A Study of Reduced Dosing of the Nonavalent HPV Vaccine in Women Living with HIV

(The NOVA-HIV Study)

Information and Consent Form for Study Participants

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Granting Agency: **Canadian Institutes of Health Research**

Non-Emergency Number: **604 875 2212, Monday-Friday 8am-4pm**
Ask for the NOVA Research Coordinator or Research Assistant

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1. Invitation

You are being asked to participate in this research study because you are a woman/adult with a cervix living with HIV. We are trying to better understand the effects of the Health Canada approved human papillomavirus (HPV) vaccine GARDASIL®9 (Nonavalent Human Papillomavirus [Types 6, 11, 16, 18, 31, 33, 45, 52, 58] Recombinant Vaccine) in women living with HIV and whether or not the vaccine can be given as only two doses instead of three. We plan to enrol 450 participants across 10 Canadian sites, with 150 of those in BC.

Use of the word 'women' is intended to be inclusive of all persons who were birth-assigned female regardless of their gender identity.

2. Your participation is voluntary

Your participation is voluntary. You have the right to decline 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 doctor 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 doctor also

must take into account the requirements for the research study. This consent form describes the tests and the vaccine delivery schedule that are being carried out for research purposes.

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

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

3. Who is conducting this study?

The study team at your clinic is being supported by a coordinating center at the University of British Columbia, Vancouver, BC. This entire team is funded by a grant from the Canadian Institutes of Health Research (CIHR). Where available, provincial supplies of the GARDASIL®9 vaccine will be used for this study. The company that makes GARDASIL®9, Merck & Co., Inc. is providing the remaining vaccine and doing serology (blood) testing free of charge.

4. Background

The Human Papillomavirus (HPV) is a common virus that is known to have more than 30 different types that infect the genital area. It is spread through close skin contact and sexual contact. Three out of 4 people will be infected with one or more types of HPV in their life. Some HPV types cause genital warts, other types cause cancer of the cervix (the top of your vagina). In Canada, the best way to prevent cervical cancer has been to test for precancerous changes (unusual cell shapes) in the cells of the cervix by doing a Pap test. A Pap test is a test for cancer, in which cells from the cervix are examined under a microscope to look for abnormal cells. More recently, studies show that testing for the HPV virus can be done instead of Pap tests to check for cancer-causing HPV types. Either a pap test or HPV testing is standard in Canada to screen for pre-cancer. The best way to prevent pre-cancer due to the HPV infection is to prevent the infection through vaccination. In women without HIV, the GARDASIL®9 vaccine has been shown to prevent HPV infection in those not previously infected with one or more of the 9 types of HPV that the vaccine protects against.

5. What is the purpose of the study?

This study plans to determine if the GARDASIL®9 vaccine can be used in a different dosing schedule than is currently recommended for women living with HIV.

Women living with HIV are known to have higher rates of genital HPV infection, and more rapid progression to cervical cancer. In addition, they can be troubled by larger external genital warts that tend to be more difficult to treat. The GARDASIL®9 vaccine is designed to protect against 9 types of HPV; 2 of these types are associated with genital warts and the other 7 are the high-risk, cancer-causing HPV types. The GARDASIL®9 studies done so far have shown excellent protection against these types of HPV in women and girls who were not previously exposed to one or more of the 9 types of HPV that the vaccine protects against. GARDASIL®9 is approved for use in Canada, for girls and women aged 9 to 45 years for the prevention of cancer of the cervix caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and prevention of other genital lesions, including genital warts, caused by types 6 and 11. So far, there are no data on the vaccine's level of protection in women living with HIV, but the previous version of the vaccine, GARDASIL™

(which protected against 4 of these HPV types), is safe, produces a good immune response, and appears to prevent cervical cancer and genital warts in women living with HIV.

The purpose of this study is to investigate whether two doses of the new vaccine (GARDASIL®9) can be given instead of three in women living with HIV. We want to study whether women living with HIV can develop an adequate immune response to only two doses of the vaccine, as compared to three, and whether women living with HIV can be protected from some or all of the types of HPV found in the vaccine. We will also be checking the immune response after the first dose of vaccine.

