Version Date: 01/18/23

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: A Double-Blind Placebo-Controlled Evaluation of Effectiveness of Oral Naltrexone in Management of Adolescent Eating Disorders

Principal Investigator: Rosemary Claire Roden, MD

Address: 905 West Governor Road, Suite 200, Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-7235. After hours call (717) 531-8521. Ask for the adolescent medicine doctor on 24-hour call.

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 will 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 have an eating disorder and are receiving care in the Partial Hospitalization Program (PHP) for Eating Disorders at Penn State Children's Hospital, Division of Adolescent Medicine

What is the purpose of this research study?

The purpose of this study is to determine the effect of oral naltrexone in adolescents seeking treatment for eating disorder. This drug is approved for treatment of another condition but is not approved for the use proposed in this research.

Approximately 60 people will take part in this research study at Hershey Medical Center.

How long will the research study last?
The study lasts six months.

What will I need to do?
You will complete all questionnaires and surveys as provided to you during care in program treatment. If you are in the adult Partial Hospitalization Program, you will complete two additional self-report measures along with the rest of the measures you take every three weeks during treatment. In addition to your regular eating disorder care, you will be provided either study medicine or placebo (a pill that looks like the study medication, but which contains an inactive substance instead) to take every day for six weeks. We also ask that you complete two extra short surveys at the start of treatment, and again at three weeks, six weeks, eight/nine weeks for post-treatment evaluation, and six months after starting treatment.

You will need to take a urine drug test at enrollment. The results of this test will not go into the medical record.

We ask that you have blood testing at enrollment, week three, and week six to assess for liver problems related to the study medicine. If you are already having bloodwork done as part of standard of care, we will not ask you to have the same bloodwork done twice.

All people assigned female at birth participating in this study will have to take a blood test for pregnancy at enrollment, and urine pregnancy tests every three weeks for six weeks.

What are the main risks of taking part in the study?
For this study, the main risks include loss of confidentiality, risk of randomization, emotional discomfort, and risk of incidental findings during the research study. Study team members will do their best to ensure that these risks will not occur during the research trial.

The main risks to know about the study drug are: nausea, possible worsening of mood or depression, and pain related to blood draws. Other risks related to the study medication include liver injury and increased thoughts of suicide or self-harm. People using opioid medications may experience opioid withdrawal as a result of the study medication.

The risks of the study medication in pregnancy are not known. It is not known if the study medication can be passed through breast milk.

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 faster recovery from your eating disorder. Results of the study may benefit other people in the future by helping us learn more about eating disorder treatment

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. It will not affect the care you get in PHP.

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?

The purpose of this study is to determine the effect of oral naltrexone in adolescents seeking treatment for eating disorder. This drug is approved for treatment of another condition but is not approved for the use proposed in this research. Oral naltrexone is FDA-approved to treat alcohol dependence and to block the effects of opioid medications and drugs.

Oral naltrexone is contraindicated in: people receiving opioid painkillers, people dependent on opioids including those maintained on agonists or partial agonists, people in opioid withdrawal, anyone with a positive urine screen for opioids, or anyone with a sensitivity to naltrexone or any components of the products.

This drug has no approved use in patients 17 years of age and younger.

Approximately 60 people will take part in this research study at Hershey Medical Center.

2. What will happen in this research study?

You will be randomly assigned to receive one of the two study treatments, either oral naltrexone or placebo. This means that whichever study treatment you receive will be determined purely by chance, like flipping a coin. You will have an equal chance of receiving any one of the study treatments. Neither you nor the research team will know which study treatment you are receiving, but we will be able to get this information quickly if we need it to ensure your safety.

You will receive the same treatment in our eating disorder clinic if you decide to enroll in this study or not. If you decide to participate in this study, in addition to routine care you will be randomly assigned to take a daily pill of either study medication (naltrexone) or placebo every day for six weeks. You will also be asked to fill out various surveys as a part of routine care for eating disorder. In addition to our routine surveys, we will ask you to fill out two extra surveys at enrollment, three weeks, six weeks, weeks 8/9 post-treatment, and six months after enrollment.

All patients are asked to complete bloodwork at enrollment into our partial hospitalization program for eating disorders. For those who enroll in this study, they will have a urine drug screen at enrollment. You will not be responsible for these costs, and the results will not go in your medical record. Participants will also need to have blood tests every three weeks for 6 weeks and at the study start if not required as part of standard of care. Women and girls participating in the study will need a blood test for pregnancy at enrollment and urine tests for pregnancy at weeks three and six. You will not be responsible for the costs of the pregnancy tests (if you need them), or for the blood tests.

Blood testing will be performed by venipuncture, or a needle inserted into a vein by a trained professional. The total volume of blood draw for this study is expected to be less than 18ml over the entirety of the study. This is about the same as three and a half tablespoons.

If you participate in this study, we will give you a $25 Greenphire Clincard, which is an electronic gift card that can be used as a debit or credit card.

We ask that you return for a follow-up visit at 6 months after enrollment, which is a part of routine eating disorder care. In addition to routine care, we ask that you complete the same battery of surveys. If your

medical provider decides that you do not need to come in for routine medical care, we will send you the surveys via secure email, and you will still have the opportunity to get an additional $25 on your Clincard. Participants will receive a total of $50 in Greenphire Clincards.

