INFORMATION AND CONSENT FORM FOR PARENTS/LEGAL GUARDIANS OF STUDY PARTICIPANT

Sponsor/Study Title:	SANZYME BIOLOGICS PVT LTD / "*A randomized, double-blind, placebo controlled, parallel clinical trial to investigate the safety and efficacy of Bacillus coagulans SNZ 1969 on immune health in healthy school-aged children*"
Protocol Number:	25SACCP01
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You must be the child's parent or legal guardian to consent to their participation in this study. By signing this form, you confirm that you have full authority to consent on your child's behalf and that there are no shared or joint decision-making arrangements with any other parent, legal guardian, or party at this time. Your permission and the assent of your child will be required. When "you" is mentioned in this form, it refers to you as the parent or legal guardian, except where otherwise stated.

Making an Informed Decision

Your child is invited to participate in a clinical research study exploring how a natural health product may help immune health in children. Participation in this study is strictly voluntary.

To help you make an informed decision about your child's participation in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to make an informed decision.

This consent form outlines the study's purpose, procedures, potential benefits, risks, and how your child's medical information will be handled. Take your time to thoroughly read all the details about the study, and do not hesitate to ask any questions you may have regarding the information given and about the study. Study staff can explain words or information that you do not understand and will answer all your questions and concerns. Reading this form and discussing it with the study staff may help you decide whether you want your child to participate. You have access to this form and can review it at your leisure before making a decision.

Once you and your child fully understand the information provided, feel comfortable with the decision to participate, and have had all your questions about the study answered to your satisfaction, you will be

asked to sign and date this form if you and your child wish to proceed. You will be provided with a signed copy of this form and are expected to keep it for your record. Once you and your child provide consent, the study assessments will proceed.

If your child voices to the study staff that they do not want to proceed with the study at any point, study staff will not proceed with the study.

Do not sign this form until you fully understand the information provided and are comfortable with your decision to allow your child to participate. If you wish to contact the study staff, please use the phone number or email address provided at the top of this page.

Background and Purpose

Many school-aged children get sick several times a year with upper respiratory infections, such as the common cold, or gastrointestinal infections like the stomach flu. Although children are among the most affected by these infections, there is a noticeable lack of options for natural health supplements that provide strong evidence for reducing the burden of cold and flu-like symptoms for children.

Bacillus coagulans is a type of beneficial bacteria known as a probiotic. It is approved for use in Canada to contribute to healthy gut flora and reduce oral plaque and gingivitis. The purpose of this study is to evaluate how *Bacillus coagulans SNZ 1969* (*B. coagulans*) helps support the immune system in children attending school.

Study Population

This study will include approximately 100 healthy males and females between 6 and 12 years of age who are attending school in person.

How Long Is the Study?

If eligible after the screening visit, your child's participation in this study will last approximately 84 days.

Important Things to Note

General

- If you are the parent or legal guardian providing consent for your child to participate in this study, you will be required to attend all future study visits with your child and must be willing and able to complete questionnaires. Please note that another parent, legal guardian, or individual cannot substitute for you at subsequent visits.
- To determine your child's eligibility to participate in this study, detailed information about their lifestyle, medications, and medical history will be collected. This information will help determine if they are a good fit for this study.
- By signing this consent form, your child is not guaranteed to be enrolled in the study. Their participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study uses competitive enrollment. Once 100 participants have enrolled and started the study, no additional participants will be accepted. Therefore, if your child completes the screening phase (including the run-in period) and are found eligible, they may still be withdrawn from the study without your and their consent if the enrollment limit has already been reached. Since no official study enrollment would take place, they would not be eligible for study compensation.

Study-Specific

- Your child should not participate in this study if they have history of severe environmental allergies that require allergy shots.
- If you and your child voluntarily agree to participate in this study, your child must be willing to:
  - Collect stool, saliva, urine (if applicable), and blood samples
  - Complete study questionnaires, records, diaries and complete all study visits
  - Maintain current lifestyle habits (such as diet, physical activity, medications and supplements, and sleep) throughout the study

Study Design

The study design describes the plan for how the study is conducted. This is a *randomized, double-blind, placebo controlled, parallel* study.