We will be enrolling participants into either a Routine vaccine dosing schedule, giving all 3 doses in 6 months or the Extended schedule which gives all 3 doses in 12 months. It is important to note here that while the vaccine manufacturer suggests following the routine schedule, they also state that all three doses should be given within a 1-year period.

6. Who can participate in this study?

In order to be eligible to participate, you must:

1. Be 18-45 years of age
2. Have a cervix (not have had your uterus removed)
3. Be able to communicate in English if adequate translation is not available
4. Not be pregnant, and not trying to become pregnant
5. Have a confirmed diagnosis of HIV infection

7. Who should not participate in this study?

You will not be eligible to participate in this study if you:

1. Received any prior doses of an HPV vaccine
2. Are unable to provide informed consent
3. Have any documented allergy to the vaccine or its components

8. What does the study involve?

STUDY TREATMENTS

In this research study there will be two treatment groups and you will randomly be assigned to one of the two groups. The Routine Group will have 7 study visits over 2 years at the clinic and the Extended Group will have 6 visits over 2 years at the clinic. The study visits will each take about 30-45 minutes more than your routine clinic visits.

- **Routine Group**: There will be a 50% chance that you will receive the new HPV vaccine (GARDASIL®9) at the routine vaccine schedule of three doses given at month 0, month 2, and month 6.
- **Extended Group**: There will be a 50% chance that you will receive the new HPV vaccine (GARDASIL®9) at an extended vaccine schedule of three doses given at month 0, month 6, and month 12.

The vaccine doses that you receive will be given by the clinic doctors or nurses and documented in your medical chart.

STUDY PROCEDURES

There will be 6 or 7 visits for this study depending on your treatment group, spaced out over 2 years. Where possible, study visits will be scheduled on the same day as your routine clinic visits for your HIV care and will not require you to make an extra visit to the clinic for study purposes; the exceptions are the Month 1 and Month 7 visits. The Month 1 and Month 7 visits are extremely important as these are the visits where we will measure your antibody response to the vaccine in your blood.

If you agree to take part in this study, the 8 procedures and number of visits you can expect are outlined below. The details of what each of the procedures involve appear after the tables below.

Schedule of Visits for Routine Group:

	Informed consent	Pregnancy Test	9vHPV Vaccine	Blood Draw	Vaginal Swab	AE Assessment	Ongoing Medical History	HPV Self-sampling Questionnaire
Month 0	X	X	X	X	X	X	X	X
Month 1				X		X	X	
Month 2		X	X			X	X	
Month 6		X	X		X	X	X	
Month 7				X		X	X	
Month 12					X	X	X	
Month 24				X	X	X	X	X

Schedule of Visits for Extended Group:

	Informed consent	Pregnancy Test	9vHPV Vaccine	Blood Draw	Vaginal Swab	AE Assessment	Ongoing Medical History	HPV Self-sampling Questionnaire
Month 0	X	X	X	X	X	X	X	X
Month 1				X		X	X	
Month 2								
Month 6		X	X	X	X	X	X	
Month 7				X		X	X	
Month 12		X	X		X	X	X	
Month 24				X	X	X	X	X

Informed Consent:

- This will be reviewed with you at your first visit. You will be given all the time you require to ask any questions you may have about the study and have these questions answered. You will be asked at the start of each visit whether you continue to provide your ongoing consent.

Pregnancy Test:

- At each of the 3 visits that you will receive a vaccine dose, you will be asked to provide a urine sample for a pregnancy test (for all participants, regardless of age or sexual activity).

Gardasil 9 (9vHPV) Vaccine:

- Both the Routine and the Extended Groups will receive 3 does of the vaccine. On the days you will receive vaccine, you will have a brief assessment, including your temperature, to see if there is a reason to delay the vaccine dose scheduled for this visit. You will be provided with a 14-day Post-Vaccine Symptom Diary and instructions for how to complete this.

Blood Draw:

- Over the 2 years of the study, you will have blood drawn 4 or 5 times during the study depending on which Group you are in. When possible, we will combine the research blood sample collection with your clinical blood collection.

Vaginal Swab:

- These will be self-collected at 4 of the visits during the study. Instructions for how to collect the swabs will be provided.
- The swab will be tested for HPV DNA. It will show what type of HPV is present, if any. The swab will also be tested for other organisms that live in the vagina, also called the microbiome.

Post-vaccine Diary:

- You will be asked to document any symptoms (such as pain, swelling) or medications taken for these symptoms for 14 days after each dose of study vaccine. The post-vaccine diary may be provided in two formats: paper or a REDCap survey. If you are given a paper diary, you will also receive a stamped envelope to return it to the study coordinating center, or you may bring it with you to your next study visit. This will allow the research team to collect important data on any potential side effects or adverse reactions to the vaccine.

Adverse Event (AE) Assessment:

- This assessment will be done 7 or 8 times during the study. You will be asked about any significant adverse events (side effects) since your last vaccination or study visit.
- One month after dose 2 for the Routine Group and dose 3 for the Extended Group, a study staff member will call you to do this assessment over the phone, as you won't be seen in-person at this time like you will be following the other doses.

Ongoing Medical History:

- You will be asked about any changes in your health status and/or medications. These questions will be asked 6 or 7 times during the study.

HPV Self-Swabbing Questionnaire:

- You will be given a short questionnaire to fill out regarding how you feel about collecting a vaginal swab from yourself for the purpose of HPV screening for cervical cancer. This will be done 2 times, once before collecting swabs the first time and then after collecting swabs for the last time.

In addition to the procedures listed above, study staff will collect basic information from your clinical chart on things such as: your general health history, HIV history and medication history.

If there are any abnormalities to the routine clinical Pap test or HPV test you have done by your doctor and your doctor sends you for any follow-up tests, we will ask your doctor for a copy of the results of those tests for your study record. If you are admitted to the hospital for any reason or visit the emergency room we will ask for the medical records and/or discharge summary for study records. We ask for this to track any reactions to the vaccine.

All of the above tests and procedures are part of your routine clinical care (you would have them performed whether you are in the study or not) except for the study procedures which include:

- the vaginal swabs
- the questionnaire about self-swabbing
- the post-vaccine diary
- the research blood samples; these are 10 ml (2 teaspoons) each time blood is drawn, which will be collected at the same time as the routine clinic blood tests where possible

The study bloodwork will be separated into 2 or 3 smaller samples. One sample will be sent to Merck & Co in North Carolina, USA and analyzed for immunity to the HPV types contained in the vaccine. The other sample will be stored at BC Women's and Children's Hospital in Vancouver, BC, Canada as a backup sample.

The vaginal swabs will also be split into 2 or 3 smaller samples. One sample will be sent to the National Microbiology Lab in Winnipeg for HPV DNA testing. The other samples will be stored at BC Women's and Children's Hospital in Vancouver, BC, Canada as a backup sample to repeat the HPV DNA testing if necessary. If it is not needed for this purpose, it will be sent to the Hill Lab at the University of Saskatchewan in Saskatoon to look at the vaginal microbiome.

There is also a third research blood sample that will be collected at **Month 0** and **Month 7** on 60 participants in the **Routine Group** and 60 participants in the **Extended Group**. This blood sample will be 20 ml (4 teaspoons) in addition to the research sample that will be collected from all participants. This sample will be used to perform a more in-depth assessment of the specific way in which the immune system has responded to the vaccine.

Please indicate, by checking the applicable box, whether you consent to provide the additional blood samples as described above.

☐ Yes, I consent to the additional blood samples for the in-depth immune system assessment.
Participant Initials: _____

☐ No, I do not consent to the additional blood samples for the in-depth immune system assessment.
Participant Initials: _____

☐ This option is not available as this sample is not being collected at this site or all 120 participants have been enrolled.
Study Staff Initials: _____

As the vaginal swabs for detection of HPV DNA will be tested in a research lab, we will not be returning the testing results to either you or your physician.

The study visits **do** require a small amount of additional time over a usual clinic appointment. About 30-45 minutes at each visit will be needed for study related activities.

HEALTH INFORMATION LINKAGE, DATA STORAGE AND SECURITY

As part of this study, we plan to follow over time if you are diagnosed with any type of cancer during or after the study period. We plan to determine this by accessing the BC Cancer Registry and/or your clinical records. In the case of using the BC Cancer Registry, in order to link to this health database, we would need to use your first name, last name, full birth date, and provincial health card number (PHN) stored in the secure NOVA-HIV Participant Master List. 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, within a high-security environment. The provincial health database and NOVA-HIV Team follow strict provincial privacy policies. This linkage will provide us with information related to Pap/HPV tests results done as part of your clinical care, as well as any results relating to pre-cancer or cancer diagnoses including biopsy results. This linkage may be done a number of years after the study is finished.

Please indicate, by checking the applicable box, whether you consent to the study team collecting your personal information for the purpose of this linkage.

☐ Yes, I consent to the collection of my first name, last name, and PHN for future linkage to the BC Cancer Registry as described above.

Participant Initials: _____

☐ No, I do not consent to the collection of my first name, last name, and PHN for future linkage to the BC Cancer Registry as described above.

Participant Initials: _____

Testing results, leftover samples and health data collected as part of this study will be kept for a maximum of 15 years after the study is finished.

9. What are my responsibilities?

If you take part in the study, you will need to visit the study doctor/clinic for the visits described above.

10. What are the possible harms and discomforts?

Risks and Discomforts from Blood Draws

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.

Vaccine Associated Risks (described as mild to moderate)
You will receive the HPV vaccine by injecting 0.5 ml (1/10 teaspoon) of liquid through a needle into the muscle in your shoulder.

As for any vaccine, vaccination with GARDASIL®9 may not result in protection for all people who receive it.

What is known about these vaccines? Has this vaccine been given to people before?
GARDASIL®9 has been approved for use in girls and women aged 9-45 years old.
In clinical studies of GARDASIL®9 about 15,776 people received at least one dose of GARDASIL®9.

GARDASIL®9 has been generally well tolerated**.**

What side effects could the study vaccine cause?

Serious Vaccine-related Side Effects:
Out of the approximately 15,776 people who received GARDASIL®9 during the clinical studies, four (4) people, 0.03%, had serious side effects judged by the study doctor to be related to GARDASIL®9. These side effects were: allergy to the vaccine, fever, asthma attack, and headache.

Common But Less Serious Vaccine-Related Side Effects:
The following occurred in 1 or more of 100 people, 1% or more, and may be related to the vaccine: pain, swelling, redness, itching, bruising, a small mass, or bleeding at the injection site, headache, fever, nausea, dizziness, fatigue, diarrhea, and mouth, throat, or muscle pain.

Adverse Events:
If you are experiencing serious side effects as a result of the vaccine, please go to the nearest hospital emergency room immediately. If you are experiencing any common side effects from the vaccine, please consult your doctor as necessary. Please inform the Research Coordinator or Research Assistant at 604 875 2212 if you experience any adverse events related to this study, including the aforementioned side effects.

Pregnancy:
Between 2006 and 2014, more than 10,000 pregnancies were followed where the GARDASIL®9 vaccine had been received during pregnancy, and increased rates of negative events were not found in these cases. However, specific safety studies with GARDASIL®9 in pregnant women have **not** been performed. Because this is a study of non-pregnant adults, we ask that you not become pregnant during the vaccination period of the study.

Participants who are sexually active during the vaccination phase of the study must use effective birth control. If you suspect that you have become pregnant during the vaccination phase of the study, you must notify your doctor and the study staff immediately.

If you have a positive pregnancy test as part of your study visit, a doctor or nurse from the clinic will speak with you about this. If you have a positive pregnancy test outside of the clinic, please call the study team and let them know. Your study participation and most study procedures will continue during your pregnancy but study vaccinations will be paused until 1 month after the end of your pregnancy.

We will ask you to sign an additional consent so that we are able to collect information on your health during your pregnancy and about the pregnancy outcome.

11. What are the potential benefits of participating?

Where available, we will use publicly available vaccine doses for you. A benefit of participating in this study is access to the vaccine at no cost to you if not publicly available. You may receive protection from up to 9 types of HPV, and therefore potentially cervical and other cancers caused by HPV, as a result of being vaccinated. However, you could receive this vaccine outside of study if you requested to. It is also possible that you may not receive any benefit from this study. However, knowledge gained from this study may help others in the future who are also living with HIV.

12. What are the alternatives to the study treatment?

You may choose not to take part in the study. You may choose to receive the HPV vaccine outside of study if you wish.

HPV vaccination is not a substitute for routine cervix (Pap or HPV) screening. It is very important that you continue regular cervix screening during the study and after study completion. Regular pelvic examinations and laboratory tests are important for the early detection of HPV infection and cancer of the cervix.

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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. The identification number for this study is NCT05495906.

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, the study team will have a discussion with you about what will happen to the information about you and your samples already collected. You have the right to request the destruction of your information and samples collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data and samples will not be able to be withdrawn, for example where the data and sample 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. If you would like to request the withdrawal of your data and samples, please let your study doctor know. If your

participation in this study includes enrolling in any optional studies, or long-term follow-up, you will be asked whether you wish to withdraw from these as well.

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, the study team may withdraw you from the study and will arrange for your care to continue. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

16. 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 Health Canada and/or the UBC Children's and Women's Research Ethics Board 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.

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.

Your vaginal swab samples will be sent to the National Microbiology Lab in Winnipeg and the Hill Lab at the University of Saskatchewan in Saskatoon, but no information about you will be sent with these samples. The samples will be sent by courier and will only be labeled with you study ID.

Your vaginal swab samples will be tested in batches so it could be a number of months until they are tested. In cases where the same type of high-risk HPV is found on 2 occasions, a minimum of 6 months apart, if you choose to provide the name and contact information for your primary health care provider, we will notify them and recommend following up with pap or HPV DNA testing or colposcopy (a procedure to closely examine your cervix and vagina for signs of disease). The research team will collect any clinical outcomes that arise from clinical care.

Please provide the name and contact information for your primary health care provider:

Name and Clinic/Office: _____

Phone Number or Email: _____

Your blood samples will be sent to a lab in North Carolina, USA but no information about you will be sent with these samples. This is being done as this laboratory has the most experience in testing for immune responses following this particular vaccine. Any study related data and samples, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, dealing with protection of information may not be as strict as in Canada. However, all study related samples that will be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site and the results will be returned attached to this code. By signing this consent form, you are consenting to the transfer of some of your samples, to organizations located outside of Canada.

17. 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. You should be aware that providing this information is not mandatory.

18. What happens if something goes wrong?

By signing this consent form, you are not waiving any of your legal rights nor are you freeing the investigators, sponsors, or the health establishment where the study takes place from their legal and professional responsibilities. In the event you suffer injury as a direct result of participating in this study, necessary medical treatment will be provided by your provincial medical plan.

In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following person can then be contacted for further information: Dr. Deborah Money or study Research Coordinator or Research Assistant at 604 875 2212.

19. What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

Reimbursement and Remuneration

There will be no financial costs to you for participating in this study. You will not be charged for the study drugs or any research procedure. You will be paid $30.00 for the first study visit as it takes longer than the others, $30 for visits at months 1 and 7 as they are the most important visits of the study, and then $25.00 for each of the other study visits. These payments are to thank you for the time it will take you to participate in the study. You will be paid at the end of each visit.

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, please contact the Research Coordinator or Research Assistant at 604 875 2212.

21. Who do I contact if I have any 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 any privacy related complaints 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 H22-02639 when calling so the Complaint Line staff can better assist you.

22. After The Study is Finished

Please contact the Research Coordinator at the Oak Tree Clinic at 604 875 2212, with any requests you may have about study updates or results. We will not be providing individual results from this study.

A Study of Reduced Dosing of the Nonavalent HPV Vaccine in Women Living with HIV

(The NOVA-HIV Study)

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- 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 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 authorize access my health records and samples as described in this consent form.

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

_____	_____	_____
Signature of Person Obtaining Consent	Printed Name	Date

<u>Future Research:</u>

Are you willing to be contacted for a future follow-up study to the current NOVA-HIV study?

☐ Yes: phone number: _____ ☐ No

Email: _____

Use of a Translator:

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 participant 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 participant 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).

Name of Person Assisting in the Consent Discussion (name only if conducted remotely)	Printed Name	Date
Signature of Person Witnessing the Translation if Conducted Remotely	Printed Name	Date