**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. We encourage you to discuss your decision with your family, friends and doctor(s).

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

This study is being done to [choose applicable text category below by deleting all other categories, category text and aligning the remaining verbiage behind the word “to” in this sentence]

[Outcomes/Observational/Other Studies] study the natural history of (name of disease/condition) and its causes and treatments.

**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 with the staff members who explain it to you and with your own advisors 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). QBRI is being paid by (insert name of agency/company/grant, i.e., intramural, fellowship, etc.), to conduct this study with (insert name of investigator) as the primary investigator.

**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]**

..

…

…

**WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?**

Are you presently participating in any other research studies? Yes  No

If yes, please state which study(ies)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

**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?**

[For randomized studies:]

If you agree to take part in this study, you will be “randomized” into one of the study groups: (describe the groups). Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the investigators will choose what group you will be in. You will have (insert description of chance - an equal/one in three/etc.) chance of being placed in any group.

**[Insert if doubled blind]**

**Neither you nor the investigator will know which group you are in.**

**[Insert if single blind]**

**You will not know what group you are in.**

**[Describe what's involved in the study. Consider inserting a simplified schema and/or calendar informing the participant of their requirements. Include whether a participant will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard]**

The procedures that are research related are:

The procedures that are not research related and standard care are:

**[For nonrandomized studies:]**

If you agree to be in this study, you will have the following tests and procedures:

**[Describe what's involved in the study. Consider inserting a simplified schema and/or calendar informing the participant of their requirements. Include whether a participant will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard].**

The procedures that are research related are:

The procedures that are not research related and standard care are:

**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, new information becomes known about the safety of the study, 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 and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study, **[Describe any serious consequences of sudden withdrawal from the study]** and 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. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. 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, receiving multiple injections, etc.) associated with the study, and describe how they will be managed, being explicit about severity and reversibility. In addition to physiological and psychological risks/discomforts, describe any social, legal or financial risks that might result from participating in the research]**.

Risks and side effects ***that may occur*** include:

|  |
| --- |
| * **[If appropriate insert "occurs in approximately X-Y% of participants"]** |

Risks and side effects ***that are less likely to occur*** include:

|  |
| --- |
| * **[If appropriate insert "occurs in approximately X-Y% of participants"]** |

|  |
| --- |
| * **[If appropriate insert "occurs in approximately X-Y% of participants"]** |

Risks and side effects ***that rarely occur*** include:

**[If applicable]**

Please tell the investigator about all medications including over the counter drugs or herbal supplement you are taking, even if you don’t think they are important.

**[If applicable - for research involving genetic or related testing, participants must be informed of any risks associated with the genetic information that may result]**

As part of this study, you will be involving in genetic testing. Risks of being in genetic testing include the misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to their employment and/or their life and/or health insurance and other benefits or entitlements. Also, there is a risk that being in a genetics study can cause psychological distress or experience tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering “yes” could cause benefits to be denied or could cause other problems including discrimination.

For more information about risks and side effects, please ask **(insert name of the investigator).**

**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:

**[Bullet point the list of alternatives including standard of care, or other investigational products or procedures and disclose any of their important potential benefits and risks]**

* You always have the option to not be in this study or to refuse any medical treatment.

**WHAT ABOUT CONFIDENTIALITY?**

Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including your personal health information and the information discovered during this study. If you do not wish to sign this permission from, you will not be allowed to participate in 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. You will not be charged for (insert appropriate tests, procedures, medications, etc.) that are part of this research study.

**WHAT IF I’M INJURED OR BECOME ILL DURING THE STUDY?**

We will make every effort to prevent injuries and illness from being in the study. In the case of an injury, illnesses, or other harm occurring during, or resulting from, the study, emergency medical treatment is available and will be given at no coast.

**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, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
* 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. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

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

For questions about the study or a research-related injury, contact the investigator, **(insert name)**, at **(telephone number)**. If you are having a medical emergency, you should go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the QBRI. Direct your questions to the Office of Research:

**CONSENT FOR STUDIES INVOLVING GENETIC MATERIAL (DNA / RNA)**

To protect you against the risk of breeching confidentiality, all DNA samples will be coded and stored without identifying information. There will be a strictly confidential record of these samples, which will remain locked in secure places.

Efforts will be made to protect your personal genetic information to the extent allowed by law. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study.

**Agreement for the use of samples for genetic testing:**

I permit coded use of my blood samples for the proposed study, and I specify the use of the samples in the following manner (please check only one of the following):

**I permit anonymized (samples cannot be linked to subject) use of my blood samples for other studies without contact.**

**I permit further contact to seek permission to do further studies on my samples.**

**I do not allow use of my blood samples for further studies.**

**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 and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with (name of principal investigator) and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

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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)**