Research Consent Form
for Biomedical Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates OHRS 04.07.14

Protocol Title: A single-arm open label biomarker study of standard-of-care Radium 223 chloride for metastatic castration-resistant prostate cancer

DF/HCC Principal Research Doctor / Institution:
Philip Saylor, MD/ Massachusetts General Hospital

A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have prostate cancer that is metastatic to your bones and has progressed despite androgen deprivation therapy (also known as "ADT" or as "hormonal therapy"). For purposes of this research, you will be referred to as a "participant". This research study is evaluating a drug called Radium-223 (Ra-223, brand name Xofigo). It is FDA approved for the treatment of prostate cancer like yours. This study makes use of Ra-223 in the standard FDA-approved way, but adds non-standard testing in an attempt to gain insight about how the drug works and how best to track patients who are receiving the drug.

It is expected that about 22 people at Massachusetts General Hospital will take part in this research study.

The sponsor of this study is Dana-Farber/Harvard Cancer Center. Bayer HealthCare Pharmaceuticals, Inc. and Blue Earth Diagnostics Ltd are also supporting this research study by providing funding for the research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

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 now and at any time in the future.

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B. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational intervention to learn whether the intervention works in treating a specific disease. "Investigational" means that the intervention is being studied.

This research study is designed to examine a treatment strategy that is standard but still relatively new. Ra-223 consists of a series of six infusions given once a month. It was FDA approved in 2013 for the treatment of prostate cancer like yours that has spread to bone and has grown despite ADT ("hormonal therapy").

Ra-223 was approved because it was shown to improve the length of the lives of the men with prostate cancer who received it. Despite that important benefit, it is not known to improve other standard markers of prostate cancer such as PSA blood tests (a blood marker that is used to track cancer activity in men who have prostate cancer) and standard imaging scans such as bone scans and computed tomography (CT) scans. If participants and their doctors do not have good markers of whether or not the cancer is responding to therapy, it is harder to make decisions about whether to continue that therapy. This is a current problem.

The purpose of this study is to look for markers of how Ra-223 improves the lives of men with prostate cancer. In this study, participants will receive standard Ra-223 treatment and be evaluated with standard and non-standard testing. The non-standard testing includes extra blood tests, non-standard analyses of standard scans, and in about half the participants two non-standard scans. These two categories of non-standard testing can be described briefly as follows:

1. Blood tests: In addition to standard blood tests for PSA and for safety, blood tests for non-standard markers of prostate cancer growth and activity will be performed throughout study participation. Non-standard markers include two methods of measuring circulating tumor cells, markers of bone remodeling, and markers of inflammation and new blood vessel formation.

2. Non-standard analyses of standard bone scans: Standard bone scans produce images of the skeleton with dark spots in areas representing prostate cancer involvement within bone. The standard method of interpreting these scans is for a radiologist to describe the change from one scan to the next using language rather than precise numbers.

Recently, experimental methods have been developed to allow computer programs to describe the changes with more precision. In this study, bone scans will be interpreted in both the standard way and the more precise computer-based way.

3. Non-standard scans: The test used in this study is called ^{18}F-fluciclovine Positron Emission Tomography (PET) / Magnetic Resonance Imaging (MRI) scanning. ^{18}F -fluciclovine is a radioactive tracer that is given by vein to participants before PET/MRI scanning. The PET scanner then detects radioactivity from the tracer that is in cells within your body and uses this information to create images (pictures) on a computer screen. ^{18}F -fluciclovine PET scanning has been shown in early studies to detect smaller amounts of prostate cancer than can be detected by standard imaging tests such as CT scan and bone scan. In addition, it is thought to be a more direct measure of tumor than bone scan. The fluciclovine is an FDA (U.S. Food and Drug Administration) approved tracer that is used for PET scans. Use of fluciclovine PET with MRI is investigational. "Investigational" means that it is still being studied and that research doctors are trying to find out more about it. It also means that the FDA has not approved this type of PET/MRI scan for your type of cancer. The information collected by this scan will determine whether this type of scanning is helpful but it will not be used to make decisions about your medical care.

If this study is successful, it will produce insights about how best to medically keep track of men who are receiving standard Ra-223 treatment for prostate cancer. It also may produce insights about the way that Ra-223 works against prostate cancer within the bones.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Receive standard Ra-223 treatment without study-related testing (i.e. the same drug, but not as part of a research study).
- Receive other standard treatment including hormonal agents (abiraterone with prednisone, enzalutamide, or others), chemotherapy (docetaxel, cabazitaxel, or others), immunotherapy with sipuleucel T, or other available treatments.

- Take part 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.

