Protocol Title: Radiation Therapy to Enhance CAR T Efficacy Early in Post-CAR T Cell Therapy Refractory Lymphoma: A Pilot Study

DF/HCC Principal Research Doctor / Institution:
Chirayu Patel, MD, MPH / Massachusetts General Hospital

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study because you have refractory lymphoma shortly after receiving CAR T cell therapy.

2. Why is this research being done?

This study is being done to learn more about radiotherapy as a treatment option in participants who still have refractory lymphoma despite recently receiving CAR T cell therapy as a treatment for refractory lymphoma. Radiation therapy is a standard treatment offered to patients with refractory lymphoma – however, few patients have received CAR T cell therapy prior to radiation therapy. The aim is to gather more information from patients who undergo radiation therapy after CAR T cell therapy.

3. Who is supporting this research?

An internal grant at Massachusetts General Hospital is supporting this research by providing funding for the research study. Radiation therapy and surveillance imaging are standard-of-care and are not covered as research expenses.

4. What does this research study involve and how long will it last?

This research study involves receiving radiotherapy following CAR T cell therapy.

The research study procedures include screening for eligibility, enrollment, biopsy following radiation, post-treatment period, and long-term follow-up.

You will receive radiotherapy at a dose and schedule determined by your study doctor. You will then be followed for up to 24 months after completion of study treatment.

It is expected that about 20 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

5. What are the risks to participating in this study?

There are risks to taking part in any research study. We want to make sure you know about a few key risks right now. There may also be rare, serious and potentially life-threatening side effects. More detailed information is provided in the “What are the risks or discomforts of the research study?” section.

There is a risk that you could have side effects from the study procedures. These side effects may be worse and may be different than you would get with other approaches for your cancer.

Some of the most common side effects that the study doctors know about are:

From biopsy:

- Pain or discomfort at biopsy site
- Skin irritation
- Risk of infection

Standard risks from radiation therapy:

- Skin redness or itchiness
- Occasional irritation from skin peeling
- Fatigue

These risks will differ based on treatment site and your study doctor will discuss these as part of standard radiation therapy consent

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Receive standard treatment including chemotherapy or radiation therapy
- Decide not to participate in this research study
- Participate in another research study.
- Receive no therapy specific to your cancer.
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Pilot Study, which is the first time investigators are examining this intervention after administration of CAR T cell therapy.

In this research study, we want to systematically investigate the safety and efficacy of radiotherapy following CAR T cell therapy in refractory lymphoma. The CAR T cell therapy you have been receiving involves genetically modifying your T cells to target tumor cells for death. Radiotherapy uses high-energy x rays, or particles, to destroy or damage cancer cells. Radiotherapy following CAR T cell therapy may have the potential to improve your immune system's response to cancer cells. Further, radiotherapy may interact with CAR T cell therapy to better treat your disease.

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the Research Starts (Screening and Enrollment):

Before research begins, there will be a Screening and Enrollment Period. Screening will occur no longer than 14 days from tumor biopsy (biopsy must be within 90 days of CAR T infusion). After Screening is completed, study enrollment will occur within 28 days of screening. Radiotherapy on study will occur within 14 days after study enrollment.

Screening:
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies. Medical history may also include assessments of any symptoms of central nervous malignancy you may be experiencing, including severe headaches and neck stiffness.
- **Performance status,** which evaluates how you are able to carry on with your usual activities.
- **An assessment of your disease status,** which includes PET-CT (Positron Emission Tomography-Computerized Tomography) scan
- **Physical Exam,** which may include height and weight measurements.

- **Vital signs,** which includes blood pressure, heart rate, oxygen saturation and temperature measurements.
- **Blood tests, totaling approximately 2 tablespoons,** to check the health of various body systems via standard laboratory tests.
- **Tumor Biopsy** may be performed. Fresh tumor biopsies are preferred; however, archival tissue (previously collected and stored tissue) is acceptable if obtained prior to the screening period, but following CAR T infusion. A biopsy may not be performed at the discretion of your study doctor.
- **Not applicable to all patients: Lumbar Puncture,** also known as a spinal tap, may be performed to examine cerebral spinal fluid based on findings from physical exam. This will only be performed if you exhibit certain symptoms of the central nervous system, such as severe headaches or neck stiffness, as determined by your study doctor if there is concern for lymphoma involving the brain or spinal cord. A biopsy of suspected tumor within the brain or spinal cord may not be feasible – as such, CSF analysis can help provide information regarding the tumor pathology. This a procedure used to obtain a sample of cerebrospinal fluid (CSF). This fluid covers the brain and the spinal cord. When a lumbar puncture is performed, a hollow needle goes through the skin at the bottom of your spine, because this is where it can be done most easily and safely. The CSF comes out through the needle and a few drops are collected. Your study doctor may require CSF because it is the fluid that has come into closest contact with the brain itself. By analyzing the CSF, they will have more information about how the brain may be affected by a medical condition. You will feel a small sharp pinch at the site where the needle is inserted, and local or general anesthesia is often used to make the procedure pain-free.

