



PARTICIPANT INFORMATION and CONSENT FORM

The BCC3 Cohort: Cellular Aging in Women Living with HIV (BC CARMA-CHIWOS Collaboration)

~ BCC3 Study ~

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1. INVITATION

You are being invited to take part in this research study because you identify as a woman and are age 16 or older. This study is being conducted by the team listed above as well as peer research associates. This team is trying to better understand how living with chronic infections, such as hepatitis C, as well as other physical and mental health conditions, impact markers of

aging that can be found in your body's cells. One of these markers is for mitochondrial DNA (mtDNA) (energy producing part of body cells) and will test the level of function of the mitochondria, another test will look at the length of DNA at the end of chromosomes. If you are a woman living with HIV, the use of different kinds of HIV medications, as well as being on and off them over time will also be considered.

This project is a collaboration of two projects that have each been running for a decade or longer. By collaborating together, these projects will be able to better understand how the lived experiences of women with HIV intersect with clinical and cellular markers of aging. There are certain aspects of this collaboration we will be looking at during this study and there will be other related projects in the future. We are going to create a cohort (group of research participants) and we hope to continue working in this area of research for many years to come.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your primary care provider between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your primary care provider also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and primary care provider before you decide.

3. WHO IS CONDUCTING THE STUDY?

This study is being funded by the Canadian Institutes of Health Research (CIHR). A team of Doctors, Researchers and Peer Research Associates are conducting this study.

4. BACKGROUND

HIV and other viruses such as hepatitis C virus and herpes simplex virus, that can stay with you for life, can cause chronic activation of the immune system (the immune system remains 'turned on' and is not able to rest), which leads to inflammation and oxidative stress (a process that creates small particles called free radicals that can cause damage to DNA). Both immune activation and oxidative stress can lead to DNA damage and early aging of the cells in our body. Social stresses such as stigma, violence, and food insecurity also contribute to stress and inflammation. This stress and inflammation could cause hormonal dysregulation in women

living with HIV, which may lead to an increase in number of diseases and a decrease in lifespan. Factors such as substance use, HIV medications, amount of HIV virus and CD4 cell count, fail to adequately explain differences in markers of aging for women living with HIV.

5. WHAT IS THE PURPOSE OF THE STUDY?

Research has shown that signs of accelerated aging such as low bone mass, heart disease and hormone dysfunction, are more evident in women living with HIV, even though their life expectancy is near that of their peers who are not living with HIV. The goal of this study is to better understand the complex interplay between an individual's viral infections such as HIV, hepatitis C and herpes, with the hormones, multiple chronic diagnoses, and personal life experiences, such as adverse childhood experiences, stigma, and violence, of women and female youth. This includes understanding their impact on either helping or worsening the aging of their cells, including those meant to fight against infections and cancers, or to help heal injuries. We will specifically examine their sexual and stress hormones, their reproductive health (fertility, menopause, etc.), as well as the diseases associated with getting older (osteoporosis, kidney disease, cardiovascular disease, etc.). We will examine whether certain habits such as smoking, how well one naturally controls HIV, depression, discrimination, support network, etc. can influence the cellular changes that naturally take place when we age, and whether the medications taken to fight HIV do as well. New knowledge gained from this study will inform approaches to health care that will promote healthy aging for women living with HIV.

This study is taking place in British Columbia, and will enrol 350 participants living with HIV and 350 participants who are not living with HIV.

6. WHO CAN PARTICIPATE IN THE STUDY?

You may be able to participate in this study if:

- a. you are able to communicate in English
- b. you are 16 years of age or older
- c. you are a cis-gender or transgender woman (currently identify as a woman)
- d. you are able to attend a study visit at a study site (no need to be a clinic client)
- e. you are living with HIV, or...
- f. you are **not** living with HIV
- g. you are **not** currently pregnant or breastfeeding

NOTE - If you are <45 years of age, a urine pregnancy test (like a home test) will be done after you have consented to participate in the study, but before any other activities. **If the test is positive, you will be advised of this, and the visit cannot proceed at that time.** This is because the hormones in your body are very different when you are pregnant compared to when you are not. We would be very happy to welcome you back for a study visit after you are no longer pregnant or breastfeeding, if applicable, and your menstrual cycle has returned to normal.