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

Before the research starts (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 and physical examination,** which includes questions about your health, current medications, and any allergies.
- **An assessment of your tumor** by the following standard assessment tools:
  -Bone Scan
  -CT (Computerized Tomography) scan
- **Blood tests,** about 40 mL of blood (less than three tablespoons) will be collected for research and other laboratory testing

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

After the screening procedures confirm that you are eligible to participate in the research study:

If you participate in this research study, you will be planned for six intravenous Ra-223 treatments. Each treatment cycle lasts 4 weeks during which you receive Ra-223 by intravenous infusion on day 1 only. Treatments are given monthly over the course of six months. These treatments are designed to be entirely standard. Extra testing during and after that six month period will be added to standard testing and monitoring. This is summarized below, first in paragraph form, then in a table.

Before treatment starts:
Fluciclovine PET/MRI will be carried out for approximately half of the study participants. This scan is designed to detect small amounts of your tumor that may not be detected by the CT scan or the bone scan. Your study doctor would discuss it with you in order to figure out whether you are willing and medically eligible to undergo this type of scan. If you are eligible and willing to undergo PET/MRI, you will be planned for this scan once before treatment starts and once prior to your third Ra-223 treatment. On the day of the scan, you will fast for at least four hours prior to being given the tracer injection by vein. You will then be scanned in the PET/MRI scanner. The entire procedure will take approximately 4 hours from start to finish. It takes place in on the MGH Charlestown campus (distinct from the main MGH campus but linked by shuttle).

Treatment 1, day 1:

- **Clinical Exam:** You will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Medical history,** which includes questions about your health, current medications, and any allergies.
- **Blood tests** that are both standard and non-standard. Standard blood tests for the function of your bone marrow and liver and kidneys will require approximately 2 teaspoons of blood. Non-standard tests will require an additional 3 to 4 tablespoons of blood. All blood on a given day will generally be obtained by way of a single successful needle stick.
- **Surveys** that are designed to ask you about your general health, any pain you are having, your day-to-day activities, and your use of pain relieving medications. They together are expected to require no more than 5 minutes to complete.
- **Drug:** If all relevant assessments indicate that it is safe to proceed with treatment, you will receive one standard dose of Ra-222 intravenously.

Three days after treatment 1, day 1:

- Blood testing that is non-standard. This will require approximately 4 teaspoons of blood.

Treatments 2, 3, 4, 5, and 6:

- Study procedures described in "Treatment 1, day 1" will be repeated every four weeks for treatments 2, 3, 4, 5, and 6. As before, standard blood tests will require approximately 2 teaspoons of blood. Based on the results of your prior testing, non-standard blood tests may require 1 to 4 tablespoons of blood.

Scan monitoring:

- **Scans (or Imaging tests):** After the start of your study treatment, we will assess your cancer by CT scan and bone scan (both standard) at two study-specified timepoints (before the third treatment, and one month after the sixth treatment).
- **Fluciclovine PET/MRI**: described above (under "Before treatment starts").

Monitoring after Ra-223 treatment concludes:

Monitoring after the conclusion of treatment will require three clinic visits that are 1 month, 4 months, and 18 months after conclusion of treatment. Each of these visits will include the following:

- **Clinical Exam:** You will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Medical history,** which includes questions about your health, current medications, and any allergies.
- **Blood tests** that are both standard and non-standard. Standard blood tests will require approximately 1 teaspoon of blood. Non-standard tests will require an additional 4 teaspoons of blood. All blood on a given day will generally be obtained by way of a single successful needle stick.
- **Surveys** that are designed to ask you about your general health, any pain you are having, your day-to-day activities, and your use of pain relieving medications. They together are expected to require no more than 5 minutes to complete.

Research Study Plan:

	S/B	C1 D1	C1 D4	C2	C3	C4	C5	C6	F/U 1M	F/U 4M	F/U 18M

		Wk 1	Wk 1	Wk 5	Wk 9	Wk 13	Wk 17	Wk 21	Wk 25	Wk 37	Wk 93
History & Physical Exam	X	X		X	X	X	X	X	X	X	X
Bone Scan	X				X				X		
CT Scan	X				X				X		
PET/MRI*	X				X						
Blood Samples		X	X	X	X	X	X	X	X	X	X
Drug Infusion		X		X	X	X	X	X			
Surveys about your symptoms		X		X	X	X	X	X	X	X	X

Note: One end of study visit will be conducted at the conclusion of study treatment if for any reason the study treatment stops prior to the sixth of six planned doses.
S: screening; B: baseline;
C1 D1: Ra-223 Cycle 1, Day 1
F/U 1M, follow-up visit 1 month after final Ra-223 administration
F/U 4M, follow-up visit 4 months after final Ra-223 administration
F/U 18M, follow-up visit 18 months after final Ra-223 administration
*PET/MRI will be discussed with you and will be carried out in approximately half of the study participants

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

Participants will receive the drugs on this study for six months as long as they do not experience intolerable side effects. Participants will be followed for 18 months after removal from protocol therapy

The research doctor may decide to take you off the research study for many reasons including if:

- 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
- Your condition worsens
- A decision is made to close the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed.