Randomized — During Visit 2, if your child is eligible to participate, they will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:

- *Bacillus coagulans* SNZ 1969 group (active ingredients)
- Placebo group (inactive ingredients)

Neither you, your child, or the study staff will be able to choose which group your child is in so that the random assignment is fair and unbiased. Your child will have an equal chance of being assigned to either group.

Reference to "study product" refers collectively to both the active study product (*Bacillus coagulans* SNZ 1969) and the placebo.

Double-blind — Neither you, your child, or the study staff will know which group you have been assigned to. However, if needed for your child's safety, the study staff can find out this information.

Placebo controlled — A placebo is an inactive substance that looks like the study product but has no active ingredients. It is used in research to help determine whether the study product has real effects beyond what might happen by chance or expectation.

Parallel — Your child will stay in the same randomly assigned group for the entire study.

What Will Happen During This Study?

Assessments and Procedures

Blood Samples – Visit 2 and 5 (*and Early Termination if applicable*)

- The total blood volume collection will be approximately 60 mL (approximately 4 tablespoons), over the period from Visit 1 to the end of the study Visit 5 (approximately 131 days). At any study visit, blood volume collected is not expected to exceed 30 mL (approximately 2 tablespoons). Additional blood samples may be collected during the study if necessary, such as in cases of abnormal test results or processing errors, or to conduct or repeat laboratory tests.

Urine Samples – Visit 1, 2 and 5 (*and Early Termination if applicable*)

- If your child is of child-bearing potential, they will be required to provide a urine sample in-clinic for a urine pregnancy test. They will be provided with a collection container and instructed on how to provide the sample.

Stool Samples – Visit 2 and 5

- Stool samples will be collected at home within 4 days of visits 2 and 5 and returned to the clinic. You and your child will receive detailed instructions on how to collect, store, and transport the sample.

Saliva Samples – Visit 2 and 5

- Saliva samples will be collected either on the morning of your child's in-clinic visit or the day before Visits 2 and 5. A collection kit with instructions will be provided to collect the samples at home.

Study Diary

- You will be asked to complete an online daily study diary on your child's behalf throughout the study (starting during the run-in period). Questions about study product use, lifestyle habits, cold/flu and gastrointestinal symptoms, missed school days, and any changes in medications (including over-the-counter medications and vaccinations) and/or health will be included.
- **Canadian Acute Respiratory Illness Flu Scale (CARIFS) and Additional Respiratory Tract Symptoms (ARTS) Questionnaire** will be included in the study diary to help assess your child's respiratory symptoms. It will ask how often these symptoms happen, how long they last, and how severe they are.
- **Gastrointestinal Tract Infection (GITI) Symptom Questionnaire** will be included in the study diary to track how often your child experiences gastrointestinal symptoms, how long they last, and how severe they are.

Schedule of Study Visits

Visit 1 – Screening
• After informed consent and assent is obtained, your child's medical history, medications, vaccination history, current health status and lifestyle will be reviewed • Blood pressure, heart rate, weight, height, urine pregnancy test (if applicable). • Study diary (including CARIFS and GITI Symptom Questionnaire), saliva and stool collection kits will be dispensed along with instructions • Your child's eligibility will be reviewed and if they are eligible, they will complete a run-in period
Run-in period
Together you will complete the study diary (including CARIFS, ARTS, and GITI symptoms questionnaires) for 14 days before coming to clinic for Visit 2
Visit 2 – Baseline/Enrollment (Day 0)
• Return to the study clinic with collected saliva and stool samples, and completed study diaries • Completed diaries including CARIFS, ARTS, and GITI symptoms questionnaires will be reviewed • Any changes in health or medications (including vaccinations) will be reviewed

- Blood pressure, heart rate, weight, height, urine pregnancy test (if applicable), blood sample collection
- If your child still meets all necessary study criteria and are eligible, they will be randomized (assigned to a study group)
- Study product, study diary, saliva and stool collection kits will be dispensed with instructions

Visit 3 (Day 28 ± 2 days) and Visit 4 (Day 56 ±2 days)

These visits will be conducted virtually

- Completed diaries will be reviewed including CARIFS, ARTS, and GITI symptoms questionnaires, and any changes in health and/or medications
- Study staff will confirm how many packets of study product are remaining to verify if the study product was taken as directed
- New study diary will be dispensed

You will be reminded to return study product, saliva and stool samples for in-clinic visit 5.

