Version Date: August 27, 2026

**CONSENT FOR RESEARCH**
The Pennsylvania State University

Title of Project: The effect of an evening snack of walnuts on diet and sleep quality in adolescents

Principal Investigator: Emily Hohman

Address: Child Health Research Center, 721 N. Atherton St, State College, PA 16802

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (814) 865-5246.

Subject's Printed Name: _____

**We are asking you to be in a research study.**

**Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.**

**This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.**

Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study, and we may ask them to agree (give assent) to take part. Throughout the consent form, when we say "you", we mean you or your child.

**KEY INFORMATION**

**The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.**

**Why am I being invited to take part in this research study?**

We are asking you to take part in this voluntary research study because you are generally healthy adolescent who eats snacks in the evening.

**What is the purpose of this research study?**

The purpose of this voluntary research study is to find out if eating walnuts as an evening snack will improve diet quality and sleep among adolescents.

**How long will the research study last?**

The entire study will take 14-16 weeks to complete, which includes a 2-4 week break in the middle of the study. This study will include 5 visits to the Penn State Clinical Research Center (1-2 hours each), and a total of 12 weeks where you will complete activities at home including surveys and wearing a sleep tracker. During 4 of those weeks, you will also eat a 1 oz portion (about a handful) of walnuts in the evening.

**What will I need to do?**
You will first attend an enrollment visit where you will taste the walnut snacks to see if you like them, have your height and weight measured, and complete surveys. You will complete two 4-week long study periods: one where you will eat 1 oz walnuts as a daily snack in the evening, and one where you will keep your usual evening snacking habits and diet. The order in which you complete the study periods will be randomly determined. During the study periods you will complete a short daily log of your snack intake. For the 2 weeks leading up to each study period as well as the final 2 weeks of each study period (8 weeks total), you will wear a sleep tracking watch and complete a short daily survey about your sleep, behaviors, and mood. At the beginning and end of each study period, you will attend a visit at the Clinical Research Center to complete additional surveys and have your height and weight measured.

**What are the main risks of taking part in the study?**
For this study, the main risks to know about are:

- Allergic reaction to walnuts due to a newly developed or previously undiscovered allergy
- Skin irritation from the sleep watch
- Psychological discomfort, boredom, or fatigue from answering surveys. You may skip any questions you do not want to answer
- Loss of confidentiality if your study data were to be accessed by someone outside the research team

**What are the possible benefits to me that may reasonably be expected from being in the research?**
We cannot promise any benefits to you from taking part in this study. However, possible benefits include improving the quality of your diet during the walnut intervention. Results of the study may benefit other people in the future by helping us learn more about how healthy snacks like walnuts can help adolescents improve their diet quality and sleep.

**What happens if I do not want to be in this research?**
Participation in research is completely voluntary. You can decide to participate or not to participate.

**DETAILED INFORMATION**
**The following is more detailed information about this study in addition to the information listed above.**

**1. Why is this research study being done?**

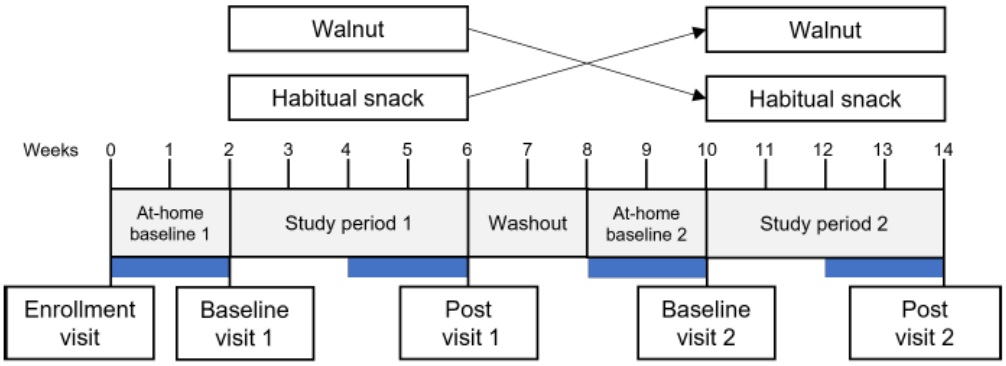
This research is being done to find out if eating walnuts as a snack in the evening will improve diet quality and sleep quality in adolescents.

Approximately 80-100 adolescent/parent pairs will take part in this research study at Penn State.