7. WHAT DOES THE STUDY INVOLVE?

If you agree to take part in this study, the visit and sample collection schedule you can expect are outlined below. There will be one visit made up of two parts - the Clinic Visit and the Community Visit. For participants in the lower mainland, the two parts of the study can happen on the same day or over a maximum of 1 month. For participants outside of the lower mainland, the community visit will be conducted either in person later during the week that we are there, or virtually within one month of the clinical visit. The Clinic Visit is expected to take between 2 and 3 hours and the Community Visit is expected to take between 1.5 and 2 hours - the total amount of time you are being asked to commit to the study is between approximately 3.0 and 4.0 hours. If you are not using a hormonal contraceptive and have had a period in the past 3 months, there will also be 1 or 2 visits for timed bloodwork. The additional timed bloodwork visit(s) would take between 15-30 minutes each.

BCC3 STUDY PART 1: The Clinic Visit (120-180 minutes)

This portion of the visit must occur first and will take place at a clinical location.

- a. If not already done, one of the study research staff will meet with you and review the study consent form, answer any questions you may have and obtain your signature on the consent form
- b. A urine pregnancy test will be done, except if you have not had your period for more than 1 year
- c. Your height, weight, waist circumference and blood pressure will be measured
- d. A trained interviewer will ask you question about:
 - i. Basic demographics (e.g. age, gender, income, education, housing)
 - ii. Medical history (e.g. diagnoses, medication use, vaccinations)
 - iii. Smoking and other substance use history
 - iv. Reproductive health
- e. A mouth-swab will be collected
- f. A blood sample will be collected
- g. A urine sample will be collected for tests in addition to the pregnancy test
- h. A hair sample will be collected
- i. Optional rectal and vaginal swab will be self-collected by you

44 ml (3 tablespoons) of blood will be collected. For participants living with HIV, HIV-related health information will be extracted from your clinical record, if available.

Your biospecimens (samples), collected as part of this study, will be tested for the following:

- genetic markers
- sexual and stress hormones
- some common chemistry and hematology tests, like sodium, potassium and hemoglobin
- lab tests like glucose and cholesterol that are used to diagnose diseases of aging such as diabetes and heart, liver or kidney disease
- we will look at the health of cells that fight infection and help heal injuries
- inflammation biomarkers (elements in the blood that show inflammation is present)
- the type of viral infections that are very common in humans can be in the body for a long time
- tests to understand the health of your immune cells

- tests to understand the health and functioning of your mitochondria (energy producing part of body cells)
- tests to understand the health and functioning of your telomeres (the length of DNA at the end of your chromosomes)
- your blood may be tested for the Hepatitis B and C viruses as well as HIV (Human Immunodeficiency Virus)
- drug levels of antiretrovirals (applicable to women living with HIV only)

Your blood will be tested in batches and these may be 6 or more months after your visit. We are requesting a hair sample to test for cortisol levels. Cortisol is a stress hormone that has many functions including keeping inflammation down, regulating your blood pressure, helping you manage stress and controlling your sleep/wake cycle. A hair sample will be able to give us information about your cortisol levels over the last 3 months.

If you have menstrual periods and are not using a hormonal contraceptive, included in the above amount of bloodwork will be testing for hormones that require your blood draw to be timed to your menstrual cycle at two different times. One is during the early follicular phase of your cycle (2-5 days after starting flow) and the other is mid-luteal phase (cycle day 21-23 after menses, or 7 days before next flow). We will do our best to time one of these at the same time as your clinical visit. For the other test, a separate visit just for the bloodwork will be required again at Oak Tree Clinic in BC Women's Hospital and Health Centre, at Life Labs, or at Valley Medical Labs. You will be reimbursed for this additional visit and it will take 15-30 minutes of your time.

If your urine pregnancy test is positive and you are a patient at Oak Tree Clinic, a nurse or your doctor will discuss this with you. If you are not a patient at Oak Tree Clinic, the Dr. Melanie Murray, the principle investigator, or her designate, will discuss this with you.

We also have plans to explore other areas of research testing including RNA-sequencing and immunology.

RNA, or ribonucleic acid, are large molecules essential in various biological roles. They transmit genetic information from DNA to proteins and control certain chemical processes in the body. RNA-sequencing is a technique that can examine the quantity and sequences of RNA, as well as analyze gene expression patterns encoded in all of the RNAs in an organism.