If these tests show that you are eligible to participate in the research study, you may begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Enrollment:
Once Screening is complete, Enrollment will occur within 14 days of beginning radiotherapy. During Enrollment, you may undergo the following:

- **Questionnaires,** which will take approximately 20 minutes. Questionnaires include questions about how you are feeling and any symptoms you may be experiencing.
- **Radiotherapy Planning,** where your study doctor determines what dose and schedule of radiotherapy will be administered to you.

Study Treatment Overview:

- **Radiotherapy:** you will receive radiotherapy based on the dose and schedule determined by your study doctor.

Radiotherapy Treatment Period:
You will have weekly clinic visits during the Radiotherapy Treatment Period. The duration of the Radiotherapy Treatment Period depends on the radiotherapy schedule determined by your study doctor.

These visits may involve the following:

- **Radiotherapy**
- **Performance status**
- **Physical exam**
- **Vital signs**
- **Research blood samples, totaling approximately 2 tablespoons,** which may include the following:
  - Pharmacodynamics, to understand the effects of your previous CAR T cell therapy on your body following radiotherapy.
  - Biomarkers, which are indicators in the blood and may be related to how your body reacts to the study treatment.

Planned Follow-up:
We would like to keep track of your medical condition. Keeping in touch with you and checking your condition helps us look at the long-term effects of the research study.

There will be a Post-Radiotherapy Period and a Long-Term Follow-Up Period.

Post-Radiotherapy Period:
You will be seen weekly for one month following completion of radiotherapy.
These visits may involve the following:

- **Performance status**
- **Questionnaires**
- **Tumor Biopsy,** which will occur one time 7-14 days after completing radiotherapy. This may or may not be performed at the discretion of your study doctor.

- **Blood tests**
- **Research blood samples**

Long Term Follow-Up:
Long term follow up will continue through 12 months after last CAR T infusion. This follow-up period will allow detection of any delayed side effects and provide information about the long-term effects of the study treatment. Long-Term Follow-Up visits occur at 6, 9, and 12 months. After month 24, you will be followed via the CIBMTR immune effector cell therapy registry. The CIBMTR is an FDA mandated long-term follow-up registry for every individual treated with an immune effector cell therapy. The study team is required to submit this data.

These visits may include the following:
- **Physical exam**
- **Questionnaires**
- **An assessment of your disease status**, which includes a PET-CT scan at 6 and 12 months
- **Blood tests**
- **Research blood samples**

In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Research Study Plan:

	Screening	Enrollment	Radiotherapy		Post-Radiotherapy				Long Term Follow-Up
			Day 0	Weekly	Week 1	Week 2	Week 3	Week 4	6, 9, 12 Months
Medical History	X								
Performance Status	X		X	X	X				
Questionnaires		X			X				X
Tumor Biopsy	X[3]				X[1]				
Disease Assessment (PET-CT Scan)	X								X[2]
Radiotherapy Planning		X							
Physical Exam	X			X					X
Vital Signs	X			X					
Blood Tests	X		X	X	X	X	X	X	X
Research Blood Samples			X	X	X	X	X	X	X
Radiotherapy			X	X					

1. Will be collected per your study doctor's decision
2. PET-CT scan will occur at the 6- and 12-month visits
3. Tumor biopsy must be within 90 days of CAR T infusion

C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. One risk is that you may get a study treatment that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study treatment to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study treatment. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study treatment taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Risks Associated with Radiotherapy:

Likely (More than a 50% chance that this will happen)

- Dermatitis, or irritation of the skin such as an itchy rash or swollen reddened skin
- Fatigue
- Skin redness and itchiness
- Tissue scarring may occur with radiation therapy to the region where you will receive radiation. This risk is dependent on the radiation dose and the region to which you will receive radiation. For example, the skin and muscles where radiation is delivered may appear tougher to the touch months to years following radiation therapy. Tissue scarring can involve organs inside the body, such as lung or intestines, but it is rare that you would get any symptoms from this. The detailed radiation planning process helps to reduce the risk of symptoms from radiation scar tissue involving body organs (less than 5% chance of occurrence).

