

Participant Information and Consent Form

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>:

A phase III randomized controlled trial and economic evaluation of **Stereotactic Ablative Radiotherapy (SABR)** for **Comprehensive treatment of OligoMETastatic (1-3 metastases) cancer: SABR-COMET-3**

Clinical Trials Registration #: NCT03862911

Protocol Version: 6.0; 07 Aug 2020

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For emergencies only: Call the cancer centre nearest you and ask for your study doctor or, if he or she is not available, ask for your usual oncologist or the oncologist on-call.

BC Cancer - Vancouver	604-877-6000
BC Cancer -Victoria	250-370-8000
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BC Cancer-Prince George	250-645-7300

For non-emergency contact numbers, see sections 20-21 below.

1. INVITATION

You are being invited to take part in this research study because you have been diagnosed with metastatic lesions from your primary tumour (called oligometastatic disease).

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.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. You also need to know that there are important differences between being in a research study and being cared for by your oncologist. When you participate in a research study, the main goal is to learn things to help other patients in the future. Outside a research study, your oncologist's sole goal is to care for your health. Nevertheless, the researchers have a duty of care to all subjects and will inform you of any information that may affect your willingness to remain in the study.

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 oncologist before you decide.

3. WHO IS CONDUCTING THE STUDY?

The study is sponsored by Dr. Rob Olson at BC Cancer – Prince George.

The study is funded by the BC Cancer Research Foundation, the Canadian Institutes for Health Research, and Varian Medical Systems, and is being conducted by the Department of Radiation Oncology.

Neither BC Cancer nor any of the investigators or staff conducting this study will receive any personal payments for conducting this study.

4. BACKGROUND

When cancer has spread from an original tumor to other sites of the body, it is classified as *metastatic*. Generally, for patients with metastatic cancer, the goal of treatment has been to slow down the cancer growth with chemotherapy and/or radiation, but treatments have been unable to get rid of the cancer altogether.

When there are only a few locations of metastatic cancer (called oligometastatic), some studies suggest that by removing or killing each of those cancer deposits, the cancer may be controlled for a long period of time. We are studying a new approach to treat oligometastatic cancers with radiotherapy and you are being invited to participate. This new treatment is called stereotactic ablative radiotherapy (SABR).

SABR is a new radiation treatment that delivers high-dose, precise radiation to small tumors in 1-2 weeks of treatment. This new technique can potentially allow radiation treatments to be focused more precisely and delivered more accurately than with older treatments. This improvement could help by reducing side effects and by improving the chance of controlling the cancer by more precisely treating the cancer.

This is a multi-centre clinical trial. Cancer centres in Ontario, British Columbia, Nova Scotia, Scotland, The Netherlands, Ireland, and Australia will be participating in this study. In total, 297 participants will be recruited to this study, with about 85% being recruited at Canadian sites.

5. WHAT IS THE PURPOSE OF THE STUDY?

This is a Phase III study. A Phase III study is a study of an experimental drug or treatment which is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information to determine whether the experimental drug or treatment can be used safely.

The purpose of this study is to compare SABR (with or without the addition of chemotherapy afterward) with a standard approach which may include chemotherapy and/or standard radiotherapy. We are also comparing the cost of delivering SABR compared to standard care to see which is most cost effective, and examining blood samples from trial participants to see which approach will work best for the participant.

6. WHO CAN PARTICIPATE IN THIS STUDY?

You may be able to participate in this study if:

- You are age 18 or older
- You are willing to provide informed consent
- You have been diagnosed with oligometastatic disease which has been confirmed by imaging or a biopsy
- Your oncologist thinks you are healthy enough to receive the treatments in this study, based on your imaging and test results
- You have a maximum of 3 metastases
- All of your metastatic lesions cannot be removed surgically
- You will not be receiving chemotherapy for the time beginning 2 weeks prior to radiation and lasting until 1 week after the last fraction
- You will not be receiving chemotherapy schemes containing potent enhancers of radiation damage (e.g. gemcitabine, doxorubicin, bevacizumab, adriamycin) within the first month after radiation
- You are able and willing to complete the questionnaires, and other assessments that are a part of this study via paper, or online using REDCap, if you provide your email on this consent form.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You cannot participate in this study if:

