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CHILDREN'S NATIONAL MEDICAL CENTER
Division of / Center for Neurology
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

STUDY TITLE: A prospective, single arm, open label study of the safety and efficacy of Nerivio™ for the acute treatment of New Daily Headache Persistence (NDHP) in adolescents

PRINCIPAL INVESTIGATOR: Marc DiSabella, DO, Neurology

Throughout this document, "You" always refers to the person (you or your child) who takes part in the study.

SUMMARY AND KEY INFORMTION

We are inviting you to be part of a research study at Children's National Medical Center (Children's National). **Taking part in this study is your choice.** You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

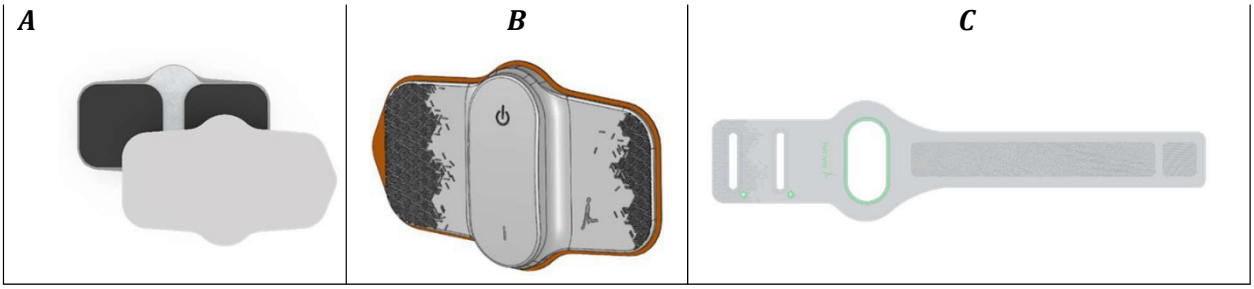
Purpose of the research

This is a research study to evaluate a new non-invasive drug-free acute treatment of headache in adolescents aged 12-17 years old. You are being asked to take part in this study because your teen suffers from persistent headaches.

Device description

The device is a wireless wearable battery-operated stimulation unit controlled by a dedicated smartphone application. Treatments with Nerivio™ are self-administered by the user at the onset of a headache. The Nerivio™ (Figure 1) includes several main components:

- A pair of electrodes covered with hydrogel and a removeable protective film
- An electronic circuitry and a battery
- A software that includes firmware and a software application for mobile platforms
- An armband to secure the attachment of the device and enable a discreet treatment



Procedures and duration of participation

Participants will receive a device and will be asked to treat headaches with it and report in the app the characteristics of the attacks at the beginning of the attack as well as at 2 hours after the treatment. The study includes 3 visits to the clinic. We expect that participants will be in this research study for 8 weeks.

Risks and benefits

The Nerivio device has been used for other conditions with few adverse reactions, therefore the study is expected to be low risk. We cannot promise any benefits to you from your taking part in this research. However, you may experience relief in your headache and other symptoms without having to take medications to treat your headache during the study. Furthermore, participating in this study may provide you the chance to receive up-to-date care, will help learn more on the effectiveness of the device for adolescents with daily persistent headaches and it is hoped that this information will help in the treatment of future patients with conditions like yours. There is also a potential risk of breach of confidentiality due to granted access to medical records and paper documents.

Alternatives to participation

The usual approach for patients who are not in a study is to use pain relieve medications and preventative treatments, physical therapy, nerve blocks, Botox, or the use of other nerve stimulators.

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. The study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research is voluntary.

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later. This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

Why is this research study being done?

You are being asked to be in the study because your teen suffers from persistent headaches.

The Nerivio device is approved by the FDA for acute treatment of migraine with or without aura in patients 12 years of age or older. The purpose of this study is to assess the effect of the Nerivio device for treating New Daily persistent Headache (NDPH) in children. The Nerivio is a non-invasive device operated via a smartphone application that changes brain activity. The device is worn on the upper arm, and the treatment is self-administered at the headache onset. The device delivers non-painful electrical pulses to the skin that stimulate the body to initiate a pain inhibition mechanism in the brain. During the treatment, the users can adjust the intensity of the pulses according to how they tolerate it.