The immune system is a complex system of structures and processes that evolved to protect us from disease. The system is made up of general defense mechanisms (also called 'innate') that come into play within hours of a foreign substance appearing in the body, and highly specialized defense mechanisms (also called 'adaptive') which are created in the body by exposure to foreign substances or vaccinations. Immunology is the study of both of these components of the immune system.

NOTIFYING YOU and/or YOUR PRIMARY CARE PROVIDER OF YOUR TEST RESULTS

As part of this study, we will be doing some lab tests to look at different makers of health in your blood, urine, and hair. Some of these tests will be done in a regular hospital lab and, if abnormal or outside of normal range, the results of these tests can be made available to you or your primary care provider. Other tests are done at a research lab where reference ranges or “normal” values may be unknown. In this case, we will contact you if the study physician feels that the results may be important for your health and we will recommend for you to follow up with a care provider.

Please indicate, by checking the applicable box, whether you would like us to notify you, your primary care provider(s) or both of you about the lab test results done as part of this study. This is not a consent to release medical information.

- Yes, I would like the study investigator to notify ONLY my primary care provider(s) about my lab test results done as part of this study.
- I would like the study investigator to notify BOTH me and my primary care provider(s) about my lab test results.
- I would like the study investigator to notify ONLY me about my lab test results.

In the future, we may have other health results available for sharing that are also based on research tools. These should be interpreted with care and will only be sent to you if you consent to this. These results may or may not be clinically actionable.

- I would also like the study team to inform me of research lab results when/if they become available.

Primary care provider(s) name(s): _____

Phone number: _____

Clinic Name: _____

My phone number is: _____

Alternate phone number and name/relationship: _____

My email address is: _____

NOTIFYING PUBLIC HEALTH, YOU and/or YOUR PRIMARY CARE PROVIDER ABOUT HBV, HCV or HIV TEST RESULTS

As part of this study, we may be testing participants' blood for HBV, HCV and HIV. Each of these are reportable conditions, which means that if you test positive for one of these three viruses and you did not know about it, the study investigator is required by law to notify Public Health about the result. We are using non-diagnostic testing for the study, so you will be required to get a clinical test to verify the result.

Please indicate, by checking the applicable box, who you would like notified about these results. This is not a consent to release medical information.

- I would like the study investigator to advise me AND my primary care provider(s), AND Public Health about my blood test results done as part of this study
- I would like the study investigator to advise me AND Public Health about my blood test results
- I would like the study investigator to advise my primary care provider, AND Public Health about my blood test results.

I would like the study investigator to notify ONLY Public Health about my blood test results

Primary care provider(s) name(s) _____

See page 6

Phone number _____

Clinic Name _____

My contact phone number _____

See page 6

Alternate phone number and name of person _____

My email address _____

NOTIFYING YOU ABOUT FINDINGS FROM MTDNA TESTING

We will also be testing the partial or complete set of genes present in your mitochondria (mtDNA). If something that may be important to your clinical care is found, Dr Murray, the site investigator, will contact you and provide a referral to a specialist who will help you understand this information. There would be no cost to you for this referral.

Please indicate below the best ways to reach you if something that may be important is found when testing your mtDNA.

My phone number is: _____

See page 6

Alternate phone number and name of person _____

My email address is: _____

Collection of Swabs for Testing Not Yet Funded

We are requesting two vaginal and two rectal swabs at this visit - to be self-collected by you. We do not currently have funding to test these swabs. We plan to submit grant applications that, if successful, will provide funds for this testing. Once we are successful with additional funds, your biospecimens will have testing done in the biological science area called “omics”. This is a field of study that looks at the group classification and measurement of pools of biological molecules that translate into the structure, function, and dynamics of an organism or organisms. These testing will be used to investigate links between the vaginal and rectal microbiome (as a surrogate for a stool/gut sample) and the other health and aging markers we are looking at in this study.

