

**PARTICIPANT INFORMATION AND CONSENT FORM  
FOR PARENTS/LEGAL GUARDIANS AND PARTICIPANTS AGES 14 TO 17 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:  
(Study Doctor)** David Crowley, MD

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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.

Your child is invited to participate in a clinical research study exploring how a natural health product may boost overall cognitive (mental) function in children.

To help you make an informed decision about your child's participation, 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 personal information will be handled. Please take your time to read the details of this study and feel free to ask the study staff for any additional information if needed. The study staff can explain words or information that you do not understand and will address 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 deciding.

Once you and your child fully understand the study, you will be asked to sign and date this form if you wish to proceed. You will receive a copy of this signed form which you should keep for your records. After you and your child provide consent, the study assessments will proceed.

**THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**

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.**

**BACKGROUND AND PURPOSE**

Good nutrition plays a big role in how children's brains develop. Lacking certain vitamins and minerals has been linked to learning and developmental problems in kids. Research shows that using micronutrient supplements can help support brain development, enhance learning abilities, and improve overall brain function, particularly in school-aged children.

Kids Plus Multi & Omega dietary supplement contains a mixture of vitamins, minerals, and omega-3 fatty acids, which are a type of fat that comes from foods you eat. Research suggests that taking omega-3 supplements can improve focus, memory, communication, and decision-making skills. The product is not yet approved for marketing in Canada and is considered investigational.

The objective of this study is to evaluate the efficacy of Kids Plus Multi & Omega dietary supplement on overall cognitive function in children.

**STUDY POPULATION**

This study will include 120 healthy children aged 4 to 17 years who are attending school.

**HOW LONG IS THE STUDY?**

This study will last approximately 49 days and consist of about 3 study visits to the study center.

**IMPORTANT THINGS TO NOTE**

- 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. 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 will be collected about their lifestyle, medical history and medications. This information will help determine if they meet the necessary inclusion and exclusion criteria 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 will use competitive enrollment. This means that when a target number of participants begin the study (120), all further enrollment will be closed. Therefore, it is possible that your child could be in the screening phase, ready to begin the study, and be discontinued without your and their consent if the target number of participants have already begun the study.

**WHAT WILL HAPPEN DURING THE STUDY?**

The following provides an overview of the study assessments, procedures and schedule of study visits.

**Assessments and Procedures*****Randomization – Visit 1***

Randomization is a process of assigning participants to different groups by chance (like flipping a coin). If eligible, your child will be enrolled into the study and will be randomized into 1 of 2 groups:

- Kids Plus Multi & Omegas group
- Placebo group

This is a triple-blind study, therefore neither you, your child, the study staff, nor the researchers analyzing the data will know which group they have been assigned to. This design ensures that the study's results are unbiased. Neither you, your child, or the study staff can choose which group your child is in, ensuring the integrity of the trial. However, if it becomes necessary for your child's health, the study staff can access this information.

***Height and Weight – Visit 1, 2 and 3***

Height and weight will be measured. Body Mass Index (BMI) will be calculated.

***Blood Pressure (BP) and Heart Rate (HR) – Visit 1, 2 and 3***

The study staff will conduct vital measurements including heart rate and blood pressure.

***Urine Pregnancy Test – Visit 1 and 3***

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

***National Institutes of Health (NIH) Toolbox Cognitive Assessment – Visit 1, 2 and 3***

This assessment includes a series of questions designed to measure attention, memory, learning, cognitive flexibility, processing speed, and language/vocabulary. This assessment will be administered to your child under supervision of study staff.

***Questionnaires – Visit 1, 2 and 3***

- *KINDL-R Questionnaire* – This questionnaire will be completed by you to assess your child's quality of life.
- *Perceived Stress Scale for Children (PSS-C)* – this questionnaire measures perceived stress over the last week. It includes questions about school and home life. The questionnaire will be administered to your child.

***Study Diary***

Completing online daily diaries will be required throughout the study. The diary will include questions pertaining to study product consumption, lifestyle habits and adverse events.

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Your child must avoid:

- High sources of caffeine (such as supplements, tea, coffee, energy drinks) for **24 hours** prior to clinic visits
- Eating or moderate-vigorous exercise for **1 hour** prior to clinic visits