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. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

F. 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 drug or study dose of a drug 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. **Please be sure to tell your doctor or a member of the study team promptly if you experience unexpected, severe, or bothersome side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs 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 drug. 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 drugs 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.

Radium-223 Dichloride

The following side effects of the study drug have been observed in previous testing.

The side effects that occurred very commonly (in greater than or equal to 10 out of 100 patients) are:

- Nausea
- Vomiting
- Diarrhea (usually mild)
- Lowering of platelet counts which may increase the risk of bleeding (thrombocytopenia)
- Lowering of white blood cell counts which may increase the risk of infection (leukopenia and neutropenia),
- Reduced white blood cells, and red blood cells, and platelets, which can lead to increased risk for infection, fatigue/shortness of breath, and bleeding, oxygen shortage and immune function issues (Pancytopenia)
- Redness of the skin, pain and swelling at the site of the injection (injection site reactions)

It is important to be aware that there may be other side effects that are not yet known and cannot be foreseen. Side effects may go away after the treatment is stopped, but it is also possible that side effects may last a long time or forever. They may range from mild to life threatening. Therefore, it is important to tell the study doctor or study nurse immediately about any changes in health that may have occurred even if you do not think they are related to the study. All intravenous injections have a slight risk of pain, bruising, bleeding, infection, and rarely, fainting and/or nerve damage. Your study doctor may give you treatment to help control side effects.

Radium-223 dichloride has shown activity only on prostate cancer that has metastasized (spread) to your bones. Radium-223 will have no activity on prostate cancer in other areas in your body, such as lymph nodes.

Risks Associated with Contrast Agents Used During Scans:

There is a small risk with using a contrast agent that is injected into a vein during the scans. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study. Uncommonly, some people have allergic reactions (such as hives and

itching) to contrast agents. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare.

Risks Associated with Fluciclovine PET/MRI scanning:
Adverse reactions reported with fluciclovine occur at a rate of less than or equal to 1%. The most common adverse reactions have been injection site pain, injection site redness, and change in taste.

Radiation Risks Associated with Scans:
As part of this research study, the approximately ten participants will each undergo two fluciclovine PET/MRI scans utilizing radioactivity will be used to evaluate your disease. You would not undergo these scans if you did not participate in this study. These two scans are the only non-standard scan testing that is required by the study. The frequency of all other scans is the same as what you would receive as standard care. In the long term, over many years, there is a very low risk of developing a new cancer as a result of radiological evaluations.

Risks Associated with MRI Scans:
When having an MRI (Magnetic Resonance Imaging) scan, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your research doctor. Your doctor may give you a medication to make you feel more comfortable. As images are taken, a loud banging noise will be produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.

Reproductive Risks:
In the event that your partner becomes pregnant, 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. The study sponsors may want to collect data on your partner's pregnancy.

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.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

This study may or may not help you. This study may help researchers learn things that may help people in the future.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being 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.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

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 drug.

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

You will not be paid to take part in this study. We may use your samples and information to develop a new product or medical test to be sold. The sponsors and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

J. WHAT ARE THE COSTS?

Taking part in this research study might lead to added costs to you or your insurance company.

As the treatment you receive will be standard-of-care Ra-223, it will be billed to your insurance as though you were not participating in a research study.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care, including standard scans (CT and bone scan) and standard blood monitoring such as PSA and blood counts. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

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 is:

- 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)

K. WHAT HAPPENS IF I AM INJURED OR 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.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for any of the sponsors of this study to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

L. WHAT ABOUT 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 DF/HCC research database. The results of this research study may be published. You will not be identified in publications without your permission.

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.

M. 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

- Philip Saylor, MD: (617) 643-1763 or (617) 724-4000

You can also call Massachusetts General Hospital at 617-726-5130 and ask your doctor to be paged.

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (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.

N. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law 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 sponsors with information arising from an adverse event or other event that relates to the safety or toxicity of the drug for the purpose of this or other research relating the study drug and its use in cancer; 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 sponsors of the study, their subcontractors, and their agent(s): DF/HCC and Bayer and Blue Earth Diagnostics Ltd.
- 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?"

O. 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

DFCI Protocol Number: 14-375	Approved Date (DFCI IRB Approval): 08/04/2018
Date Posted for Use: 08/07/2018	

Adult Participants

To be completed by person obtaining consent:

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, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ 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 spoken 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 illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

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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