**INTRODUCTION**

We invite you to take part in a research study called (insert Project title). You were selected as a possible participant in this study because you fall in the category of our research spectrum. Please take your time to read this form, ask any questions you may have and make your decision.

**WHAT IS THE PURPOSE OF THIS STUDY?**

This study is being done to [….]

**WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?**

It is important that you read and understand several points that apply to all who take part in our studies:

* Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
* You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
* You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study and we will explain it to you prior to agreeing to participate.

**WHO IS IN CHARGE OF THIS STUDY?**

The investigator is (Insert Name of Investigator). The research is being sponsored by (insert name of agency/company or the word “investigator”, if applicable).

**WHO CANNOT PARTICIPATE IN THIS STUDY?**

You cannot be in this study if any of the following apply to you: **[Bullet point list of exclusion criteria]**

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…

…

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About **(#)** people will take part in this study.

**WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?**

If you agree to take part in this study, you will […..]

**HOW LONG WILL I BE IN THE STUDY?**

We think you will be in the study for (months/weeks, until a certain event).

**[Where appropriate, state that the study will involve either short or long-term follow-up or require responding to a questionnaire]**

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator.

If you suddenly withdraw from the study, we may not be able to use any of the information gathered from your participation.

**WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?**

If you decide to participate in this study, you should know there may be risks. Potential risks and side effects related to this study include:

**[List below all reasonably foreseeable physical and nonphysical risks,(e.g. the inability to work, emotional distress, etc.) and discomforts (e.g. sitting in one place for a long time, being in a confined space, reliving painful memories, etc.) associated with the study. In addition to physiological and psychological risks/discomforts, describe any social, legal or financial risks that might result from participating in the research]**.

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

**[If there is no intended benefit to any participants, insert the following statement: "This study is not designed to provide direct benefits to any participants."]**.

You may or may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

**WHAT OTHER OPTIONS ARE THERE?**

Instead of being in this study, you have these options:

* You always have the option to not be in this study

**WHAT ABOUT CONFIDENTIALITY?**

The information collected will be anonymous. You will not be identified by name in any publications resulting from this study.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

You **[choose one]** (will/will not) be paid for being in this study. **[If participant is compensated]** (state payment schedule/amount). Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of QBRI not to provide financial compensation to you should this occur.

**WHAT ARE THE COSTS?**

You do not have to pay anything to be in this study.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

* You have the right to be told about the nature and purpose of the study;
* You have the right to be given an explanation of the exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
* You have the right to be informed of any appropriate alternatives to the study ;
* You have the right to ask any questions you may have about the study;
* You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
* You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time.

**WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study, contact the investigator, **(insert name)**, at **(telephone number)**.

**SIGNATURES**

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual’s satisfaction.

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**Signature of Person Obtaining Consent Date of Signature**

I, the undersigned have been informed about this study’s purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision. I agree to cooperate with (name of principal investigator) and the research staff.

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**Participant’s Signature Date of Signature**

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**Signature of Witness Date of Signature**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Legally Authorized Representative (When Appropriate) Date of Signature**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Relationship to Participant (When Appropriate)**