Research Consent Form
for Biomedical Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates OHRS 09.23.16a

Protocol Title: Ivabradine in the management of cardiac autonomic dysfunction associated with thoracic radiation therapy

DF/HCC Principal Research Doctor / Institution: Anju Nohria, MD/BWH/DFCI

DF/HCC Site-Responsible Research Doctor(s) / Institution(s):

BWH/DFCI: Anju Nohria, MD

BCH: Ming Hui Chen, MD

MGH: Tomas Neilan, MD

A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have a history of lymphoma that was treated with neck and/or chest radiation. Prior radiation treatment can cause abnormalities of the cardiac autonomic nervous system. The autonomic nervous system regulates changes in heart rate, the pumping efficiency of the heart, and blood pressure during exercise. Radiation induced abnormalities of the cardiac autonomic system can lead to decreased exercise tolerance and decreased survival in some people. This research study is studying a drug called Ivabradine. Our study will explore the effect that ivabradine treatment has on survivors of lymphoma who have cardiac autonomic dysfunction as a side effect of prior radiation treatment.

The names of the study drugs involved in this study are:

- *Ivabradine and*
- *Placebo*

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

It is expected that about 60 people will take part in this research study.

Amgen, a pharmaceutical company, is supporting this research study by providing funding for the research study and the study drug.

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

DFCI Protocol Number:	17-022	Date DFCI IRB Approved this Consent Form:	09/04/2019
Date Posted for Use:	09/18/2019		

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.

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 a Pilot Study, which is the first time investigators are examining this study intervention for this particular problem.

In this research study, we are studying a drug called ivabradine. We are exploring whether ivabradine can be used to reduce heart rate, increase exercise duration, and improve quality of life in survivors of lymphoma who received radiation to their chest as a part of their cancer treatment.

The U.S. Food and Drug Administration (FDA) has not approved ivabradine for your specific disease, but it has approved the drug as an oral medication to lower heart rate in heart failure patients.

Survivors of lymphoma who were treated with neck and/or chest radiation can have an elevated resting heart rate and an abnormal rate of decline in their heart rate after exercise, also known as cardiac autonomic dysfunction. These abnormalities can limit exercise duration and worsen quality of life in some radiation treated survivors of lymphoma.

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:

- Lifestyle measures that include avoiding medications, food (e.g. chocolate) and beverages (e.g. coffee) that contain stimulants that increase heart rate.
- Participate in a regular exercise training program.
- Receive other drugs that lower resting heart rate and blood pressure, including beta-blockers and calcium channel blockers. However, these have also not been specifically studied in lymphoma survivors with radiation induced autonomic dysfunction.
- No treatment.

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?

Because no one knows which of the study options is best, you will be "randomized" into one of two study groups: ivabradine or placebo. Ivabradine is the active drug we are studying and placebo is a pill that contains no active medicine. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the research doctor will choose what group you will be in. Neither you nor the research doctor will know what group you are in. You will have an equal chance of being placed in any of the following groups:

- Arm A: Ivabradine for 6 weeks
- Arm B: Placebo for 6 weeks

You will be given a study medication and it will contain either ivabradine or placebo.

You will be asked to maintain a diary to record your drug usage throughout the study. If you miss or vomit a study drug dose during the study, we will ask you to record the reason that you missed the dose in the diary. Please take your next study drug dose as scheduled.

Since ivabradine is currently not FDA approved for lymphoma survivors with radiation induced autonomic dysfunction, it may not be available after the study ends.

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. This visit will last approximately 1 hour.

- **A medical history,** which includes questions about your health, prior illnesses and testing, current medications, and any allergies. We will also review any liver and kidney function tests that you may have had within the previous year.

- **Physical Examination,** to ensure that you do not have any clinical findings that would exclude you from this study.

- **Urine pregnancy test,** if you are a female of child bearing age and are not menopausal or have not undergone surgery to prevent childbearing.

- **Electrocardiogram (EKG),** to quantify your resting heart rate. This test checks the electrical activity of your heart. We will place several small, sticky pads on your chest, arms, and legs. Each pad has a wire attached. The wires connect to a machine that makes a recording of your heart rhythm. This painless test takes about 15 minutes.

- **Laboratory testing,** to assess liver and kidney function tests if you have not had them within the past year.

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

Study Visit 1: This visit involves baseline testing to assess your resting heart rate, your exercise capacity, and quality of life prior to starting the study drug. This visit will last approximately 2-3 hours.

Participants will also be randomized to undergo additional tests to assess their heart rate and blood pressure response to certain special maneuvers (cardiac autonomic function testing). Therefore, there is a 50-50 chance that you may undergo these additional tests that will last approximately 2-3 hours.

This visit will involve the following:

- **Clinical Exam:** During this visit 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.