If treatment involves any regions of chest: possible (less than 50% chance of occurrence)

- Pneumonitis, or inflammation of the lungs. This may cause a cough, shortness of breath, and may require treatment with antibiotics and/or hospitalization

- Esophagitis, or inflammation, irritation or swelling of the esophagus (the tube that leads from the back of the mouth to the stomach)

Rare (<1% at 10 years following radiation):

- Years following radiation therapy, you have a small risk of developing a cancer within the radiation field that was caused by radiation therapy and is unrelated to your lymphoma. The treatment of this cancer would depend on the type of cancer that develops, and may or may not be curable.

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

Risks Associated with Biopsies:
Biopsies are normally performed under the guidance of an imaging technique. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Risks Associated with Lumbar Puncture:
Prior to the lumbar puncture, you will be given a local anesthetic to numb the area. The procedure may cause headache, local pain or discomfort, bleeding, or infection. After the procedure, you may develop a headache that may be accompanied by nausea, vomiting, and dizziness. There is a rare, but serious risk of cerebral herniation in which the brain is squeezed through the base of the skull, which may be fatal.

Reproductive Risks:
The treatment used in this research study may affect a fetus.

While participating in this research study, you should not:

- Become pregnant
- Nurse a baby
- Father a baby

We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

If your partner becomes pregnant while you are on the study, it may be critical to share information regarding your participation in this research study with that person. Your research doctor should also be told if this happens.

Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the study treatment.

In some cases, the abrupt stopping of a treatment can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

It is important to note that although you may withdraw from study participation, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from study records. Additionally, the research doctor may consult public records after you have withdrawn from the study.

E. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about refractory lymphoma.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

G. WHAT ARE YOUR COSTS?

Taking part in this research study may lead to added costs to you or your insurance company. This may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your disease. You may:

- Have more travel costs
- Need to take more time off work
- Have other additional personal costs

You or your insurance company will be charged for portions of your care during this research study that are considered standard care, including radiotherapy. Standard of care is the care that you would receive regardless of whether you were enrolled in the study or not. You may be responsible for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. This includes the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests, done for research only, are supplied at no charge.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Massachusetts General Hospital: (617) 726-2191

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov
or 1-800-4-CANCER (1-800-422-6237)

H. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.
If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

I. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Massachusetts General Hospital

- Chirayu Patel, MD, MPH: 617-724-2430

24-hour contact: Please contact Massachusetts General Hospital at 617-724-4000 and ask that your doctor be paged

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

J. RETURN OF RESEARCH RESULTS

Tests done on samples in this research study, with your identifiable information, will give results that have meaning for your health care. One of your doctors will share the clinically relevant research test results, such as biopsy and PET/CT scan results, with you. If you do not wish to receive the results from these research tests, please notify your study doctor.

K. CLINICALTRIALS.GOV (CT.GOV)

A description of this clinical trial 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.

L. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study may be stored and used for future research. Any personal identifiers will be removed, before they are shared, so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify and destroy them.

Investigators, including investigators from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.

Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research, if the samples and specimens are de-identified. There is a risk that you might be reidentified in the future as genetic research progresses

M. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a research database.

Participation in this study involves providing a specimen of your tissue; please know that if the research doctor leaves the institution, the research and the tissue might remain at the research doctor's current institute or might be transferred to another institution.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

Your de-identified specimens or genetic data may also be placed into one or more publicly-accessible scientific databases. Through such databases, researchers from around the world will have access to de-identified samples or data for future research.

There is a risk that de-identified research data that is shared with outside collaborators may be reidentified. When deidentified data and specimens are shared with outside

collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

N. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing the study intervention. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

O. GENETIC RESEARCH

This research will involve genomic or germline testing.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at http://www.genome.gov/10002328.

P. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the treatment used in the study and for the purpose of this or other research relating the study treatment and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor of the study, its subcontractors, representatives, business partners, and its agent: DF/HCC
- The funder of the study, its subcontractors, representatives, business partners, and its agent: Internal MGH Pilot Grant
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

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