- I **agree** to collect a vaginal swab at this visit for testing at a later date when funding becomes available

- I **do not agree** to collect a vaginal swab and have it tested at a later date when funding becomes available

- I **agree** to collect a rectal swab at this visit for testing at a later date when funding becomes available

- I **do not agree** to collect a rectal swab and have it tested at a later date when funding becomes available

BCC3 STUDY PART 2: The Community Visit (1-2 hours)

This portion of the visit must occur after Part 1, can take place 0-31 days (1 month) afterward and can take place remotely, at a community or clinical location. A trained interviewer will contact you to schedule your visit. They will ask you questions about your:

- Demographics (e.g. age, gender)
- Lifestyle/experiences (e.g. exercise, food security, sleep, oral health, incarceration)
- Mental health
- Sexual health
- Use of health care and social services
- Experience with other stresses, stigma, and trauma
- Wellbeing, social support, and resilience

The interview will take place in a quiet, confidential space at a local clinic, community organization, in your home, via telephone, or via videoconference (Skype or Zoom). If you participate via videoconference, you may keep your camera off throughout the interview and can log in using a nickname or your study number if you prefer. The information you share will be saved on a secure online database. Your name, contact information and other personal information that can identify you will be kept separate from your answers to the survey. Therefore, it is not possible to connect you to the answers you have shared.

If you have previously participated in either the CARMA or CHIWOS studies before, data collected as part of your previous participation in the CARMA or CHIWOS studies will be accessed and included in this study.

Some of the tests for the study are being done using non-diagnostic methods of testing (for research use only), and as such, we will not be able to give these testing results to your or your primary care provider.

8. HEALTH INFORMATION LINKAGE AND SECURITY

As part of this study, we plan to link data from the BCC3 biospecimens, as well as Part 1 and 2 surveys to provincial health databases (e.g. birth, death, name change, cancer or pharmacy registries). In order to link to these health databases, we use your first name, last name, birth date and provincial health card number (PHN) stored in the secure BCC3 Participant Database. Once linkage is made, a non-identifying, unique LINKAGE ID is assigned across all files so that data sets can be linked without needing to access your personal identifying information again. Linkage will be done by only one authorized member of the study team, the Data Analyst, within a high-security environment. The provincial health databases and BCC3 Team follow strict provincial PRIVACY policies. We want to link health databases to get accurate data and because it is not possible to ask about all important health information such as blood work results, lifetime hospitalizations, use of health care services, emergency room visits and medication information in a 2.5-hour interview. This linkage will provide us with extra information to help better understand the health of women living with HIV. It may also be done many years from now, to see if there is a relationship between the markers we measure now and your future health. If you do not feel comfortable with providing your PHN or if you are

concerned about the privacy and confidentiality of this linkage it would be best for you not to participate in this study.

9. DATA STORAGE AND SECURITY

Signed consent forms will be stored securely in a locked filing cabinet in a locked office on the secure premises of the BC Women's Hospital + Health Centre. If consent forms are signed off site, they will be securely transported in a locked file folder with one of our research staff to BC Women's for filing. Survey data will be captured using the survey feature within an online database called REDCap (<https://projectredcap.org>). Any information that can identify you (i.e. name, contact details) will be entered and stored in a separate password-protected BCC3 Study Master File. No data will remain on the tablet / computer used to conduct the interview. Only the Research Staff will have access to the consent forms and the BCC3 Study Master File. Study investigators will only have access to de-identified data, stripped of any information that could identify you. Your biospecimens and data will be identified using a unique study ID only and will not contain any personally identifying information such as your name or date of birth. Testing results and health data collected as part of this study will be kept for a maximum of 25 years after the study is finished or for an indefinite period of time if you have also signed the Bio-Banking Consent.

10. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

Blood drawing may cause some discomfort, bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or there may be swelling in the area. Rarely, fainting or a local infection at the puncture site may occur. In some cases, women experience minor discomfort when [the vaginal and](#) rectal swabs are collected.

Some of the survey questions are very personal. They might bring up feelings like discomfort, sadness, grief, stress, or anger. Again, you do not have to answer any question that makes you feel uncomfortable, and you are welcome to skip questions or to stop the interview at any time.

If you agree to link your BCC3 survey data to other provincial health databases, your personal information, including name, date of birth, and Personal Health Number (PHN), will be used to make data linkages. If you participate, your security and privacy will be maximized, but in a rare event may not be guaranteed; a breach has never occurred with such databases and linkages in Canada.

At the end of the interview, you will be provided with a list of local resources and free counseling services should you want to access them.