Marc DiSabella is the person responsible for this research study at Children's National. He is called the Principal Investigator.

Theranica, the manufacturer of the Nerivio device being used in this study, provides the study device to the researcher or research participant without costs. If the patient

damages or loses the device, we can replace up to one device per patient, if needed. We will not request any compensation for that or hold any claims for that.

How many people will be in the study?

The study will involve up to 100 people taking part at one institution nationally. All participants will be recruited at Children's National.

What will happen in this research study?

- If you agree to be in the study, you will answer questions regarding your general medical state and your headaches in order to determine whether you are eligible to participate in the study. If you are a girl and have had your first period, we will ask you to supply a urine sample for pregnancy testing. Each patient will complete the Columbia-Suicide Severity Rating Scale (C-SSRS) at screening. If reports of suicidal ideation with intent to act (endorse item 4 or 5), reports of actual, aborted, or interrupted suicide attempts, or reports of behavior preparatory for an attempt are identified, the investigator is to appropriately manage the subject in accordance with standard of care.

Each participant will receive a device to be used at home for the acute treatment of your headaches. The device produces electrostimulation parameters aimed to relief headache pain. In addition, an app will be installed on your smartphone to control the device and record your headaches and your feedback regarding the effect of the device on your headaches.

The table below outlines what you will be responsible for during the course of this study.

Schedule	What you do
Enrollment Visit 1 (Day 0)	• Arrive to Children's National Medical Center with one of your parents, for your scheduled appointment. Bring packages of any medications you are taking (for any medical condition). • Eligibility assessment

	• Meet with Dr. DiSabella or one of the colleagues and/or the study team to answer questions about your general health and your headaches. • If this form is received today, you and your parent(s) can take time to read it carefully and make sure all your questions and concerns are answered. • You may request another appointment in case you would like to read this form at home and consult with family members or friends. • If you are a girl and have had your first period, you will provide a urine sample for a pregnancy test. • If you agree to participate, a member of the study staff will install the app on your smartphone. We will provide an explanation on how to operate the smartphone application. • We will train you how to complete your headache diary.
Run-in phase (Days 1-28)	• Complete the diary whenever you experience a new headache. • The study staff will contact you to schedule your next visit
Device training Visit 2 (Day 29-37)	• Eligibility to continue in the study will be assessed based on your reports and compliance in the run-in phase. • You will receive a device. • We will train you how to use the device and find the intensity level that is best for you • You can ask us any questions. • You will take the Nerivio home with you.
Treatment phase Day 1-28 following visit 2	• Always have the device and your smartphone available. • Use the device for the treatment of your headache onset (and always with 60 minutes of onset). • To comply, you: ▪ Avoid taking rescue medication from the time of symptoms onset until 2 hours from treatment start (≈75 minutes from the end of the treatment). ▪ Report the 2-hour post treatment feedback through the smartphone application • The application will ask you to rate your headache pain level at the beginning of the treatment, after 2 hours, and after 24 hours post treatment on a scale of 0-3 (0= no pain; 1= mild; 2= moderate; 3= severe) • Call the study team if there is any change in your medical condition.

	• At the end of this phase, you will be contacted by a member of the study team to schedule your next visit.
End of study visit 3	• Arrive to Children's National Medical Center for your scheduled appointment. • Complete the study questionnaires, if required • Return the device.

Please note:

- The procedures above are crucial to the success of the study. If you feel that you will not be able to comply with these procedures, please reconsider your participation in the study and inform us about your hesitations.
- The device was created using a designated 45min cycle under the idea that it takes this duration of time to reduce headache and result in prolonged relief. This duration was the only time frame approved by the FDA for pediatric and adult use and using it for any other duration would be experimental. There is no known risk to shortening the duration however the company has reported reduced efficacy and 24 hr relief from patient experience.

Is it O.K. to take other medications, dietary supplements, or alternative medicines while I am in this research study?