- You have a medical condition that would prevent you from receiving radiation treatment
- You only have metastatic lesions in your brain and nowhere else
- You have received previous radiation treatment to one of the metastatic sites that requires treatment that exceeds the dosing limits allowed in this study
- You have a tumour within 2mm of your spinal cord, as seen on Magnetic Resonance Imaging (MRI)
- You are a woman who is pregnant or breastfeeding

8. WHAT DOES THE STUDY INVOLVE?

Overview of the Study

This study will compare two different treatments, called Arm 1 and Arm 2.

Arm 1: Standard of Care Radiotherapy

Participants in this arm will receive standard radiation treatment to any painful metastatic lesions. Depending on the site of the lesions, treatment will range from 1-10 radiation treatments, given over 1-10 days. Your oncologist will discuss this in more detail with you.

Arm 2: Stereotactic Ablative Radiotherapy (SABR)

Participants in this arm will receive SABR to all metastatic lesions. SABR treatment will be given either daily or every other day, and depending on the number of metastases, is generally completed within 1-3 weeks.

In both treatment arms, participants may also receive further chemotherapy treatment, or other standard of care treatments with the exception of radiotherapy, depending on the recommendation of their oncologist.

Assignment to treatment arm

Participants will be assigned to a treatment arm by chance, through a process called randomization. Randomization for this study will be done in a 1 to 2 ratio. This means for every person assigned to Arm 1, there will be 2 people assigned to Arm 2.

Duration of the study

After treatment is complete, you will be seen by your oncologist at 6 weeks, 3 months, and then every 6 months after treatment for the first two years, and then every year for the next three years. The frequency of follow-up visits is the same for patients who are not participating in this study.

As part of the study, you will be asked to fill out the following questionnaires:

1. Functional Assessment of Cancer Therapy - General (FACT-G): this questionnaire will ask questions about your physical, emotional, and social well-being. The questionnaire will take about 5-10 minutes to complete; **or** Cancer specific questionnaire(s), for example FACT-Br for brain cancer, FACT-L for lung cancer, Brief Pain Inventory for bone metastases, etc. These questionnaires will also ask questions about your physical, emotional, and social well-being, but in relation to your metastatic site(s).
2. EuroQol-5 Dimensions 5-Level (EQ-5D-5L): this questionnaire is for the economic evaluation portion of the study and will ask questions about your mobility, self-care, usual activities, pain and discomfort, and anxiety and mood. This will give us your health-related quality of life score which will then be used to calculate your quality-adjusted life year (QALY). A QALY is a generic measure of disease burden that looks at both the quality and the quantity of life lived. This will be used in the economic evaluation to assess the treatment's value for money. The questionnaire will take about 5-10 minutes to complete.
3. Resource utilization questionnaire: this questionnaire will ask you about the types of health or medical resources (for example: physiotherapist visits, health unit visits) you have accessed since your last follow-up appointment. The questionnaires will take approximately 5 minutes to complete.

You will need to complete these questionnaires before treatment and at each follow-up visit. You can either complete the questionnaires when you come in for your appointment, or you can complete them at home, online using REDCap, or on paper. You are not required to answer any questions that you are not comfortable answering.

Therefore, this will take up to an additional 5-9 hours of your time over the course of the study.

We will also look at your medical record to collect information on the number of cycles of further chemotherapy and/or systemic therapy, targeted- and immune-therapies you received and the number of Emergency Room visits and hospital admissions you made over the duration of the study. This information will also be used for the economic evaluation portion of the study.

