

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**PARTICIPANT INFORMATION AND ASSENT FORM
FOR CHILD PARTICIPANTS AGES 7 TO 13 YEARS**

Sponsor/Study Title: SmartyPants Vitamins Inc. / “A randomized, triple-blind, placebo-controlled trial evaluating the efficacy of the study product on overall cognitive function in children”

Protocol Number: 24SVCFS01

**Principal Investigator:
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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 parent or guardian needs to agree too.

WHAT IS THIS RESEARCH STUDY ABOUT?

The study team is learning about a study gummy called Kids Plus Multi & Omegas. They want to know if the study gummy is safe and if it can help kids think, learn, and use their brains better.

About 120 children who go to school and are 4 to 17 years old will be asked to join this study.

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

A study team member who works here will ask you and your parent or guardian some questions about your health and if you are taking any medications.

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

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Here is a list of the things that will happen during the study:

- You will have about 3 visits to the study clinic
- You will take 2 study gummies every morning with food for about 49 days
 - If you take any medications or natural health products, you will take the study product a few hours before or after the study gummies
- The study team will check your blood pressure, heartbeat, weight, and how tall you are
- You and your caregiver will answer forms with questions that are used to get more information about you
- 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 pee (urine) to make sure you are not pregnant. This will happen about 2 times
- You and your caregiver will fill out online diaries every day
- The study team will ask you not to eat or exercise for 1 hour before you come for your visits and avoid high sources of caffeine (such as supplements, tea, coffee, energy drinks) for 24 hours before your visits
- You will bring the remaining study gummies back at each visit so the study team can count them

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 parent or guardian and the study team how you feel right away.

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 gummy.

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. You must agree to practice abstinence (no sexual intercourse) or use a medically approved method of birth control. The study team will explain what you need to do. 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.

WHAT IS A STUDY GROUP?

This study will have 2 study groups. One group will be taking gummies that have the study

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ingredients, and the other group will take gummies which look the same but do 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). 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 parent or guardian.

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 \$500 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 also decide to start the study now and then stop being in it at any time. No one will be mad at you 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 parent or guardian 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 parent or guardian 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:

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- 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
- You must not share the study gummies with anyone else

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