There are many drugs (prescription and over-the-counter) and dietary supplements (including what are sometimes called "complementary" or "alternative" remedies) that might interact with the experimental study drug(s). Tell the study doctor about all of the medications and supplements you are currently taking. The study doctor will review all of these with you and decide if you can participate in the study. Also, you should not take any new medications or dietary supplements without discussing it with the study doctor first.

How long will my participation in the research study last?

- *Length of participation*. We will ask you to come to the hospital for 3 visits (enrollment, treatment and end of study) for questionnaires, training on the Nerivo and to see if the device is working and to see if there are any unexpected side effects.

- *Regarding a decision to drop out*. Participants may withdraw consent at any time without and do not have to provide an explanation. You should tell us if you decide to stop being in the study.
- *Regarding early withdrawal by the PI.* We will ask you to drop out of the study if:
    - Participant is lost to follow-up
    - Refusal of the participant to continue treatment and/or follow-up observations
    - Serious adverse event
    - Participants encountering difficulties with the investigational product (IP) (e.g. cannot tolerate the treatment, unable to operate the application)
    - Significant protocol deviation/violation or noncompliance, either by the patient or the investigator
    - Decision made by the investigator that termination is in the patient's best medical interest
    - Device malfunction
    - Other ethical or clinical considerations upon investigator discretion

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

You may have side effects while participating in this study. The device used in this study may cause temporary mild side effects that should resolve shortly after the treatment. The side effects that were reported in previous studies include

- Warmth sensation
- Redness
- Numbness of the hand/arm
- Weakness of the arm
- Itching
- Tingling
- Muscle spasms

All the side effects were mild and resolved after the treatment without any need for medical interventions. You should talk to your study doctor about any side effects experienced while taking part in the study. The Nerivio device has been used for other conditions with few adverse reactions, therefore the study is expected to be low risk. For more information about risks and side effects, ask your study doctor. There is also a potential risk of breach of confidentiality due to granted access to medical records and paper documents.

For female participants: Are there additional risks if I get pregnant or breastfeed my baby?

The Nerivio device used in this research study may have an effect on an unborn baby. You should not become pregnant or breastfeed your baby while you are taking part in

this study. If you are sexually active and are at risk of getting pregnant, you and your male partner(s) must use an effective method to avoid pregnancy or you must not have sex.

The study doctor will talk to you about acceptable methods to avoid pregnancy while you are participating in this study. You will have to use the chosen method to avoid pregnancy or abstain (not have sexual intercourse) during your participation.

Natural family planning methods (such as the rhythm method) will not be a permissible means of avoiding pregnancy while you are in this study. If you have questions about this or want to change your method to avoid pregnancy, please ask the study doctor. If you become pregnant during the research study, please tell the study doctor immediately.

You should not breastfeed your baby while you are taking part in this study. You may need to continue to avoid breastfeeding even after your participation in the study is over. Talk to the study doctor about the length of time you need to avoid breastfeeding.

For male participants: Are there additional risks if I father a baby?

The Nerivio device used in this research study can damage sperm. You should not father a child while you are taking part in this study because the Nerivio device may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use an effective method to avoid pregnancy, or you must not have sex.

The study doctor will talk to you about acceptable methods to avoid pregnancy while you are participating in this study. You will have to use the chosen method to avoid pregnancy or abstain (not have sexual intercourse) during your participation.

Natural family planning methods (such as the rhythm method) will not be a permissible means of avoiding pregnancy while you are in this study. If you have questions about this or want to change your method to avoid pregnancy, please ask the study doctor. If your partner becomes pregnant during the research study, please tell the study doctor immediately.

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

- We cannot promise any benefits to you or others from your taking part in this research. However, you may experience relief in your headache and other

symptoms without having to take medications to treat your headache in the course of the study.

- Participating in this study may provide you the chance to receive up-to-date care, will help learn more on the effectiveness of the device for adolescents with daily persistent headaches and it is hoped that this information will help in the treatment of future patients with conditions like yours.