We will make every effort to protect your privacy and confidentiality during the study; however, it is possible that people may learn you are participating in this study and this may make you uncomfortable. The chances that research data would be accidentally released are estimated to be exceedingly small.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

The blood tests done in the regular hospital lab may be used by your primary care provider as part of your care and treatment, yet you may not receive any benefit from participating in this study. However, knowledge gained from this study may, in the future, help healthcare providers and caregivers better understand how to optimize the health of women living with HIV.

12. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study.

13. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You are under no obligation to be included in this study. You may withdraw from this study at any time without giving reasons. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

You have the right to request the withdrawal of your information collected during the study, and the destruction of any specimen collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. Similarly, if a specimen has already been used, we can only delete data obtained from it. If you would like to request the withdrawal of your data, please contact Dr. Helene Cote, Co-Principal Investigator, at 778 288 5125.

14. HOW WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the Sponsor, UBC Children's and Women's Research Ethics Board, Simon Fraser University Research Ethics Board and any other entity as required by law for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent, unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Disclosure of Race/Ethnicity

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

15. WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this form, you do not give up any of your legal rights and you do not release the sponsor, study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided by your provincial medical plan.

16. WHAT WILL THE STUDY COST ME?

All research-related activities that occur during your participation in this study will be at no cost to you.

Reimbursement

BCC3 PART 1: The Clinic Visit - You will be paid \$50 at this visit to assist with the cost of parking and transportation. You will be paid at the time of your visit and receipts are not required.

If you are a menstruating woman, you will have 1-2 additional visits to complete the timed bloodwork, and will be paid \$25 for each additional visit to assist with the cost of parking and transportation. You will be paid at the time of your visits and receipts are not required.

BCC3 PART 2: The Community Visit - You will be paid \$40 at this visit to assist with the cost of parking and transportation. Even if the visit takes place remotely, you will receive the same amount. You will be paid at the time of your visit if in person and after your visits by e-transfer or cheque if done remotely; receipts are not required.

17. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during participation, you can contact Dr Melanie Murray at 604 875 2212 or Dr Helene Cote at 778 288 5125.

18. WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line

in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H19-00896) when contacting the Complaint Line so the staff can better assist you. You may also contact the Fraser Health Research Ethics Board co-Chair by calling 604-587-4681 if you have any concerns about your rights as a research participant.

19. AFTER THE STUDY IS FINISHED

Please contact Dr Helene Cote 778-288-5125, with any requests you may have about study updates or results. We will not be providing individual results from this study.

20. FUTURE SHARING of DATA

As per our Sponsor's (CIHR) policy, your de-identified research data (which means your name, birthdate, and other identifiers have been removed) may/will be deposited into a publicly accessible location at the time of publication. This can enhance the transparency of the research data and allows for external validation and fraud control, but it also allows others to access the data for re-analysis of this study or to do other kinds of analyses in the future beyond those you are consenting to in this study. Also, this future use of your data may not be subject to oversight by a research ethics board, and thus the data may be publicly shared and used in currently unknown ways. Once the data are made publicly available, you will not be able to withdraw your data nor will your child have the chance to individual consent to this use at the age of majority. Even though the identifying information will be removed from the data it is possible that others may be able to find out who you are. The chance of this is currently thought to be extremely low.

21. FUTURE RESEARCH

We understand some women are interested in women's health issues and women's health research. Creation of a database of women who are interested in being involved in future research will allow us to inform them about upcoming studies for which they may be eligible.

The research team would like to ask you for permission to contact you in the future for opportunities related to this current project, and also other research opportunities. If you agree to have your contact information kept on file, it does not mean you are obligated in any way to participate in any future research.

- I AGREE that a member of Dr Murray's research team may contact me in the future to ask if I am interested in participating in other research studies not described in this form.

Phone: _____

Email: _____

See page 6

Mailing address: _____

Other: _____

- I DO NOT AGREE to have my contact information kept on file or to be contacted for future research.

The BCC3 Cohort:
Cellular Aging in Women Living with HIV
(BC CARMA-CHIWOS Collaboration)

BCC3 Participant Consent and Signature Page

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records and biospecimens as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that this study will provide no direct benefit to me.

I will receive a signed copy of this consent form for my own records

I have read this form and I consent to my participation in this study

Printed name and signature of **participant**

Date

Printed name and signature of **person obtaining consent**

Date