

INFORMATION AND ASSENT FORM FOR PARTICIPANTS 7 TO 12 YEARS OLD

Sponsor: SANZYME BIOLOGICS PVT LTD

Study Title: “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

**Principal Investigator:
(Study Doctor)** David Crowley, MD

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We would like to invite you to join a research study. This form explains the study. Please take your time to read all the pages. After reading this form, you can decide to be in the study, or you can decide not to be in the study. Either choice is okay. If you decide to start the study and then change your mind, you can stop being in the study at any time.

Please ask the study team to explain anything you do not understand. They will answer all the questions you have. You can ask questions about the study at any time. If you want to talk to the study team alone without your caregiver (parents or legal guardian), please ask.

Being in this study is your choice, and your caregiver needs to agree too.

WHAT IS THIS RESEARCH STUDY ABOUT?

The study team is learning about a study product called *Bacillus coagulans* SNZ 1969. They want to know if it is safe and how it can help with your health by looking at how often you get sick, how long you feel sick, and how bad the feelings are, such as a stuffy nose or tummy troubles.

About 100 children who go to school and are 6 – 12 years old will be asked to join this study.

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

There are rules to be part of this research study. If you meet these rules, you will be able to join the study.

A study team member who works here will:

- Ask you and your caregiver some questions about your health and if you are taking any medications
- Ask you and your caregiver to answer questionnaires that are used to learn more information about you
- Check your blood pressure, heartbeat, weight, and how tall you are
- Use a small needle poke to test some of your blood about 2 times during the study
- If you are a female and have had your period, the study team will ask you to pee in a cup and they will test your urine (pee) to make sure you are not pregnant. This will happen about 3 times during the study

If you join the study, you will:

- Have about 5 study visits – 3 to the study clinic and 2 online visits
- Fill out online diaries and questionnaires at home every day with your caregiver
- Collect a saliva (spit) and a stool (poop) sample at home about 2 times during the study
- Drink 1 packet of the study product after fully mixing it with about 3 tablespoons of water everyday before breakfast for about 84 days. If you forget to take it, you can take it as soon as you remember on the same day or the next day
- You are not allowed to take more than 2 packets a day
- Bring the remaining study product packets back at the end of the study so the study team can count them

FEMALES SHOULD KNOW:

It is extremely important that you understand that you should not get pregnant during the study as there may be unknown risks to you or the baby if you become pregnant. If you think you might be pregnant, you must tell your caregiver and the study team right away. If you are a girl and have had your period, the study team will ask you to pee in a cup so they can test your urine to make sure you are not pregnant.

IS THERE ANY RISK TO ME?

During the study you could feel different than how you normally feel. If you feel sick or different during the study, please explain to your caregiver and the study team how you feel right away. The study team will need to take a small amount of blood from your arm using a needle. This might feel like a quick pinch and your arm might be a little sore or have a small bruise afterward, but it usually goes away quickly. If you feel nervous or scared, that's okay — you can tell the study team and they will help you feel as comfortable as possible.

WILL THIS STUDY BENEFIT ME?

This study may or may not benefit you, but the results from this study can help the scientists learn more about the study product.

WHAT IS A STUDY GROUP?

This study will have 2 study groups. One group will be taking the product that has the study ingredients, and the other group will take the product which looks the same but does not have the study ingredients. All the children who join this study will be put into one of these groups by chance (like flipping a coin). You will have an equal chance of being put into either group. Nobody will be able to pick which group you are in and nobody will know which group you are in. The study team can find out which group you are in if they need to know for your health.

WILL MY INFORMATION BE PRIVATE?

If you decide to join the study, you will be given a special screening number. This number helps the study team keep track of your information and makes sure everything stays private and safe. The study team may write down the information you tell them. Information that is written down about you will be seen by the study team, and other people who run and manage the study. People who make sure that the study is being done the right way may also see it. If the information about the study is sent anywhere else, it will not have your name on it. What the study team learns about you may also be shared with your caregiver.

WILL I GET ANYTHING FOR BEING IN THE STUDY?

If you complete the entire study, all the study visits, and all the requirements, you will get \$1,000 for your time and participation in the study.

WHAT IF I DON'T WANT TO BE IN THIS STUDY?

You do not have to be in the study if you do not want to. You can say no even if your caregiver has agreed for you to be in the study. You can also decide to start the study now and then stop being in it at any time. No one will be mad at you or ask for a reason why if you decide not to be in the study or if you decide to stop being in the study later. If you decide to leave the study, the information collected about you up to that point may still be used. If you do not want your information to be used, you or your caregiver must tell the study team at the time you decide to leave the study. However, any information that has already been studied or included in reports cannot be removed.

WHO CAN I TALK TO ABOUT THIS STUDY?

If you have any questions about the study, you can talk to your caregiver or the study staff in the study clinic or by using the contact information listed at the top of this form.

If you have questions about this study but want to talk to someone else who is not a part of this study, you can call Univo Research Ethics Board (REB) at 919-910-7743.

IMPORTANT INFORMATION:

- It is important that you take your time to read all the pages in this form and understand everything about the study before you decide to join
- It is important to ask any questions you have so that you feel comfortable and know exactly what will happen during the study. If you have any questions, ask the study team and they will answer all your questions
- Being in this study is completely your choice. Even if you decide to join the study, you can change your mind anytime, and no one will be upset with you, and it will not affect your healthcare.
- You must not share the study product with anyone else and keep it safe away from any pets

STATEMENT OF ASSENT

I agree to follow all the instructions in this form.

I understand everything about this study, and I want to be in this study.

I will get a copy of this form to keep.

Printed Name of Participant

Signature of Participant

Date (mmm,dd,yyyy)

Time (HH:MM) AM/PM

FOR THE PERSON OBTAINING ASSENT

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date (mmm,dd,yyyy)

Time (HH:MM) AM/PM

FOR ELECTRONIC ASSENT:

For electronic assent, your name, signature, date and time of assent will be added below by program. Signing this way is just like signing a paper with a pen. By signing this form, it means you have read (or had someone explain) all the information and you understand everything about this study, want to be in this study, and agree to follow all the instructions in this form.

Participant - I voluntarily agree to participate in this study ↓

questions, and voluntarily agreed to be in this study ↓

Person Explaining Assent - I attest that the participant had enough time to consider this information, had an opportunity to ask