**2. What will happen in this research study?**

In this study, adolescents will complete two 4-week long snack study intervention periods. During one period, you will consume a 1 oz portion (about 1 handful) of walnuts each evening as a snack, about 2 hours before your usual bedtime (and ideally at least 1 hour after dinner). We will provide pre-portioned packages of the walnuts. You will be able to choose from plain and flavored walnuts. In the other study period, you will maintain your habitual evening snacking habits ("control period"). You will also attend research visits, complete daily surveys, wear a sleep watch, and complete diet records. The study design is shown in the image below (Figure 1), and additional details for each part of the study are listed below.

**Figure 1: Study design**




Blue bars indicate measurement burst period for 24-hour recalls, actigraphy, and daily diaries.

If you participate in this study, you will complete the following activities:

A. Enrollment Visit: In person at Clinical Research Center
   - This visit will take approximately 2 hours
   - You will learn more about the study and complete informed consent
   - Adolescents will complete a taste test of different walnut varieties to determine if they like them and are willing to eat walnuts daily for four weeks. If you do not feel you can commit to eating the walnuts daily for four weeks, you will be withdrawn from the study. If you continue in the study, you will let the study team know what types of walnuts you'd like to receive during your walnut intervention.
   - Adolescents will have their height and weight measured
   - Parents will complete an electronic survey using a tablet. The survey will ask questions about demographics, your child's habitual schedule and activities, eating behaviors, and sleep habits
   - Adolescents will complete an electronic survey using a tablet. The survey will ask questions about your sleep habits and preferences
   - Adolescents will be provided with sleep tracker watch to wear for the study. A study team member will help you set up the mobile app that works with the sleep tracker. If you do not have or prefer not to use a personal device (smartphone or tablet) for the study, we will provide a loaner smartphone for adolescents to use during the study. The loaner smartphone will only provide access to the apps and content needed to complete the study
   - You will receive instruction on how to complete the at-home portion of the study, including instructions on wearing the sleep tracker, completing daily diary surveys, and completing dietary recalls using the online Automated Self-Administered 24-hour Dietary Assessment Tool (ASA-24) system. As part of the instruction, you will complete one entire 24-hour recall on the foods and drinks you ate yesterday. Additional details on these activities are listed in the next section.

B. At-home baseline period 1. For two weeks following the enrollment visit, you will complete the following activities at home:
   - Adolescents will maintain their usual diet and snacking habits.

- Adolescents will wear the sleep watch continuously. The device may be removed short periods as needed (e.g., showering, school activities that prohibit wearing such devices) but must be worn as much as possible during the day and overnight for accurate measurement.
- You will follow instructions provided for syncing and charging the sleep watch.
- Adolescents will complete the daily diary survey each evening. The survey link will be sent by text message to adolescents' personal device or study loaner smart phone about 2 hours before their usual bedtime. The survey should take less than 5 minutes to complete, and will ask about the quality of your sleep the previous night, level of sleepiness during the day and your overall mood during the day. You will receive up to 3 reminder texts to complete the survey over the hour following the initial text.
- You will complete two additional 24-hour dietary recalls using the ASA-24 system. The ASA-24 website was created by the National Institutes of Health (NIH) as a way to collect dietary information in research studies. A 24-hour dietary recall is a measure where you report on all the foods and drinks you consumed in the previous day. The system is user friendly and will guide you through the process of remembering what and how much you ate the previous day. Depending on what day your Enrollment visit happened, you will complete recalls for 2 weekdays or for 1 weekday and 1 weekend day. You will reminders by text message, email, and/or phone call when it is time to complete a recall. Each recall takes around 30 minutes to complete.

C. Baseline visit 1: In person at Clinical Research Center
   - At the end of the 2-week at-home baseline period 1, you will attend an in-person research visit, which will take approximately 1 hour
   - You will bring the sleep watch, sleep watch charger and, if applicable, loaner smartphone and charger to the visit
   - Adolescents will have their height and weight measured
   - Adolescents will complete an electronic survey using a tablet. The survey will ask about your sleep habits, behaviors, and mood over the past 2 weeks
   - Parents will complete an electronic survey using a tablet. The survey will ask about your child's sleep habits, behaviors, mood, and eating behaviors over the past 2 weeks
   - If you did not complete all of your 24-hour dietary recalls during the at-home data collection period, you will complete one during the visit
   - You will be provided with instructions on completing the next part of the study. You will be randomly assigned to complete the walnut intervention or habitual snacking control first. If you are assigned to the walnut intervention first, you will be provided with pre-packaged walnuts in your requested flavors to last the 4 weeks of the study.