If you agree to take part in this study, the procedures and visits you can expect will include the following:

Screening Visit/ Initial Visit/Before You Begin the Study

In order to determine if you are eligible for this study and depending on the location(s) of your metastatic lesion(s), you may be required to have a full body Computed Tomography/Positron Emission Tomography (CT/PET) scan or a CT scan plus a bone scan, a spine MRI scan, and/or a brain CT or MRI. Most of these scans take anywhere from 15-45 minutes. However, the CT/PET scan requires an injection of a 'dye' about 2 hours prior to the scan. The CT/PET scan itself takes about 45 minutes so the whole process can take up to 3 hours of your time. If any of the scans needed for your type of cancer have been done at least 12 weeks prior to your treatment, they will not need to be repeated.

You will also require a Complete Blood Count (CBC) test, and may also require a pregnancy test within 4 weeks prior to treatment.

Randomization

Once all of your eligibility tests are complete and your oncologist states that you are eligible for the study, you will be randomized to either Arm 1 or Arm 2.

Study Visits

Arm 1: Standard of Care Radiotherapy

If you are assigned to the standard treatment group, immediate treatment can include standard radiation therapy to painful metastatic lesions plus chemotherapy. If you have painful metastatic lesions, you will receive radiation therapy to those lesions and you may receive chemotherapy if it is recommended by your oncologist. If you do not have any painful metastatic lesions, you will receive chemotherapy treatment alone. You will discuss this further with your oncologist. The amount of radiation and number of treatments you receive depends on the location and the number of your metastatic lesions.

Arm 2: SABR

If you are assigned to the 'SABR' group, you will undergo radiation treatments to all sites of metastases. The radiation planning process may involve construction of a plastic mask or special bean-bag to hold your head or body still for treatment, followed by a CT simulation scan. This CT scan is different than the CT scan you may have had to diagnose your cancer or to determine your eligibility for this trial. The information from the CT scan will be used to target the tumor and minimize the radiation dose to normal tissues. The CT scan and the appointment to construct the plastic mask or bean-bag may take place on the same day or on different days. You will be notified of these appointments in advance. These appointments will take an additional 2-3 hours of your time.

Radiation treatments will be given either daily or every other day, on weekdays, over 1-3 weeks, depending on the number and location of metastases being treated. A CT scan through the region being treated will be taken on the radiation unit prior to treatment each day and your position for the treatment adjusted if necessary. Once your positioning is confirmed, the treatment will be given.

Expected Follow-up

After treatment is complete, you will be seen by your oncologist at 6 weeks, 3 months (if you agree to participate in the biomarker portion of the study and consent to blood collection), and then every 6

months for the first two years and then every year for the next three years. The frequency of follow-up visits is the same for patients who are not participating in this study.

Every 6 months, you will have a bone scan and a CT scan of your chest/abdomen/pelvis. A CT of your head will only be required for cancers with a risk of brain metastases. Bone scans require you to have an injection of a 'dye' approximately 2 hours prior to the scan itself. The frequency of these scans is the same for patients who are not participating in this study.

As mentioned above, you will complete the Cancer specific quality of life questionnaires (FACT-G or subscale and EQ-5D-5L questionnaires) and we will collect information on your resource utilization from your medical record at each visit until completion of the study.

In addition, there is an international effort underway to better understand outcomes for patients with less-common types of cancers, specifically studying patients who do not have a cancer from the breast, lung, prostate, colon, or rectum. If you do not have one of those cancers, your anonymous data will be shared with investigators from the European Organization for Research and Treatment of Cancer, to pool together with other trials looking at these less-common types of cancer.

9. WHAT ARE MY RESPONSIBILITIES?

It is important that you notify your study doctor of any side effects you experience and any new medications you plan on taking.

10. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

Potential side effects from radiation depend on the area being treated. The side effects listed below are for SABR:

- Radiation treatments to the head and neck area or brain may commonly cause headache, hair loss, mild sunburn of the skin, decreased hearing or irritation of the ears, dryness or irritation of the eyes and dry or sore mouth or throat or loss of taste during radiation treatments. Common delayed (more than 6 months after treatment) side effects from radiation treatments to the head and neck area may include persistent dry mouth (common) as well as changes in thinking or memory (rare and only if the brain is treated).
- Radiation treatments to the chest area may commonly cause dry cough, sore throat or difficulty swallowing as well as mild sunburn of the skin. Delayed (late, more than 6months post treatment) side effects from radiation treatments to the chest area may rarely cause new or persistent difficulties with swallowing; shortness of breath or cough.
- Radiation treatments to the abdomen or pelvic area commonly include diarrhea or cramping of the bowels, discomfort or frequency of urination and possibly nausea. Rarely, delayed (late, more than 6months post treatment) side effects from radiation treatments may occur including persistent cramping, diarrhea or bleeding from the bowel; frequency or discomfort with urination or bleeding from the bladder.
- Radiation treatments to bone can be associated with increased pain, redness of the skin, and a risk of a broken bone.
- Fatigue during and following radiation treatments to any of these areas is common
- Radiation treatments are associated with a small risk of serious injury to tissues or organs that are included in the area being treated. This injury may show up months to years post treatment.

In very rare instances, these side effects may result in death. Some of these side effects include (depending on whether these areas are being treated):

- Brain injury resulting in loss of strength, sensation or thinking ability
- Spinal cord injury resulting in paraplegia
- Lung injury resulting in shortness of breath
- Esophagus injury resulting in difficulty swallowing
- Heart injury resulting in a heart attack or fluid collection on the heart
- Bone injury resulting in a broken bone
- Rectal or bowel injury resulting in bleeding or perforation (hole) or fistula (abnormal connection between the bowel and another organ)
- Bladder injury resulting in bleeding or perforation (hole) or fistula (abnormal connection between the bowel and another organ)
- Adrenal dysfunction resulting in adrenal insufficiency
- Tissue injury resulting in avascular necrosis
- Your oncologist will monitor your therapy and make adjustments to your treatment or prescribe medicines in order to manage side effects that occur during treatment. The radiation technique, daily dose and total dose of radiation for your treatment will be prescribed by your physician in order to minimize the chance of late serious injury as outlined above.

Since SABR delivers much higher doses of radiation, this may increase the likelihood and severity of radiation reactions.

There will be an independent group of experts, called the Data and Safety Monitoring Board, that will review the study data for safety at intervals throughout the study.

The risks and side effects of the standard treatment, Arm 1, will be explained to you as part of your standard care.

Reproductive Risks

Because of the effects that the radiation treatment may have on an unborn child are unknown, you should not become pregnant or father a baby while on this study. An effective method to avoid pregnancy should be used while you are on study treatment. Ask your oncologist about counseling and more information about preventing pregnancy. If you (or your partner) become pregnant while you are on this study, you should notify your oncologist.

11. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

If you choose not to participate in this study or to withdraw at a later date, you will be treated with the standard treatment given to all patients outside of this study. This treatment is the same as Arm 1 in this study. You can discuss these options with your oncologist before deciding whether or not to participate in this research project.

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

If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

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

You may withdraw from this study at any time without giving reasons.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis in order to protect the integrity of the research. However, no further information will be collected.

15. CAN I BE ASKED TO LEAVE THE STUDY?

If you are not able to follow the requirements of the study or for any other reason, your oncologist may withdraw you from the study and will arrange for your care to continue. On receiving new information about the treatment, your oncologist might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health.

16. PRIVACY AND CONFIDENTIALITY

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the study is referred to as the 'study-related data'. This data may include your medical records, biological materials, genetic information, completed questionnaires and/or diaries, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer unless otherwise specified in this form (this is referred to as 'coded data').
- Coded data (including genetic information) from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these

future studies is to benefit people by improving our understanding of health conditions like cancer.

Who will know I participated?

- Your family doctor will be notified that you are taking part in this study so that your study doctor and family doctor can provide the proper medical care.
- If required by law, your medical information may also need to be given out. If this should happen, the study doctors and staff will do their best to make sure that any information that is shared will not directly identify you.

Genetic research

When you donate your blood or tissue for genetic testing or research, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA.

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.

WHO WILL HAVE ACCESS TO YOUR STUDY-RELATED DATA?