<b>VISIT 1 (DAY 0) – SCREENING/ENROLLMENT</b>
<ul style="list-style-type: none"> <li>Once consent and assent are obtained, the screening visit will proceed. Your child will be given a screening number to keep their information confidential.</li> <li>Your child's medical history, medications, current health status, and any health issues that arise before the study begins (adverse events) will be reviewed.</li> </ul> <p><u>Assessments and procedures:</u></p> <ul style="list-style-type: none"> <li>Blood pressure, heart rate, weight, height, urine pregnancy test (if applicable), NIH Toolbox Cognitive Assessment, KINDL-R questionnaire, PSS-C questionnaire</li> </ul> <p>If your child meets all necessary study criteria and are eligible, they will be enrolled and randomized. The study product, study diary and instructions will be given.</p>
<b>VISIT 2 (DAY 28 ± 2 DAYS)</b>
<ul style="list-style-type: none"> <li>Together you will return to the study clinic with completed online study diaries and remaining study product in its original packaging. Study staff will count and re-dispense the remaining study product</li> <li>Your child's medications, current health status, study diaries and any adverse events will be reviewed</li> </ul> <p><u>Assessments and procedures:</u></p> <ul style="list-style-type: none"> <li>Blood pressure, heart rate, weight, height, NIH Toolbox Cognitive Assessment, KINDL-R questionnaire, PSS-C questionnaire</li> </ul>
<b>VISIT 3 (DAY 49 ± 2 DAYS) – END OF STUDY</b>
<ul style="list-style-type: none"> <li>Together you will return to the study clinic with completed online study diaries and remaining study product in its original packaging. Study staff will count the remaining study product</li> <li>Your child's medications, current health status, study diaries and any adverse events will be reviewed</li> </ul> <p><u>Assessments and procedures:</u></p> <ul style="list-style-type: none"> <li>Blood pressure, heart rate, weight, height, urine pregnancy test (if applicable), NIH Toolbox Cognitive Assessment, KINDL-R questionnaire, PSS-C questionnaire</li> </ul>

**MEDICATIONS, SUPPLEMENTS, 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.

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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 assessed for eligibility 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 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, or foods) 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 an individual of child-bearing potential, they must have a negative screening/enrollment urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study. All hormonal birth control must have been in use for a minimum of three months and be used through the duration of participation in this study.

Acceptable methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, or hormone implant
- Double-barrier method
- Intrauterine devices
- Non-heterosexual lifestyle and agrees to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agrees to use contraception if planning to become sexually active during the study

Since the study product is investigational, it is extremely important that your child does not become pregnant during the study as there may be unknown risks to your child, the pregnancy, embryo, or fetus if your child becomes pregnant.

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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.

**STUDY PRODUCT INFORMATION**

The study product and placebo will be in the form of a gummy.

**Study Product – Kids Plus Multi & Omegas**

<b>Active Ingredients</b>	<b>Quantity per day (2 gummies)</b>
Vitamin A (all-trans-Retinyl palmitate)	180 mcg
Vitamin C (ascorbic acid)	45 mg
Vitamin D (cholecalciferol)	20 mcg (800 IU)
Vitamin E (d-alpha-tocopherol from sunflower oil)	6.6 mg
Vitamin K (phyloquinone)	20 mcg
Thiamin (thiamin mononitrate)	0.1 mg
Riboflavin	0.16 mg
Vitamin B6 (pyridoxine HCL)	1 mg
Folate (L-5-Methyltetrahydrofolate)	147 mcg
Vitamin B12 (methylcobalamin)	2.4 mcg
Biotin	16 mcg
Iodine (potassium iodine)	90 mcg
Zinc (zinc citrate)	1.6 mg
Total Omega-3 Fatty Acids (derived from algal oil)	85 mg
Docosahexaenoic acid	45 mg
Eicosapentaenoic acid	23 mg
Inositol	2 mg
<b>Non-active ingredients:</b> Organic Cane Sugar, Organic Tapioca Syrup, Pectin, Gelatin, Citric Acid, Natural Flavors, Trisodium Citrate, Colors Added (Organic Annatto Extract, Organic Turmeric Extract, Organic Black Carrot Juice Concentrate)	

**mcg** – microgram; **mg** – milligram; **IU** – International Unit

**Placebo:**

Ingredients: Organic Cane Sugar, Organic Tapioca Syrup, Pectin, Citric Acid, Natural Flavors, Colors Added (Organic Annatto Extract)

**Directions:**

- Your child will take two gummies once daily with food, a few hours before or after taking any other medications or natural health products, for the duration of the study starting on Day 1. It is recommended to take the two gummies in the morning for consistency.

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- If your child forgets to take the gummies, they should take them as soon as you or they remember. They are not to take more than two gummies a day.
- Save all unused and open packages and return them at each study visit. Study staff will count the remaining gummies to ensure proper study product consumption.

**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 any 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 should 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 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:

- Gastrointestinal disturbance (such as stomach pain, nausea, vomiting, diarrhea, constipation)
- Troubles sleeping
- Skin rash
- Paleness

**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. Please read the study ingredients carefully to make sure your child is not allergic to any of them.