- **Treadmill exercise stress test:** This test will be conducted by trained professionals in the exercise stress testing laboratory at Brigham and Women's Hospital. The treadmill exercise test includes walking and/or jogging on a moving belt for the purpose of testing the function of the heart and the blood supply to the heart. Preparation for the test includes shaving the chest (if needed), rubbing the chest with alcohol and abrasive material (which may cause some skin irritation) in order to attach EKG leads to evaluate the electrical activity of your heart while you are exercising. You will start exercising slowly with frequent EKGs and blood pressure measurements. The speed and incline of the treadmill will be increased every 3 minutes. You will be encouraged to exercise until you get exhausted or if the exercise technologist/physician feels that you have symptoms or EKG changes that suggest that you should stop.

- **SF-36 Questionnaire:** You will be asked to fill out a 36 question form about your general health and well-being, quality of life, mental health, emotional health, mood, and memory.

- **24 hour holter monitor:** This test measures your average heart rate over 24 hours. A holter monitor, which is a small, portable digital recorder that records your EKG (your heart's electrical activity) for 24 hours, will be placed on you in the cardiology clinic at Brigham and Women's Hospital. Electrodes will be placed on your chest after it has been cleaned to remove oils and shaved, if required. The recorder will be placed in a holding pouch with a strap so that you can carry it easily. You will be given a diary to list any symptoms noticed during the test. The recorder is also equipped with an event marker to be pressed when symptoms occur. You will return after 24 hours to have the monitor removed. The monitor will be connected to a special computer to scan your EKG.

- **Cardiac Autonomic Function Testing:** If you are randomized to have this test, it will be performed in the autonomic function testing laboratory at Faulkner Hospital and lasts approximately 2 hours. This test involves 3 parts:

1) Deep breathing: You will be asked to avoid smoking, caffeinated beverages, and strenuous exercise for 12 hours before the test. You will be asked to empty your bladder before the test. You will then be asked to lie quietly for 20 minutes. A baseline EKG recording will be obtained for one minute to ensure a stable resting heart rate. You will then be asked to breathe in and out slowly at a rate of 6 breaths/minute and a continuous EKG will be recorded during deep breathing. This tests the parasympathetic system which is responsible for slowing down your heart rate.
2) The Valsalva maneuver: You will be asked to lie down quietly. You will then be asked to breathe into a 10 cc plastic syringe that is connected to a pressure gauge. You will be asked to take a deep breath and blow into the syringe and keep the pressure at 40 mm Hg for 15 seconds. You will asked to practice this until you can do it correctly. Once you have mastered the maneuver, you will be asked to rest for 3-5 minutes before performing the maneuver. Your heart rate and blood pressure will be recorded by a machine that will be connected to your finger. The heart rate response to the Valsalva maneuver tests your parasympathetic system which is responsible for slowing down your heart rate and your blood pressure response to the Valsalva maneuver tests your sympathetic system which is responsible for speeding up your heart rate and increasing your blood pressure.
3) Tilt tests predominantly evaluate the body's heart rate and blood pressure response to change in body position from lying to standing. You will be asked to lie down and your heart rate and blood pressure will be measured over 5-10 minutes. You will then be tilted up to an angle of 70 degrees over 5-10 seconds. You will be monitored closely for chest pain, shortness of breath, dizziness, or fainting. If you have no adverse reaction, your heart rate and blood pressure will be recorded every minute for 10 minutes. You will then be returned to a lying position.
4) Sudomotor Testing: You will be asked to complete a short questionnaire asking whether you have nerve pain symptoms. You will also be asked to place both palms and soles on large area stainless-steel electrodes for 3-minutes. A low voltage (<4 V) current will be applied incrementally to the electrodes to measure your skin conductance.

Study Intervention Overview: After the baseline evaluation is completed, you will be given study drug to take home with you.

- **Oral Study Drug(s):** Each study intervention lasts 6 weeks during which time you will be taking the study drug 2 times per day. It is important for you to follow our instructions about how to take the study drug. After approximately 14 days, the dose of the study drug may be adjusted based on your heart rate. Please bring your drug diary with you to your subsequent visits. Please also bring any unused study drug with you to your subsequent visits.

Study Visit 2: This visit will occur approximately 14 days after starting the study drug. The purpose of this visit is to adjust the dose of your study medication based on your resting heart rate and symptoms. This visit will take approximately 30 minutes. At this visit, you will have the following:

- **Clinical Exam:** During this visit you will have a physical exam and you will be asked questions about any side effects to the study drug or health problems since your last visit.

- **EKG:** To measure your resting heart rate.

If you are tolerating the medication at the current dose without significant side effects and your resting heart rate is greater than or equal to 60 beats per minute, we will increase the dose of the study medication. If your heart rate is less than or equal to 50 beats per minute or you are experiencing side effects related to a slow heart rate, we will decrease the dose of your study medication.