- Information gained from this research could lead Nerivio to help others with daily persistent headaches in the future.

What kinds of information will the study collect? Will any information be shared with me?

Information that the study will collect include questionnaires asking about headache frequency, severity, and disability as well as a mood questionnaire to assess eligibility. The eDiary will collect headache information relating to headache frequency, relief of pain, frequency of the device use, and any adverse effects from using the device.

General considerations

Baseline demographic and other baseline characteristics, together with safety analyses will be performed on all participants who underwent the treatment phase. Baseline values are defined as the last valid value prior to treatment.

Demographic and other baseline variables

Demographic and baseline condition related characteristics will be recorded. Continuous variables will be summarized by a mean, standard deviation, minimum, median and maximum, and categorical variables by a count and percentage.

Safety analysis

Safety and tolerability will be assessed by review of all safety parameters, including adverse events. Serious adverse events, device-related SAEs, adverse events (by type and overall), device-related AE, adverse device reactions and device malfunction rates will be documented. Treatment tolerability, the number and percent of subjects who fail to complete the study and the number and percent of subjects who fail to complete the study because of adverse events will be presented. Time to withdrawal will also be assessed.

Efficacy analysis

The efficacy endpoints will be assessed on evaluable treatments of qualifying attacks. The first use of the device is considered a training treatment and will not be included in the efficacy analyses. The first treatment of a qualifying attack after the training treatment is considered a test treatment and will be used for all efficacy assessments. If this treatment is not evaluable (i.e., no pain data at 2 hours post-treatment), a subsequent treatment of a qualifying attack with evaluable data will be considered the test treatment.

Use of rescue medication before the 2-hours assessment will be considered a treatment failure for the 2-hours endpoints, and before the 24 hours assessment for the sustained 24-hours endpoints

All patients with baseline and 2 hours values will be included in the analyses. Aresponse in each associated symptom (nausea, vomiting, photophobia, phonophobia) isdefined as change from presence of a specific associated symptom at baseline to absence of the same associated symptom at 2 hours post-treatment.

The first secondary endpoint (pain relief at 2 hours) may also be evaluated in attacks with aura and attacks without aura separately.

We will tell you about any new information that may affect your health, welfare or change your decision to be in this study.

Will the information that I give you be shared with others? How will you protect my privacy?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization and representatives from federal and state government oversight agencies such as the Food and Drug Administration. The IRB and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing

this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

Regarding publication of findings.
The results of this research may be presented at meetings or in publications. You will not be personally identified.

Regarding PowerTrials

Information that you are participating in this study will be entered into your electronic medical record. This information will be seen by any medical provider caring for you at Children's National and its affiliated institutions. In the uncommon event that you are treated outside of this research study by a medical provider affiliated with Children's National, there is a possibility that the medical provider may contact the Principal Investigator regarding your participation in this research study. This could be necessary for your safety if the experimental treatment used in this study might interfere with a treatment being considered by the provider. The Principal Investigator will carefully decide on the type and amount of information he/she gives to the medical provider and will maintain your privacy and the confidentiality of the information to the extent possible.

If identifiers like your name, address, date of birth and phone number are removed from the data and samples that are collected during this research, that information or those samples could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

What other choices do I have if I don't want to take part in the study?

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Instead of being in this research study,

your choices may include getting treatment or care for your headaches without being in a study.

Please talk to your doctor about your choices before deciding if you will take part in this study. Your alternatives include pain relieve medications and preventative treatments, physical therapy, nerve blocks, Botox, or the use of other nerve stimulators as well as not participating in this study or participating in another study to treat headaches

Will it cost me anything to take part in the study?

If no research-related costs.

You will not incur any additional costs by participating in this study. The study device will be provided at no charge to you. You will not be charged for any study-related activities, including study visits. If you damage or lose the device, we can replace up to one device per patient, if needed. We will not request any compensation for that or hold any claims for that.

For routine or standard care costs.