Some signs of an allergic reaction that could be 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

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Your child should get medical help or go to the emergency room immediately if they have any of the above-listed symptoms or other symptoms which you think require medical attention during the study. Refer to section “Whom to Contact About This Study” for instructions on what to do in case of an emergency.

Please tell the study staff right away if your child experiences any side-effects, problems with their health or changes in the way they feel during the study, whether you think these problems are related to the study products or not.

Ask the study staff if you have questions about the signs or symptoms of any potential side-effects you read about in this consent form.

**WITHDRAWAL FROM THE STUDY**

You and your child are free to choose to stop participating in the study at any time 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 and study products to the clinic.
- Your child may be asked to undergo some final visit procedures. These may include returning to the clinic for any end-of-study assessments and procedures.
- If the study doctor or study staff finds out any non-study related information that may greatly affect your child’s well-being (for example, information related to their health), they will share it with you immediately.
- Any data collected up to the point of withdrawal, including any data collected during final visit assessments, may still be used in the study. If you and your child do not want the data to be used, you must inform the study staff at the time of consent withdrawal. However, data that has already been analyzed or included in published results cannot be removed.

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

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

- Missing scheduled study visits
- Not taking study product as directed
- Not completing required assessments, procedures, tests and/or documents
- 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.



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While there may be no immediate benefit to you or your child, the results of this study will provide some of the required scientific evidence for the study products in this clinical research study. Your child's 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 assessment 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) will continue to pay for expenses for your child's current medical care and/or prescriptions. These expenses not related to the study will not be paid as part of your participation in this study.

The Sponsor of this study is paying your child's 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 \$500 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). Processing times may apply before funds become available on 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 (randomized and study product dispensed) into the study at visit 1, the compensation breakdown is as follows:

- Visit 1 (Screening/Enrollment) \*: \$100
- Visit 2: \$175
- Visit 3: \$225

\* Please note, if your child completes visit 1 and they are not enrolled into the study for any reason, they will not be compensated for this visit.

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

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back all study related materials and your child will be requested to complete some visit procedures if you and your child consent to doing so. If your child completes the early termination visit, your child 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 and dating this form, you are not giving up your or 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, except as authorized by the consent you provide by signing this form, to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a locked file. The documents on which your child's information is entered will not contain your child's 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.
- Your 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.
- 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.

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- 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 staff.
- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your 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 study doctor, 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 <http://www.ClinicalTrials.gov> as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**FUTURE USE OF DATA**

Your child's personal information collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information cannot be linked back to your child. As a result, we will no longer be able to identify them or your child.

Study doctors, including study doctors from collaborating institutions, can request this data for new research. Data may also be shared with outside non-profit academic investigators as well as with for-profit investigators or commercial entities, with whom we collaborate.

You and your child will not be asked to provide additional informed consent for the use of their de-identified information in future research.

**FUTURE CONTACT**

By signing this form, 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 would be required after they have completed the study, or the study has concluded or expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You and your child may choose not to provide

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additional information if contacted in the future, without any penalty or effect on the care or benefits they receive.

**WHOM TO CONTACT ABOUT THIS STUDY**

During the study, you can contact the study staff via email or by the telephone listed on the first page of this document if your child experiences any medical problems, suffers a research-related injury, or 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;
- Your responsibilities as the participants parent or legal guardian;
- 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](mailto:info@univo-group.com).

**VOLUNTARY CONSENT TO PARTICIPATE**

By signing and dating this document, I confirm that I have carefully read and understand all pages of this consent form, including the information it contains about the study, in a language that I understand. I have been provided sufficient 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 have been given the opportunity to ask any questions I have regarding the study, and all my questions have been answered to my satisfaction. I understand that I may consult with the study staff at any time if I have further questions or if any part of the study becomes unclear.

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 Institutional Review Board (Research Ethics Review 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 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. I understand that I will receive a copy of this signed and dated consent form and be asked to keep it for my records.

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.

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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.

By signing and dating this informed consent form, you acknowledge that you have read and fully understand all pages of this document and the information presented. I will receive a copy of this document after I have signed and dated it.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Printed Name of Participant's Parent/Legal Guardian

\_\_\_\_\_  
Signature of Participant's Parent/Legal Guardian

\_\_\_\_\_  
Date (MMM,DD,YYYY)

\_\_\_\_\_  
Time (HH:MM) AM/PM

**FOR PERSON EXPLAINING CONSENT**

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 be in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Consent

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date (MMM,DD,YYYY)

\_\_\_\_\_  
Time (HH:MM) AM/PM

**THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE****FOR PARTICIPANTS 14 YEARS AND OLDER**

I have been told that my parents/legal guardian agreed for me to participate in this research study as a minor. I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily agree to continue to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

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Printed Name of Participant

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Signature of Participant

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Date (MMM,DD,YYYY)

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Time (HH:MM) AM/PM