D. Intervention period 1: At home
   - The 4-week intervention period starts after Baseline visit 1
   - You will be assigned to complete either the walnut intervention or habitual snacking condition first
   - If you are assigned to the walnut intervention first:
     - Adolescents will eat one 1 oz package of walnuts each evening for four weeks. The walnuts should be consumed in place of usual evening snacks, and should be eaten about 2 hours before going to bed.
     - Adolescents will complete a daily snack log, which will be sent as an electronic survey link via text message to their personal device or study-provided phone. The log will be sent about 2 hours before adolescents' habitual bedtime. It will also serve as a reminder to eat the walnut snack. The log will take 2 minutes or less to complete. Adolescents will

indicate if they ate the walnuts, the approximate time they ate them, and indicate if there was anything unusual about the day (e.g., if they were sick, if there was no school on a usual school day). You will receive up to 3 reminder texts to complete the snack log over the hour following the initial text, as well as a final reminder the following morning about 30 minutes after habitual wake up time.

- If you are assigned to complete the habitual snack condition first:
    - Adolescents will maintain their usual evening snacking habits. You should not make any changes to your usual diet, other than to refrain from eating walnuts.
    - Adolescents will complete a daily snack log, which will be sent as an electronic survey link via text message to their personal device or study-provided phone. The log will be sent about 2 hours before adolescents' habitual bedtime and will take 2 minutes or less to complete. The log is similar to the log in the walnut condition, except that instead adolescents will indicate if they ate a snack in the evening, the approximate time they ate the snack, select the type of snack from a list of categories (e.g., salty snacks, sweets) and indicate if there was anything unusual about the day (e.g., if they were sick, if there was no school on a typical school day). You will receive up to 3 reminder texts to complete the snack log over the hour following the initial text, as well as a final reminder the following morning about 30 minutes after habitual wake up time.
- Regardless of intervention assignment, in the last 2 weeks of the 4-week intervention period, you will complete the same measures as you did during the at-home baseline period, including:
    - Wearing the sleep watch
    - Completing the daily diary survey. This will be combined with the snack log so that you only have to complete 1 electronic survey per day
    - Completing 3 dietary recalls using the ASA-24 system. One recall will be for a weekend and day and 2 will be for weekdays.
    - The study team will provide reminders via text, email, and/or phone call for these activities.

E. Post-intervention visit 1: In person at Clinical Research Center
- At the end of the 4-week intervention period 1, you will attend an in-person research visit, which will take approximately 1 hour
- You will bring the sleep watch, sleep watch charger and, if applicable, loaner smartphone and charger to the visit
- Adolescents will have their height and weight measured
- Adolescents will complete an electronic survey using a tablet. The survey will ask about your sleep habits, behaviors, and mood over the past 2 weeks
- Parents will complete an electronic survey using a tablet. The survey will ask about your child's sleep habits, behaviors, mood, and eating behaviors over the past 2 weeks
- If you did not complete all of your 24-hour dietary recalls during the at-home data collection period, you will complete one during the visit

F. Washout/Break period (2-4 weeks)
- After the post-intervention visit 1, you will have a period where you are not required to do anything for the study. This is called a "washout" period and will allow time for any effects of your first intervention condition to go away before you start the second intervention period. It also gives you a break from having to do anything!
- The washout period will be at least 2 weeks, but can be up to 4 weeks long to allow for schedule flexibility

G. At-home baseline period 2.
- When your washout period is almost up, a study team member will contact you to go over how to start the 2-week long at-home baseline period 2. You will not need to attend an in-person visit at this time.
- The procedure for at-home baseline period 2 is the same as at-home baseline period 1. Please see the description above in section B for details. Briefly, the activities you will complete include:
    - Wearing the sleep watch
    - Completing the daily diary surveys
    - Completing 3 dietary recalls using ASA-24

H. Baseline visit 2: In person at Clinical Research Center
- At the end of the 2-week at-home baseline period 2, you will attend an in-person research visit, which will take approximately 1 hour
- You will bring the sleep watch, sleep watch charger, and, if applicable, loaner smartphone to the visit
- The procedures of the visit will be the same as Baseline visit 1. Please see the description above in section C for details. Briefly, the activities you will complete include:
    - Adolescent height and weight measurement
    - Adolescent and parent surveys
    - If all 3 dietary recalls were not completed during at-home baseline period 2, you will complete one during the visit
    - Instructions for completing intervention period 2

I. Intervention period 2
- The 4-week intervention period 2 starts after Baseline visit 2
- You will complete the study condition (walnut or habitual snack control) that you did not complete during intervention period 1. See above in section D for details about the study conditions
- Other than completing a different intervention condition, the procedures for intervention period 2 are the same as intervention period 1. See section D for details. Briefly, the activities you will complete include:
    - Completing your second assigned study condition (walnut or habitual snack control)
    - Completing daily snack logs (all 4 weeks)
    - Wearing the sleep watch (last 2 weeks)
    - Completing daily diary surveys (last 2 weeks)
    - Completing 3 dietary recalls using ASA-24 (last 2 weeks)

J. Post-intervention visit 2: In person at Clinical Research Center
- At the end of the 4-week intervention period 2, you will attend the final in-person research visit, which will take approximately 1 hour
- The procedures are the same as post-intervention visit 1. See section E above for details. Briefly, you will complete the following activities:
    - Adolescent height and weight measurement
    - Adolescent and parent surveys
    - If all 3 dietary recalls were not completed during at-home baseline period 2, you will complete one during the visit

**3. What are the risks and possible discomforts from being in this research study?**

There is a risk of allergic reaction to walnuts. In order to be eligible for this study, you reported that you do not currently have an allergy to walnuts, other tree nuts, or peanuts; have never had an allergic reaction to walnuts, tree nuts, or peanuts; and do not have any other severe food allergies. Though most tree nut allergies emerge in early childhood, it is possible that you may develop an allergy or discover a previously unknown allergy when eating walnuts, even if you have previously eaten walnuts without any problems. The chance of this happening is rare and is the same as it would be if you were eating walnuts in your everyday life.

If you experience any allergy symptoms when eating walnuts, such as skin rashes, hives, vomiting, or respiratory symptoms, please stop eating them immediately and contact the study team for further instruction.

There is a risk of food-borne illness (sometimes called "food poisoning"). The walnut snacks are prepared and packaged in a research kitchen by our team. All team members have completed food safety training (ServSafe) and follow standard food safety procedures. Though these practices reduce the likelihood of food-borne illness, the risk cannot be completely eliminated. The risk of experiencing food-borne illness from this study is similar to the risk you would experience eating food prepared in a commercial setting (e.g., restaurant, cafeteria).

With any change in dietary pattern, there is a risk of gastrointestinal symptoms, such as nausea, bloating, or changes in bowel movements. The amount of walnuts you are being asked to eat (1 oz per day) is a typical portion that many people include in their diet regularly without problems. If any symptoms occur, we expect that they will be mild and temporary as your body becomes accustomed to walnuts in your diet, but it is possible you could experience more severe or ongoing symptoms. Please let the study team know if you experience any symptoms.

<u>Other risks:</u>

Some people experience skin irritation (or dermatitis) from wearing the sleep tracker watch. We will provide you with tips to reduce the chance of this happening, such as making sure the watch and your wrist are completely dry after hand washing. If you experience bothersome symptoms, please let the study team know.

You may experience boredom, fatigue, or discomfort from completing daily diaries, logs, surveys, and 24-hour recalls. You may also experience psychological distress when completing questionnaire if you find the questions to be sensitive or uncomfortable. We do not expect the surveys to be any more distressing than what you might experience filling out a questionnaire at a doctor's office. You are free to skip any questions you do not wish to answer.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

**4. What are the possible benefits from being in this research study?**

**4a. What are the possible benefits to me?**

You may improve the quality of your diet by participating in the walnut intervention. However, there is no guaranteed benefit.

**4b. What are the possible benefits to others?**
The results of this research may inform future interventions to help adolescents improve their diet quality and sleep.

**5. What other options are available instead of being in this research study?**

You may choose not to be in this research study.

**6. How long will I take part in this research study?**

If you agree to take part, the total duration of the study is 14-16 weeks including the 2-4 week washout/break period. This includes 5 visits to the Clinical Research Center and 12 weeks of at-home data collection. We estimate the time to complete these activities as the following:

- Enrollment visit at CRC – 2 hours
- Baseline and follow-up visits at CRC – 1 hour/visit x 4 visits = 4 hours
- Daily diaries – 5 minutes/day x 56 days (8 weeks) = 4.7 hours
- Snack log – 2 minutes/day x 56 days (8 weeks) = 1.9 hours
- ASA24 dietary recalls – 30 minutes/recall x 12 recalls = 6 hours
- Eating walnut snack – 5 minutes/day x 28 days (4 weeks) = 2.3 hours

The total active time for adolescent participants is 20.9 hours throughout the 14-16 weeks. For parents, the total time includes attending the in-person visits with your child (6 hours total) plus some additional time helping your child complete study activities at home as needed (variable).

**7. How will you protect my privacy and confidentiality if I decide to take part in this research study?**
**7a. What happens to the information collected for the research?**

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- A list that matches your name with your code number will be kept in a locked file in Dr. Hohman's office.
- Your research records will be labeled with your code number and will be kept in a safe area in Dr. Hohman's research office.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsors, the United States Department of Agriculture and the California Walnut Commission
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement, if applicable, to ensure it continues to be used under the terms of this consent and authorization.