Visit 5 – End of Study (Day 84 ± 2 days)

- Return to the study clinic with collected saliva and stool samples, completed study diaries, and unused study product
- Completed diaries including CARIFS, ARTS, and GITI symptoms questionnaires will be reviewed
- Any changes in health and/or medications will be reviewed
- Blood pressure, heart rate, weight, height, urine pregnancy test (if applicable), blood sample collection
- Study staff will count how many packets of study product are remaining to verify if the study product was taken as directed

Medications, Supplements/Natural Health Products, and Food/Drinks

If your child is taking any prescribed medications, you must agree to maintain their dosing regimen during the study, unless otherwise recommended by their general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately. Your child should not discontinue their regular medications unless explicitly instructed by their general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen their health. If your child does stop their regular medications, inform the study staff immediately.

- If they are taking any prescribed medications and/or treatments which may affect the study outcomes, they may only be considered for the study if they have been taken off these therapies by their general/nurse practitioner. The study doctor will recommend an appropriate washout period prior to enrollment in the study.

- If they use any over-the-counter medications, supplements/natural health products, and/or foods and drinks which may affect the study outcomes, they must be willing to stop taking them and agree not to consume these items during the study. The study doctor will recommend an appropriate washout period prior to enrollment in the study.

Washout Period: This is a period of time recommended by the study doctor to allow restricted substances (such as medications, supplements/natural health products, foods or drinks) to clear from the body before the study begins. If your child has recently taken or stopped any restricted substances or participated in activities that conflict with the study, a washout period may be required before enrollment.

Birth Control, Pregnancy, and Breastfeeding

The effect of the study product on pregnancy and breast milk is not known. Your child must not participate if they are pregnant, breastfeeding or planning to become pregnant during the study. If your child is of child-bearing potential (have already had their first period), they must have a negative urine pregnancy test at Visit 1 and 2.

If your child becomes pregnant during the study, they must stop taking the study product immediately and contact the study staff. They will be withdrawn from the study and the study doctor will follow up with them until the child's birth, collect information about their pregnancy, its outcome, and the health of their child.

Since the study product is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if your child becomes pregnant.

Study Product Information

The study products will be in small, sealed packets (sachets).

Bacillus coagulans SNZ 1969:

Medicinal Ingredient	Quantity (per dose)
Bacillus coagulans SNZ 1969	1 Billion CFU/g

***CFU** – Colony-Forming Unit*

Non-medicinal ingredients: Glucidex (maltodextrin), Magnesium stearate, Banana dry mix flavour

Placebo:

Ingredients: Maltodextrin, Magnesium Stearate, Banana dry mix flavour

Directions:

- Your child will start taking the study product on Day 1 (the day after Visit 2) and will continue taking it throughout the duration of the study.
- The content of one sachet will be completely dissolved in approximately 50 ml (about 3 tablespoons) of water, and your child will drink the entire mixture before breakfast.
- If any powder remains in the cup, add more water to dissolve it and have your child drink the remaining mixture.
- If a dose is missed, they should take the missed dose as soon as you or your child remembers on the same day or the next day. They are not to take more than 2 sachets daily.
- Store the study product at room temperature and do not expose it to direct sunlight or heat.
- Save all unused and open study product packaging and return them to the clinic at Visit 5.

Alternative Treatments

This study is not designed to diagnose, treat, or prevent any disease. Your child's alternative is to not take part in the study.

Additional Safeguards

If your child needs regular medical care for current medical conditions, they should continue with this medical care unless otherwise instructed by their regular physician or other healthcare professional. For their safety, you must discuss your child's current medical care with the study staff, as well as changes in medical conditions during the study. In addition, all new medications including supplements and natural health products (NHPs) that are taken during the study must be reported to the study staff.

The study product is intended for your child's use only, as the study participant. It should not be given to anyone else or left in a place where a small child or a pet could accidentally swallow it.

Risks To Your Child

It is possible that your child could have problems or side effects from the study product that nobody knows about yet. There may be unknown risks with taking the study product. Potential side-effects of taking the study product may include:

- Abdominal discomfort (such as pain, nausea, changes in bowel habits)
- Dislike of taste
- Worsening of respiratory or gastrointestinal symptoms

You may give your child over-the-counter medications for symptoms like fever or cough. Please record any over-the-counter medications used in the study diary. If your child's symptoms persist or get worse, contact their healthcare provider immediately and inform study staff.

If your child experiences fever, vomiting, bloody diarrhea or severe abdominal pain, contact the study staff immediately.

Some risks associated with blood collection may include pain, bruising, and infection at the site. Alcohol swabs and proper blood collection procedures will be followed to minimize the risk of infection. Fainting during a blood draw can occur, though it is not common. Please advise the study staff if your child normally faints with blood draws.

Could My Child Have an Allergic Reaction?

It is possible for people to have allergic reactions to the study product. If your child has a serious allergic reaction, they could die. Read the study ingredients carefully to make sure your child is not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of Breathing
- Wheezing
- Sudden drop in blood pressure (making them feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If your child experiences any of the above-listed effects or any other side effects during the study, they should get medical help or go to the emergency room immediately and then contact the study staff. Refer to section "Whom To Contact About This Study" for instructions on what to do in case of an emergency.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form. Inform the study staff right away if your child experiences any side-effect, problems with their health or the way they feel during the study, whether you think these problems are related to the study products or not.

Potential Risks From E-Consent

You may receive a link via email/text message to download a PDF copy of this signed consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Withdrawal From the Study

- You and your child have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which your child is otherwise entitled.
- If your child discontinues the study for whatever reason, you are expected to return all study materials such as study product to the clinic.
- Your child may be asked to undergo some final visit procedures. These may include returning to the clinic to provide a final blood sample to test their markers of general health, any end-of-study assessments or questionnaires.
- If the study doctor or study staff finds out any related information that may greatly affect your child's well-being (for example, information related to your child's health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your child's participation in the study at any time without your or your child's consent, but you will be informed about the reason. Reasons for this may include, but are not limited to:

- Missing scheduled study visits
- Not taking study product as directed
- Not completing required assessments or procedures
- Development of medical conditions or serious side-effects that may pose a health risk to your child or the study outcomes
- The need for restricted medication(s) during the study
- If your child becomes pregnant during the study

New Findings

Any significant findings that become available during the study which may influence your child's continued participation in the study will be disclosed to you and your child as soon as possible.

Benefits

While there may or may not be any immediate benefit to your child, the results of this study will provide some of the required scientific evidence for the study products in this research study. Your collective participation in this study supports the research that is required to ensure the science behind the study products.

Costs To You

- All the tests, study products, examinations, and medical care required as part of this study are provided at no cost to you, the public health plan, or your private medical insurance. All costs will be paid for by the Sponsor of this study.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your child's current medical care and/or prescriptions. These expenses will not be paid as part of your child's participation in this study.
- The Sponsor of this study is paying the study doctor for the time, effort, and expenses to conduct this study.

Compensation For Participation

For your child's time and participation in the study, they will be compensated a total of $1,000 if they complete the entire study and all associated requirements.

Your child's compensation will be provided to you after completion of the study on a ClinCard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Compensation will be processed and received approximately 20 business days from the date your child completes the study. Processing times may apply before funds become available on the ClinCard.

The ClinCard will be given directly to you by the study staff. It is your responsibility to provide the study compensation to your child, who is the participant in the study. By signing this consent form, you agree to provide your child the full compensation they are entitled to as the study participant.

If your child is enrolled (completed visit 2 and received study product), the compensation breakdown is as follows:

- Screening Visit 1: $0
- Run-in period: $0
- Visit 2: $ 250
- Visit 3: $ 220
- Visit 4: $ 230
- Visit 5: $ 300

Once enrolled, for any case in which you, your child, or the study doctor determine your child cannot complete all the study visits and assessments, your child will receive compensation for the visits they have

completed. An early termination visit will be requested where you will bring back all study-related materials and your child will be requested to complete some blood work and visit procedures if they consent to doing so. If your child completes the early termination visit, they will be compensated $50.

Compensation And Treatment for Injury

- In case of an injury or illness suffered while, and solely as a result of participating in this study, your child will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your child's legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.
- Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your child's medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in secure room or server. Forms on which your child's information is entered will not contain their name (except for the study intake form and/or external requisitions if applicable).
- Any of your child's personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You child will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your child's personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies
- While the Sponsor will not have access to your child's personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your child's name.
- You have the right to check your child's study records and request changes if the information is incorrect.

- While every effort will be made to protect the privacy of your child's information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your child's privacy.
- As part of this research, you/your child may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about them. While using these, information about your child may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.
- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your/your child's rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your child's rights as a research participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your child's health information as described above.

A description of this clinical trial will be available on https://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.

Future Contact

By participating in this study, you agree that the study staff may contact you and/or your child in the future should additional information be needed. This contact would only occur if more data specifically related to your child's participation in this study were required after they have completed the study, or the study has concluded/expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You and/or your child may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits your child receives.

Whom To Contact About This Study

You can contact the study staff via email or by telephone listed on the first page of this document during the study if your child experiences any medical problems, suffers a research-related injury, or if you/your child have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your child's responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw your child from participation;
- Results of tests and/or procedures;

If your child seeks emergency care, or hospitalization is required, alert the treating physician that they are participating in this research study and inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your child's rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com.

Voluntary Consent to Participate

By signing and dating this document I agree that I have been provided enough time to read and consider whether to allow my child to participate in this study. I have discussed participation with my child, and I confirm that my child is willing to take part in the study. I confirm that I have reviewed and understand all pages of the consent form and information it contains regarding the study in a language that I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study staff, should anything become unclear or if I have further questions.

As the parent or legal guardian of the child who will participate in this study, I confirm that I am providing consent of my own free will and without any pressure or influence from the study staff. I understand that participation in this study is entirely voluntary and that I or my child may choose to withdraw from the study at any time, without providing a reason and without affecting my child's healthcare. I understand that if I or my child decides to withdraw from the study, I must notify the study staff.

I have been informed of and understand the potential risks involved with my child's participation in this study. I agree to follow the study instructions provided to me and my child by the study staff. I also understand that my child may not participate in another research study while enrolled in this study.

I consent to the collection, use, and disclosure of mine and my child's personal information for the purposes outlined in this document and in the manner described. I understand that a de-identified version of my child's data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Research Ethics Board, Health Canada and other foreign regulatory agencies. I understand that my child's personal information will be treated as strictly confidential as described in this document, except where disclosure is required by law. I acknowledge that absolute confidentiality cannot be guaranteed.

I confirm that I have full authority to consent on my child's behalf and that there are no shared or joint decision-making arrangements with any other parent, legal guardian, or party at this time. As the parent or legal guardian of the child who will participate in this study, I confirm that I fully understand the responsibilities and implications of my consent.

I understand that I am expected to keep a copy of this signed and dated consent form for my record.

I acknowledge that the study product is for my child's use only. I will not share it with anyone and will store it in a safe place away from other children, pets, or others for whom it is not intended.

Except as expressly stated, by signing and dating this document, I do not waive any of my or my child's rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I voluntarily consent to my child's participation in this study on the terms and conditions outlined above.

IN THE EVENT THAT ELECTRONIC CONSENT IS NOT AVAILABLE:

By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had enough time to consider this information, had an opportunity to ask questions, and voluntarily consent for your child to participate in this study.

_____
Printed Name of Participant

_____
Printed Name of Participant's Parent/Legal Guardian

_____ _____ _____AM/PM
Signature of Participant's Parent/Legal Guardian Date (MMM,DD,YYYY) Time (HH:MM)

I attest that the participant and participant's parent/legal guardian named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate.

_____
Printed Name of Person Explaining Consent

_____ _____ _____AM/PM
Signature of Person Explaining Consent Date (MMM,DD,YYYY) Time (HH:MM)

FOR ELECTRONIC CONSENT:

For electronic consent, your name, digital signature, date and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all the pages of the information presented in it.

Participant's Parent/Legal Guardian

I voluntarily consent for my child to participate in this study ↓

Person Explaining Consent

I attest that the participant and participant's parent/legal guardian had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate ↓