportunities to take breaks or discontinue the study when appropriate.

Potential physical risks to exercise. Completing the psychotherapy intervention, which focuses on increasing physical activity and exercise, may introduce physical discomfort and/or pain. It will be determined at your screening visit whether you have any contraindications or limitations to exercise. The study staff will get medical clearance from your doctor or the study physician to confirm you can safely engage in physical activity before enrolling in the study.

Potential risks associated with Depression and/or Nonresponse to Treatment. It is possible that your depression symptoms could worsen during the study. Adverse mental health events, including suicidality, are possible in patients with depression. The study staff will ask you to provide information about a family member, friend, or doctor who will be your emergency contact. If the study staff become concerned about your safety during the study, we may reach out to your emergency contact unless you specify otherwise. If at any time during the study you develop serious thoughts about suicide or harming yourself, you should immediately contact Madhukar Trivedi, MD by calling 214-648-4689.

If we learn information from you during the study that indicates intent to seriously harm others or yourself, we may share that information with third parties, including authorities on public safety, law enforcement, or child abuse and neglect. We may take other precautions to protect against such harm.

Risk of loss of confidentiality. Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The information collected will be stored in locked cabinets in locked rooms, in our database with de-identified participant number. Audio-recordings will not contain any PHI and will be saved on a password-protected flash drive.

For more information about risks, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes collecting height and weight, returning your Fitbit, and completing self-report questionnaires. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
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.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating is, with increased physical activity, you may have improvement in self-esteem, energy, motivation, and depressive symptoms.

There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

The study clinician will discuss and inform you of available alternative treatment options. Your other choices may include other antidepressant medications, psychotherapy, transcranial magnetic stimulation (TMS), or electroconvulsive therapy (ECT).

Payments – Will there be any payments for participation?

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation of $25.00 will be credited to the card upon completion of visit/session 1 (Week 0), visit/session 4 (Week 3), visit/session 8 (Week 7), visit/session 10 (Week 11), and the one-month and two-month follow-up visits. The total possible amount earned for the study is $150.00. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.
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.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

The Behavioral Activation Teletherapy will be provided at no cost during this study. A Fitbit will also be provided to you for the duration of the study and will be allowed to keep the Fitbit at the end of your participation.

The standard medical care for your condition (care you would have received whether or not you were in the study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

Confidentiality – How will your records be kept confidential?

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.

Certificate of Confidentiality:

To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

How will my information be used?
Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

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. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

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 whose it 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 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 this research study. In carrying out this research, the health information we will see and use about you will include: your medical history, information we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to BAT, information that is created or collected during your participation in the treatment including medical and treatment history, information you give us during your participation in the study such as during 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.

We will get this information by asking you, asking your doctor, or by looking at your chart at UT Southwestern Medical Center.

How will your PHI be shared?

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

- The Sponsor, NIMH, funding the investigational treatment. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the treatment. The sponsor may look at your health information to assure the quality of the information used in the treatment.
- 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.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

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 the 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.

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 of the Center for Depression Research and Clinical Care at UT Southwestern for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

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 need to say this in writing and send your letter to:

Attn: Dr. Madhukar Trivedi, MD
UT Southwestern Medical Center
Department of Psychiatry
1440 Empire Central
Level 3 Mood Disorders
Dallas, TX 75247-9119

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.

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.

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?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until March 31, 2034. This permission to use your personal health information expires on the date noted above.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact our clinic at 214-648-4689. The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will 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 HRPP by calling the office at 214-648-3060.

Title of Study: Adapted Tele-Behavioral Activation Targeted to Increase Physical Activity in Depression

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time (AM / PM)

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time (AM / PM)

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)

I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time (AM / PM)

Printed Name of witness	Signature of witness	Date	Time (AM / PM)

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM