Part 1 of 2: Master Adult Consent Form

Protocol Title: A Phase 1b, double-blind, randomized, dose-escalating, age de-escalating, placebo-controlled study to assess the safety and immunogenicity of one or two doses of Sing2016 M2SR H3N2 influenza vaccine delivered intranasally in a healthy pediatric population 6 months through 17 years of age. (DMID Protocol Number: 20-0009)

Study No.: HP-00096648

Site Name: University of Maryland, Baltimore

Principal Investigator: James D. Campbell, MD, MS [redacted]

Sponsor: National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID)

Now that you are 18 years old, you are being re-invited to consider continuing participating in this research study. This document is called a consent form. It will explain what the study is all about. You have already assented to be in the study. Assent was done using an assent form that contained simplified language. This form is the one used for adults. It states very similar information, but in greater detail. This form covers everything we covered with your parents when we asked for permission to enroll you in this study. This study is what we call a multi-site study, meaning it will take place at several different locations. This consent form is broken into two parts. Part 1 is called the **Master Consent Form** and includes information that applies to all study sites. Part 2 is the **Study Site Information Adult Consent**. It includes information specific to the study site where you are being asked to consider continuing your enrollment. Both parts together make up the full consent form, and both will be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

This is a study of an experimental vaccine for influenza (the flu). The vaccine is given as a spray in the nose in the months when we usually don't give the routine flu vaccine. We are testing to see how well the vaccine is tolerated (side effects) and whether it can lead to immune responses (tests on blood and nasal washes) that might be protective. The study is part of a broader plan to discover flu vaccines that might work better than the ones we use now. This vaccine has been given to adults and older children in previous studies. This is the first study to test it in younger children.

If you choose to continue participation, you will have up to two more blood draws and nasal washes (depending on when you turned 18 and signed this form) and we will continue to follow you for safety and side effects. We will also give you the routine, licensed seasonal flu vaccine when available in the Fall.

The possible risks of the study include reactions to the vaccine and discomfort from the blood draws and nasal washes. There are no known benefits to you, but we may learn this vaccine leads to a better response than the regular flu vaccine. It is up to you to decide if you want to continue participating in this study or if you want to stop. If you decide to stop, please see the relative section below for steps to do so.

If you remain interested, please read on because more details are found below.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to give consent to continue participating in this research study. It is your choice to continue participating in this study. You may choose not to continue in this study. That choice will not change your healthcare, services, or other rights. You can also decide to stop participation in this study at any time. If you choose to stop participating in this study, we would like to still follow you up for safety. No additional study procedures such as nasal washes and blood draws will be performed. If so, please follow the procedures noted below to notify us of your decision.

If we learn something new that may affect your participation in the study, you will be told so and you can decide whether you still want to be in this study. If at any time, the study physicians feel your participation in this study needs to be halted, you will be withdrawn and informed about this decision.

Side effects and risks that you can expect if you take part in this study:
The possible risks of continuing participation in this study are (1) the side effects of the vaccines, (2) the risks and discomforts of having blood drawn and nasal washes/swabs, (3) the unknown risks to a fetus if you, (if female) become pregnant or (if male) father a child, (4) the risk of loss of confidentiality, and (5) other possible risks.

(1) Risks of the vaccines:
The risks of the study vaccine. This study required you to be no older than 17 years at enrollment. Now that you are 18 years-old, we will not be giving you any additional study vaccine product. Those risks were explained to you and your parent when you first joined.

The risks of licensed seasonal flu vaccine shot. As part of this study, since you will be receiving the seasonal flu shot, you could have the side effects associated with the seasonal vaccine. We will provide you with the Vaccine Information Sheet (VIS) that all people get when they get vaccinated. It explains the possible risks. They will likely be the same as when you would normally get the flu shot.

Allergy. All vaccines could cause an allergic reaction. Serious allergic reactions occur less than 1 in a million times with the routine flu shot. They can be serious and can cause hives; swelling around the mouth, throat, or eyes; difficulty breathing; a fast pulse; or loss of blood pressure. If these reactions occur, they can usually be stopped by the administration of emergency medications by the study personnel. As with any vaccine or medication, there is a very small chance of a fatal reaction (death), although researchers do not expect this to occur.

Wheezing. Wheezing is when you hear a high-pitched whistling noise when you breathe. Since the study vaccine does not replicate, we do not expect this with the study vaccine, however, it may occur. If you have wheezing, please let the study team know. You will be instructed on how to notify us and how to record it in your eDiary.

Guillain-Barré Syndrome (GBS). During the 1976 vaccine campaign directed against swine influenza, which was caused by a type A H1N1 influenza virus, some recipients developed an illness called GBS. GBS is a problem which causes weakness or paralysis. For the 1976 swine influenza vaccine, about 1 per every 100,000 vaccine recipients got GBS. This problem is rare and has not been reported with the currently licensed seasonal flu vaccine. It is not expected with the study vaccine given in this study.

(2) Possible side effects of the procedures (blood drawing and nasal washes/swabs):

Drawing Blood. Drawing blood is typically well tolerated and uneventful but may cause temporary mild discomfort. It may uncommonly cause fainting or near fainting. Bruising at the blood draw site may occur. The risk of injury from a blood draw is not higher in this study relative to routine clinical care.

Nasal Washes and Nasal Swabs. Obtaining a nasal wash/swab may cause mild discomfort and on rare occasions may cause a nosebleed. A nosebleed due to a nasal wash/swab is temporary and can be managed by applying pressure for a short duration of time.

(3) Possible risks of vaccine during pregnancy:

Pregnancy. It is unknown if this vaccine poses any risks to a pregnant woman or her unborn child. Because of that, if you are female and of "childbearing potential", you must agree to use an effective method of birth control or abstinence. If you are male, who is sexually active with a female of childbearing potential, you must agree to use an acceptable method of contraception. Once enrolled, pregnancy or fathering a child should be avoided for up to 60 days after final dose of study vaccination given we do not know if the vaccine can cause birth defects.

(4) Possible risk of loss of confidentiality:

Loss of Confidentiality. You will be asked to provide health information. We will try to keep this confidential. However, there is a chance that unauthorized persons could gain access to this information. All hard copy study records will be kept in a locked file cabinet or maintained in a locked room at the participating site. Electronic files will be password protected. Only people who are involved in the conduct, oversight, monitoring, or auditing of this trial will be allowed access to the information that is collected. Any publications from this trial will not use information that will identify participants by name.

A description of this clinical trial will be available on https://clinicaltrials.govv, as required by US law. This web site will not include information that can identify participants. At most, this web site will include a summary of the results.

(5) Other possible risks:

Other potential risks. Uncommonly, "live" influenza vaccines have been found to transmit between humans. We do not anticipate this with the study vaccine because it is non-replicating.

Unknown Risks. There could be unknown risks associated with participation.

Good effects that might result from this study.

This study may provide benefits to society by contributing important information to create a better flu vaccine. However, you may not benefit directly from participation. It is also possible that the vaccine will help to protect you against flu. If you received placebo, you may not draw any benefit from participating in this trial.

Procedures.

The section below describes the procedures that will occur. A complete detailed schedule will be given to you if you choose to continue participating.

Screening. Screening is the process by which we had determined if you were eligible for enrollment. It is based on a set of criteria. When we completed your screening, we had reviewed your medical, vaccination, and medication history, and did a physical examination. We found you eligible and hence obtained your written assent for participation. You no longer need to be screened.

Overall, about 200 children will enroll with about two-thirds receiving the nasal spray vaccine and about one third receiving the salt water (placebo) spray. You are always welcome to ask any questions you have during the screening visit.

Enrollment. Given the study requires that you were 17 years old or younger when you enrolled and received the study vaccine and you are now 18 years old, we will not be describing the enrollment procedures to you including administration of study vaccination in detail again.

When you enrolled in the study, a computer had decided, by chance, whether you got the nasal spray study vaccine or saltwater placebo spray. We and you could not choose which you got and do not know what you got. This is called "double blinded". Given you got the study vaccination on the day of enrollment, you will not receive any additional study vaccine or placebo. At enrollment, you received either the study vaccine or a placebo in both nostrils, as a spray. All participants in the study will get the licensed seasonal flu shot with first dose between September and November.

Follow Up Visits and eDiaries. You will have or have had a number of visits after you received your study vaccine. We plan on calling you to follow-up with you for the study. We have already provided you and your parent with the schedule. We will have three in-person follow-ups 28 days after receiving either the study vaccine or licensed seasonal flu vaccine where you will be asked questions about your health and medications. We also plan on calling you three times: about two and seven days after study vaccination and a final time the following year around April. You will also receive your licensed seasonal flu vaccine 28 days after your study vaccination. You will have two blood draws and two nasal washes after having received the nasal spray study or licensed seasonal flu vaccine. These are done to look for immune responses to the study vaccine. You will also complete or have completed an eDiary in which you electronically record any side affects you may have noticed. You were taught how to record in the eDiary, items such as your temperature and whether or not you had a runny nose. eDiaries are used for the week after each study vaccination and throughout the study. Ask your study team if you have any questions or would like to review this with them again or like to know how many more phone, in-person visits you have left.

Follow-up for Wheezing. If you have any wheezing episodes, please contact the research team. We will collect information about how ill you are and may ask you to come in to get a nasal swab to test for germs that can cause infections of the nose, throat, and lungs. Wheezing is when a high-pitched whistling noise is heard by your doctor when you breathe. If you see your own doctor for wheezing, please be sure you let your study nurse know as soon as possible.

Blood drawing. The total amount of blood drawn at any visit and over the study duration will be around 27 milliliters, mL (around 5 teaspoons), for a total of around 81 mL (around 16 teaspoons) of blood for the whole study. We will draw your blood up to two more times in this study. One was before your first vaccination and at up to two other visits after vaccination. Your study staff member can clarify how many more draws you have left and when they will be done.
Nasal washes. A nasal wash is a procedure where a member of the research team squirts salt water into your nostril and then collects it for testing. It is done with a "bulb syringe"- the same thing a parent uses to remove nasal secretions from a baby's nose. This is done 3 times throughout the study, at the same visits as when blood is drawn.

Pregnancy tests. Given you will not be receiving any additional study vaccine product, this will not be performed again.

Total Duration.
You began in the study during the flu off-season. You will be followed up until April of the following year.

Reasons why the study doctor may ask you to stop participating.
If we believe that it is in your best interest to stop participating, the study doctor may ask you to withdraw. Also, if you are unable to make the visits or continue to follow the procedures, we may also withdraw participation. There may be other reasons and the study doctor will discuss them with you, if necessary, to allow you to make a decision on whether you want to withdraw or not.

What will happen if you decide to stop participating in this study?
If you decide to stop being a part of the study, you should tell your study doctor or study staff member. Deciding to not be part of the study will not change your regular medical care in anyway. The study team may ask to continue follow-ups with you after you stop participating to make sure we see no concerns with what you have received.

Clinical Trials Registry.
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. 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.

Privacy.
The samples and information we collect may be made available to others to use for research. Both your samples and your health data will be stored with a coded identifier. The association of your coded identifier with your name will only be stored and maintained at the site where you enrolled. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers, learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Secondary Use and Biorepository.
As part of this study, we are obtaining blood and nasal samples from you. There may be blood or nasal samples that we collect for this research study left over after the research tests are done. You will be asked to give permission for your data and remaining samples to be placed in a biorepository. All the information you need to know about the biorepository is contained in a separate consent form. Details about specific types of research that are allowable under the biorepository protocol will be provided to you during the biorepository consent process. Please do not hesitate to ask your consenting practitioner questions. Your information or leftover specimen that are collected as part of this research, will not be used or distributed for future research studies if you choose not to consent for the biorepository.

Study Results.

The results from your individual participation will not be shared with your healthcare providers. This is for research only.

Part 2 of 2: Study Site Information Adult Consent Form

This is the second part of the consent form. It includes information about the site that is asking you, as an 18 year-old, who began participation when you were 17, to continue to participate in this study and is specific to participation at your site only. Before making your decision, both the general study information (above in **Part 1**) and the site-specific information (here in **Part 2**) and will be reviewed with you.

What are my responsibilities if I take part in this study?

If you take part in this research, you will be responsible to:

- Comply with all planned study procedures and be available for all study visits
- Complete a memory aid (diary card) to record any reactions you experience following vaccination(s)
- Contact the study staff or doctor if you have severe symptoms (not feeling well) or are hospitalized, or feel concerned about symptoms
- If you are of child-bearing potential, agree to abstain from sexual intercourse or correctly use an acceptable method of contraception
- If you are a male who is sexually active with a female of child-bearing potential, agree to use an acceptable method of contraception
- Agree to not join another clinical trial that includes an investigational agent or device during the study period
- Agree that you do not plan to receive a licensed live vaccine within the 30 days following the last study vaccination
- Agree that you do not plan to receive a licensed inactivated vaccine within the 30 days following the last study vaccination
- Agree that you do not plan to receive an influenza vaccine, except the influenza vaccine being provided as part of this study, within the 30 days following the last study vaccination.
- Agree that you do not plan to receive immunoglobulin or other blood products during the period of study participation
- Agree that you will not receive another experimental agent or device during the study period unless clinically necessary

Payments for your time spent taking part in this study:

You will be compensated for your time and inconvenience for the study visits, taking study phone calls, and completing the eDiary. The total amount depends on the number of each type of visit and activity that you perform for the remainder of the study. The total amount will be approximately [redacted] for those receiving 1 intranasal vaccine dose and approximately [redacted] for those receiving 2 doses. The exact amount may vary depending on whether or not there are unscheduled visits and if you are able to complete all the visits, take all the calls, and complete

the eDiary. The compensation will be given by eGift Cards with a number of options for where they can be used. You will only be compensated for the visits and activities you complete.

You will be paid for the visits you complete according to the payment schedule that is provided to you.

We ask that you notify the Internal Revenue Service (IRS) of this income. A Form 1099-MISC (for miscellaneous income) will be mailed to you for you to report this compensation to the IRS.

Costs to you if you take part in this study:
There will be no charge to you for your continued participation in this study. The study vaccine, study-related procedures, and study visits will be provided at no charge to your or your parent/guardian's insurance company. You or your parent/guardian's insurance company may be billed for any standard medical care that is not required for the research study.

Payment in case you are injured because of this research study:
Immediate necessary medical care is available at the site where you joined and/or one of its affiliated institutions or health care groups if you are injured as a result of your participation in this research study. However, our site will not provide monetary compensation or on-going free medical care to you in the event of a study-related injury. In addition, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the federal government.

For questions about the study or research-related injury, contact James D. Campbell, MD, MS at [redacted] during regular business hours or at [redacted] after hours and on weekends and holidays.

Who to call for any questions or in case you are injured:
For questions about the study or a research-related injury, or if you have problems, concerns, questions, or suggestions about the research, contact Dr. James D. Campbell at [redacted] (Baltimore - business hours), [redacted] (Baltimore - 24 hours), and [redacted] (Frederick – 24 hours).

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the University of Maryland Baltimore Institutional Review Board at [redacted].

Confidentiality:
We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information will be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the

research. Your personal information will not be shared with investigators at the other participating sites. Your personal information may be given out if required by law.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you from voluntarily releasing information about your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you must also actively protect your own privacy.

Finally, you should understand that the investigators are not prevented from taking steps, including reporting to authorities for serious social harm including, but not limited to child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to you or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected. Disclosures of information that may have been made prior to you turning 18 are not subject to the policy highlighted here.

If you agree to participate, the personal information about you that you provide today and that is added to our study files will be kept indefinitely. If you change your mind and decide that you do not want to participate in the study, we will change your status. No new information about you will be collected other than data needed to keep track of your withdrawal.

Your data may be shared with people who oversee the conduct of this study. Monitors, sponsor, auditors, the Institutional Review Board (IRB)/Ethics Committee (EC), and regulatory

authorities, such as the FDA, will be allowed to look at your medical and research records. They check that the procedures are being done correctly. They will protect your confidentiality within the fullest extent of the law.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name and other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of our site, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Can I share information about the study?

If you agree to continue to participate in this study, you should feel free to discuss the study with family and with other people who are close to you. It is recommended to tell your health care provider about your participation in the study. However, to help make sure that the information from the study is as accurate and reliable as possible, please do not discuss information about the study in public places while the study is in progress. Public places include things like social media (Facebook, Instagram, Twitter), blogging, and speaking to the media. You may, however, share your experiences participating in this study with family and friends who may be interested in participating in our clinical trial and refer them to us if they express interest.

University Statement Concerning Research Risks

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under state and federal law. You give up none of your legal rights by signing this consent form or by continuing to participate in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for your specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury. No long-term medical care or financial

compensation for research-related injuries will be provided by the NIH or the Federal government.

By signing this form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
[redacted]

Health Insurance Portability and Accountability Act (HIPAA)
Authorization to obtain, use and disclose Protected Health Information For Research

Name of Study Participant:_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: A Phase 1b, double-blind, randomized, dose-escalating, age de-escalating, placebo-controlled study to assess the safety and immunogenicity of one or two doses of Sing2016 M2SR H3N2 influenza vaccine delivered intranasally in a healthy pediatric population 6 months through 17 years of age. (DMID Protocol Number: 20-0009)

UMB IRB APPROVAL NUMBER: *HP-00096648*

RESEARCHER'S NAME: *JAMES D. CAMPBELL, MD, MS*

RESEARCHER'S CONTACT INFORMATION:

Center for Vaccine Development and Global Health
University of Maryland School of Medicine (UMSOM)
685 West Baltimore St., Suite 480
[redacted]

This research study will use health information that identifies you. If you agree to continue to participate, this researcher will use just the health information listed below.

The Specific Health Information To Be Used or Shared:

- Health-related information you have been asked to provide for the study during interviews and via questionnaires
- Results of medical tests, laboratory tests, research procedures carried out for the purpose of the study
- Medical records from another health care facility that may be needed to determine whether a side effect or other problem is related to the study
- Billing and payment information and the medical information required to justify it.

Federal laws require this researcher to protect the privacy of this health information. He will share it only with the people and groups described here.

People and Organizations Who Will Use or Share This Information:

- Dr. James Campbell and his research team, including the nursing, laboratory, administrative and regulatory affairs staff at the Center for Vaccine Development and Global Health (CVD), and contracted affiliates of the CVD
- The sponsor of the study, the National Institute of Allergy and Infectious Diseases of the National Institutes of Health or its agents, such as data repositories or contract research organizations

- Federal and state agencies that have authority over the research, including the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Office of Human Research Protections
- University of Maryland Medical System (UMMS)
- Clinical staff not involved in the study who may become involved in your care if it is potentially relevant to treatment
- Organizations that will coordinate health care billing or compliance such as offices within University of Medicine School of Medicine (UMSOM); the University of Maryland, Baltimore (UMB); University of Maryland Faculty Physicians, Inc. (FPI) and the faculty practices of the UMB; and University of Maryland Medical System (UMMS)
- Your health insurer to pay for covered treatments

This Authorization Will Not Expire. But You Can Revoke it at Any Time.
To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered.

Additional Information:
- You can refuse to sign this form. If you do not sign it, you cannot continue to participate in this study. This will not affect the care you receive at:
    - University of Maryland Faculty Physicians, Inc. (FPI)
    - University of Maryland Medical System (UMMS)
- It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, FPI, or UMMS to give copies to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from him/her.

My signature below indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Privacy Questions? Call the UMSOM Privacy Official ([redacted]) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the study, or to obtain information or offer input about the study. I have read this consent form and agree to continue to be in this study, with the understanding that I may withdraw at any time. I also understand that agreeing to continue in this study does not obligate me to participate in any research studies that I may be approached about in the future. I understand that if I agree to participate in a future study, I will sign a separate consent specifically for that study. I have been told that I will be given a signed and dated copy of this consent form.

_____

Printed name of the participant

_____

Signature of participant Date

_____

Printed name of the research staff member obtaining consent

_____

Signature of the research staff member obtaining consent

_____ _____

Date Time