- You or your insurance company will have to pay for the costs of any routine or standard medical care that is not part of the study. This may include, but is not limited to, visits to the clinic, having to stay in the hospital, laboratory tests, x-rays, or other tests. If your insurance company does not pay for the routine or standard care, you will be responsible for paying for it.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

ClinicalTrials.gov

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 you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What happens if I get hurt or sick because of taking part in this research study?

Children's National Medical Center cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that you are hurt, sick, or otherwise harmed because of something to do with the study, please call the Principal Investigator, Marc DiSabella at 20010, 202-476-2120.

- In case of a medical emergency, call 911 or go directly to the hospital. Be sure to tell the Emergency Room personnel and your doctor that you are in this study.
- If you have any non-emergency side effects or bad reactions, call the Principal Investigator, Marc DiSabella, at 20010, 202-476-2120 right away.

We will give you any urgent medical care needed because of your participation in this research study if reported in a timely manner. Children's National will seek payment from your health insurance company or other third-party payer for any medical care or services you receive. Children's National has no program to provide you with any additional payments for any injuries.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Marc DiSabella and his research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- Laboratory results obtained on specimens collected from you (blood, urine, tissue)
- Questionnaires or surveys you complete
- Verbal information, such as in phone calls made as part of this research
- Records about the study device
- Electronic information, which is information stored in computer systems.

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study
- Government agencies that have the right to see or review your PHI including, but not limited to:
    - The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
    - The Food and Drug Administration
- Children's National Medical Center Institutional Review Board
- Children's National Medical Center Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program at Children's National Medical Center

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

- The Data Safety Monitoring Board (a group of people who examine the medical information during the study)
- The Patient Advocate or Research Ombudsman (person who watches out for your best interest)
- Staff at all the research study sites
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research.
- Representatives from federal and state government oversight agencies such as the Food and Drug Administration.
- Representatives from Western Institutional Review Board® (WIRB®), the group of people that oversee research at this institution.

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by the Neurology department at Children's National.

Please indicate your approval of any or all of the following by checking a box next to each statement and initialing your choice:

- My personal health information may be stored in the above named database for future analysis related to this study.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database for future analysis related to this study (A prospective, single arm, open label study of the safety and efficacy of Nerivio™ for the acute treatment of New Daily Headache Persistence (NDHP) in adolescents).

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.

  ☐ Yes ☐ No Initials _____

- My personal health information may be stored without any of my identifying information for use in other studies of other diseases.

  ☐ Yes ☐ No Initials_____

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

- If you revoke the Authorization, you must send a written letter to the Principal Investigator to inform him of your decision.

  Marc DiSabella
  Children's National Medical Center
  Neurology
  111 Michigan Avenue, N.W.
  Washington, DC 20010-2970

- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will not be allowed to review the information collected for this research study until after the study is completed. If you are not allowed to review your information during participation in the study, when the study is over you will have the right to access the information.

This Authorization does not expire

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-476-6464.

Whom can I call if I have questions about this research study?

We want you to ask questions about any part of this research study at any time.

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Marc DiSabella, at 20010, 202-476-2120

Whom can I call if I have questions or concerns about my rights as a research study participant?

The Children's National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant

- Your concerns about the research
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8447.

Children's National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.

You may contact the research advocate at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can contact the research advocate at 202-476-5586 or by email at RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.
- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a signed copy of this Informed Consent/Parental Permission form to keep.

Signature of Parent(s)/Guardian(s) for participant under the age of 18 years

Printed Name of Participant: _____

Printed Name of Parent/Guardian:_____

Signature of Parent/Guardian: _____

Date and Time:_____a.m. / p.m. (circle one)

Printed Name of 2nd Parent/Guardian: _____

Signature of 2nd Parent/Guardian: _____

Date and Time:_____a.m. / p.m. (circle one)

Signature of language interpreter (if applicable)

Printed Name of Interpreter:_____

Interpreter's Signature:_____

Language:_____Date and Time:_____a.m. / p.m. (circle one)

Signature of Witness to Consent Process (if applicable)

Printed Name of Witness:_____

Witness's Signature: _____

Date and Time:_____a.m. / p.m. (circle one)