**7b. What will happen to my research information after the study is completed?**

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any identifying information. Your research data will only be available to researchers who have received approval from the scientific database and/or Institutional Review Boards. Some of these databases are maintained by Penn State, some are maintained by the federal government, and some are maintained by private companies and other institutions.

**8. What are the costs of taking part in this research study?**

If you choose to use your personal smartphone or tablet device to complete the daily diary surveys, snack logs, ASA-24h recalls, and to sync the data from the sleep tracker, these activities will use your personal internet, mobile data, and text messaging plan. If there are any additional charges from your mobile or internet provider for this additional use, you will be responsible for those charges.

If you prefer not to use a personal device or do not have one, we will provide you with a loaner smartphone with a data plan at no charge for you to use during the study. The smartphone must be returned to the research team at the end of the study.

**9. Will I be paid to take part in this research study?**

You may receive up to $450 if you complete all study activities. The amount you receive is based on the study visits you attend, the number of the daily diary surveys, snack logs, and 24-hour dietary recalls you complete, and the amount of time you wear the sleep tracker. You will receive bonuses if you complete a certain proportion of the daily diary surveys, snack logs, and 24-hour recalls. The details of how your compensation is determined is listed in the table below. If you do not complete

all study activities, you will still be compensated for what you did complete. There is not separate compensation for parent participation.

| Activity | Compensation | Bonus compensation** | Total possible |
|---|---|---|---|
| CRC visits | $20/visit x 5 visits = $100 | N/A | $100 |
| ASA24 dietary recalls | $10/recall x 12 recalls = $120 | $20 for completing 10+ recalls | $140 |
| Sleep watch | $10/week of valid wear* x 8 weeks = $80 | $20 for completing all 8 weeks | $100 |
| Daily diary and snack log surveys | $1/day x 12 weeks = $84 | $26 for completing ≥80% of surveys | $110 |
| Total | | | $450 |

*In order for a week to count as a valid week for the sleep tracker, you must have at least 4 days where you wore the device a) during the entire overnight period and b) during the day with no gaps greater than 4 hours.
**Bonuses will only be given if the listed criteria are met and all study devices (sleep tracker, loaner phone if you received one) are returned to the study team

If you receive payment for participating in this research study, it is considered to be taxable income under U.S. law. In some situations, Penn State is required to report research payments to the Internal Revenue Service (IRS). To meet IRS requirements, we may need to collect certain personal information from you, such as your name, address, and Social Security Number. Payment totals are calculated across all research participation at Penn State if you participate in multiple studies.

If you have questions about how research payments may affect your taxes, please contact a tax professional or the IRS. Study staff and the IRB cannot provide tax advice.

**10. Who is paying for this research study?**

The institution and investigators are receiving a grant from the United States Department of Agriculture (USDA) to support this research. The USDA grant is co-sponsored and co-funded by the California Walnut Commission (CWC). CWC is also supplying the walnuts used in this study free of charge.

**11. What are my rights if I take part in this research study?**

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include unwillingness to consume the walnut snacks or allergic symptoms following walnut consumption.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

**12. If I have questions or concerns about this research study, whom should I call?**

Please call the head of the research study (principal investigator), Dr. Emily Hohman at (814) 865-5245 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://researchsupport.psu.edu/orp/irb/information-for-participants/ if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. 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.

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**INFORMED CONSENT TO TAKE PART IN RESEARCH**

**Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____ _____ _____
Signature of person who explained this research Date Printed Name
(Only approved investigators for this research may explain the research and obtain informed consent.)

**Signature of Person Giving Informed Consent and Authorization**
Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

**Signature of Subject**

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____ _____ _____
Signature of Subject Date Printed Name

**Signature of Parent(s)/Guardian for Child**

By signing this consent form, you indicate that you permit your child to be in this research and authorize your child's information to be used and shared as described above.

_____
Printed name of child

_____ _____ _____
Signature of Parent/Guardian Date Printed Name

☐ Parent
☐ Individual legally authorized to consent to the child's general medical care. (See note below.)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

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**ASSENT FOR RESEARCH**

The research study has been explained to you. You have had a chance to ask questions to help you understand what will happen in this research.

You Do Not have to be in the research study. If you agree to participate and later change your mind, you can tell the researchers, and the research will be stopped.

You have decided: **(Initial one)**

___ To take part in the research.
___ NOT to take part in the research.

| _____ | _____ | _____ |
|---|---|---|
| Signature of subject | Date | Printed Name |

OR

☐ Assent not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.