Your signed consent form will be included in your study-related data, and in any electronic medical record(s). Your healthcare team will also be alerted that you are on a study to ensure they can treat you safely according to the study protocol.

Your study-related data will be reviewed by the sponsor of this study, or their representatives at BC Cancer. The BC Cancer Research Ethics Board or regulatory authorities and auditors may also look at your study-related data for the purpose of overseeing the conduct of the study. These reviews may be conducted on site or remotely which requires sharing the study-related data electronically through a secure process. All study-related data is treated confidentially and all efforts are made to restrict access and to transfer your study-related data as securely as possible. Only essential study-related data is shared and is coded with your study code. However, there may be times when identifiable information may also be shared but access to this information will be restricted only to authorized personnel.

Table 2 sets out the organizations that may access your study-related data and for what purposes. By signing this form you are authorizing such access.

Table 2: Access to your study-related data

WHO	WHAT	WHERE	PURPOSE
Study Monitors	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial, review of data accuracy

WHO	WHAT	WHERE	PURPOSE
Auditors	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial, review of trial conduct
BC Cancer REB	Study-related records and data (including your medical records) that include information that can identify you, such as your birth month and year that we will collect to confirm age eligibility.	Canada	Oversight of trial

Although you may not be aware of this fact, emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States). Due to the fact that future emails contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue. If you choose not to consent, you will not be able to access REDCap. Providing your email means that you voluntarily agree and give your consent for BC Cancer to use your personal email for these services.

Email address: _____

17. AFTER THE STUDY IS FINISHED

Once the study is complete, you may be able to receive SABR treatment, depending on the location of your cancer and the recommendation of your oncologist. If you needed further treatment after the study is finished, your oncologist would discuss options with you.

18. WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your legal rights against the investigators, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

For studies sponsored by not-for-profit organizations like this one, there may be extra costs that are not covered by your medical plan that you will have to pay yourself; some examples may be physiotherapy or certain pain medications.

19. WHAT WILL THE STUDY COST ME?

Reimbursement

As part of your participation in this study, you may incur additional expenses. For example, if you are in treatment Arm 2, you will need to undergo treatment over a period of 1-3 weeks depending on the number and location of metastases being treated. This may result in increased parking or transit expenses.

You will not be reimbursed for these study related expenses.

Remuneration:

You will not be paid for participating in this study.

20. 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, or if you experience any adverse effects, you can contact your study doctor:

Study Doctor's Name	Telephone Number
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In the event of a research related injury, please speak to your study doctor (indicated above) or (after hours) call the BC Cancer site or hospital nearest you and ask for your study doctor or, if he or she is not available, the oncologist on call.

Or, you can speak to the doctor who is the BC Cancer principal investigator, Dr. R. Olson, at 250-645-7325.

Or, BC Cancer patients can speak to the Head of the Radiation Therapy Program of the BC Cancer Agency. That person can be reached at 604-877-6000.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT?

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services 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 H18-03173 when contacting the Complaint Line so the staff can better assist you.

22. SIGNATURES

A phase III randomized controlled trial and economic evaluation of Stereotactic Ablative Radiotherapy (SABR) for Comprehensive treatment of OligoMETastatic (1-3 metastases) cancer: **SABR-COMET-3**

Participant Consent

My signature on this consent form means:

- I have read and understood the subject information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity 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 objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my health records and samples 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 there is no guarantee that this study will provide any benefits to me.
- I understand I need to provide my email address if I choose to complete the questionnaires online using the REDCap system

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

I consent to participate in this study.

Participant's Signature	Printed name	Date
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Signature of Person Obtaining Consent	Printed name	Study Role	Date
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If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the subject assisted during the consent process in one of ways listed below?

Yes No [Note: For typical situations where the person conducting the consent

discussion simply reads the consent with the subject to ensure that informed consent is properly obtained, check "no".]

If yes, please check the relevant box and complete the signature space below:

- The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).
- The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

Signature of Person Assisting
in the Consent Discussion

Printed Name

Date