Study Visit 3: This visit will occur approximately 6 weeks after starting taking the study drug. This visit is exactly the same as Visit 1. If you are a female of child bearing age and are not menopausal or have not undergone surgery to prevent childbearing, you will be asked to undergo a urine pregnancy test. This visit will take approximately 2-3 hours if you are not randomized to undergo autonomic function testing. If you are randomized to undergo autonomic function testing, this visit will take an additional 2-3 hours. You will take the final dose of the study drug on the morning of this visit. You will be asked to bring any unused study drug to this visit.

After You Complete the Study:
After you complete the study, we will refer you back to your own doctor for your ongoing medical care.

Research Study Plan:

	Screening	Visit 1 Day 1	Visit 2 Day 14	Visit 3 Day 42
Medical History & Physical Exam	X	X	X	X
EKG	X	X	X	X
Pregnancy Test	X			X
Autonomic Function Tests		X		X
Treadmill exercise stress test		X		X
SF-36 questionaire		X		X
24 Holter monitor		X		X
Receive study drug		X		
Adjust study drug dose			X	
Return study drug				X

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

You will be in this research study for approximately 6 weeks.

You may be taken off the research study drug for many reasons including if:

- It is considered to be in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study interventions and procedures
- Your condition worsens
- You are a female and become pregnant or plan to become pregnant
- 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 medical 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 medications 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. 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.

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 Ivabradine:

Occasional (1-10%):

- Slow heart rate
- High blood pressure
- Atrial fibrillation (an irregular heart rate)

- Phosphenes or visual brightness
- Shortness of breath

Rare (less than 1%):

- Syncope (fainting)
- Hypotension (low blood pressure)
- Angioedema (swelling of the face and throat)
- Rash
- Itching
- Urticaria (hives)
- Vertigo (sensation that the room is spinning)
- Diplopia (double vision)
- Visual impairment

Risks Associated with Sophisticated Autonomic Function Testing:

While you are in this research study, you will undergo a tilt table test to evaluate the degree of radiation induced autonomic dysfunction before and after taking study drug. A rapid change in body position can occasionally cause:

- Dizziness
- Fainting
- Chest pain
- Shortness of breath

If these occur, you will be immediately returned to a lying position.
You may experience a slight buzzing sensation in your palms and soles during sudomotor testing.

Risks Associated with Exercise Treadmill Tests:

While you are in this research study, exercise treadmill tests will be done to assess your exercise capacity. During the test, you can occasionally develop:

- Abnormal blood pressure (low or high)
- Rhythm disturbances of the heart
- Chest pain
- Shortness of breath

Rarely, you can have a:

- Heart attack.

In addition, there is a chance of having an abnormal stress test. This could require further testing or treatment. If you have an abnormal stress test, you may be withdrawn from the study and will be referred for further care to your primary physician. If one of the research doctors is involved in your clinical care, they

may decide what additional testing and/or treatment is required after reviewing your stress test results.

Reproductive Risks:
The drugs used in this research study may affect a fetus. While participating in this research study, you should not become pregnant or father a baby, and should not nurse a baby while you are taking the study drug and for 2 weeks after the last dose of the study drug. We will provide counseling about preventing pregnancy for either male or female study participants. We will check a urine pregnancy test in all women of child bearing age who are not post-menopausal or do not have a documented history of surgery to prevent conception before you start study drug and at the end of the study.

Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child during the study or within 2 weeks of study completion.

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 sponsor 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?

Taking part in this study may or may not help you. Taking part in this research study may help us learn more about ivabradine as a treatment for radiation induced autonomic dysfunction that may help other 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 ivabradine. 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.

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

The study sponsor will reimburse you for travel/parking costs incurred during each of your study visits ($25 per visit). Study staff will review the reimbursement plan and any requirements for reimbursement with you.

J. WHAT ARE THE COSTS?

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

You will not be charged for ivabradine or the tests described above that are done as part of this study.

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:

- Boston Children's Hospital: (617) 355-7188
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Dana-Farber Cancer Institute: (617) 632-3455

- Dana-Farber Cancer Institute/Faulkner Hospital: (617) 632-3455

K. 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 will be billed to your insurance company. You will be responsible for deductibles and co-payments. 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.

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:

Brigham and Women's Hospital/Dana Farber Cancer Institute

- Anju Nohria, MD: (617) 525-7052
- John Groarke, MD: (617) 732-6632
- Peter Novak, MD: (617) 983-7580

If you need to contact study staff outside normal business hours, please page either Drs. Nohria or Groarke through the Brigham and Women's page operator:

24-hour contact: Anju Nohria, MD at (617) 525-7052 beeper 30350 or John Groarke, MD at 617-732-6632 beeper 31692

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.

Massachusetts General Hospital Boston Children's Hospital

- Shawn Clinton Pun, MD: (617) 726-3453
- Tomas Neilan, MD: (617) 724-5351

Boston Children's Hospital

- Ming Hui Chen, MD: (617) 355-8366

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 sponsor 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 related to the study drug;
- 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(s) of the study, its subcontractors, representatives, business partners, and its agent(s): Amgen
- 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 FDA, 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

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 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 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