We have developed the following table to show when all study interventions are planned to happen. Thinks marked with a superscript ^{o} are things that only happen for the study, and are not a part of routine care in PHP or IOP.

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Intervention	Pre-Enrollment Screening: Medical	Enrollment	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6 (end of treatment)	Week 8-9 (post-treatment)	Six Months
Initial Medical Assessment	x									
Subsequent Medical Assessment, including comprehensive review of systems			x		x		x		x	x
Initial Psychiatry Assessment	x									
Subsequent Psychiatric Assessment, including suicidal ideation			x	x	x	x	x	x	x	x
Discussion of risks and benefits, inclusion and exclusion criteria[o]		x								
Consent/Assent[o]		x								
$25 Greenphire Clincard[o]		x								x
Urine Drug Screen[o]		x								
Serum Pregnancy Test (female participants)[o]		x								
Urine Pregnancy Test (female participants)[o]					x			x		
Administer Study Article[o]			x	x	x	x	x	x		
EKG	x									
AST	x				x[o]			x[o]		
ALT	x				x[o]			x[o]		
Total Bilirubin	x				x[o]			x[o]		
Direct bilirubin	x				x[o]			x[o]		
Heart Rate	x		x	x	x	x	x	x	x	x
BMI	x		x	x	x	x	x	x	x	x
Height	x		x	x	x	x	x	x	x	x
Weight	x		x	x	x	x	x	x	x	x
Blood Pressure	x		x	x	x	x	x	x	x	x
Temperature	x		x	x	x	x	x	x	x	x
Adverse event monitoring			x	x	x	x	x	x	x	x
Suicidal Ideation Screening (ASQ for age <17 or C-SSRS for age 18+)		x	x	x	x	x	x	x	x	x

ED-15		x	x		x			x	X	x
EDE-Q		x	x		x			x	X	x
ABUSI[o]		x	x		x			x	X	x
PHQ-9		x	x		x			x	X	x
GAD7		x	x		x			x	X	x
BIS/BAS[o]		x	x		x			x	X	X

A majority of these screening tests would be done even if you do not take part in the research study. These tests are routine for patients with your disease who are about to start therapy.

The study team will monitor the content of your questionnaires during the six months you are enrolled in this study but will not be responding to any of the information in "real time." This means we may not be immediately aware of any entries you make that could indicate health treatment is needed. If you are feeling depressed or suicidal, or are having difficulty coping, please contact your primary doctor or go to your local emergency room as soon as possible.

If you are pregnant or nursing, you will be excluded from participation in the study. If you are a sexually active person, you must be willing to use a highly effective method of birth control, such as intrauterine device, birth control pills, contraceptive implant, contraceptive patches, contraceptive vaginal ring, or injectable contraception. Condoms alone are not considered a highly effective form of birth control. If you become pregnant during the study, we will have to take you out of the study. You can continue with your eating disorder care even if you are withdrawn from the study.

If, during the course of this study, you engage in sex where a penis enters a vagina either without the use of contraception or with contraceptive failure (such as a broken condom with no second method of contraception), you will be offered a prescription for emergency contraceptive (ulipristal acetate or levonorgesterel 1.5mg) within 72 hours after sex and pregnancy testing 14 days after the episode of sex with referral according to results. You will also be withdrawn from the study. You can continue with your eating disorder care even if you are withdrawn from the study.
If your urine drug screen is positive for opioid substances, you will be provided a referral for addiction treatment services, which you may choose to accept or to decline. You will be excluded from participation in the study.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Taking your medicine every day
- Blood tests at enrollment as part of routine care, and blood tests every three weeks for 6 weeks (at week 3 and week 6).
- Urine pregnancy tests at weeks three and six for all assigned female patients
- For your safety, you must tell the study doctor or nurse about all the prescription drugs, herbal products, over-the-counter drugs (OTC), vitamins and other supplements you are taking. Check with the study doctor before starting any new medicines (including prescription, OTC drugs, vitamins and herbal supplements) or changing doses of medications that you are already taking.
- You will be asked to complete two surveys every three weeks in addition to the routine surveys in PHP and IOP
- Disclosure of coitus during study participation if there was no use of contraception or the conception failed

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

You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments. If you are in the group that receives placebo, your condition will be treated only with the standard of care and not with additional study medication.

There is a risk of loss of confidentiality if your medical information or your identity are obtained by someone other than the investigators, but precautions will be taken to prevent this from happening.

Oral naltrexone is associated with the following adverse effects: nausea, possible worsening of mood or depression, liver injury and increased thoughts of suicide or self-harm. People using opioid medications may experience opioid withdrawal as a result of the study medication.

If you are a person who can become pregnant: You should understand that you must not be pregnant when you enter the study. You also must not become pregnant during the study. If you are or become pregnant, the treatment involved in this study may hurt you or the baby. It is important for you to understand that you need to use prescription birth control while on this study. Check with your doctor about what kind of birth control methods to use and how long to use them. Some birth control methods might not be approved for use in this study. You may be tested for pregnancy to make sure that you are not pregnant. If you become pregnant during this study, you must notify the study doctor or study staff right away.

Some of the questionnaires and interview questions will be about your feelings, such as depression, sadness and anxiety. If your responses indicate that you are having suicidal thoughts or may be at risk of hurting yourself or others, we will need to respond to that. The response may involve breaking confidentiality and contacting a licensed mental health professional or a law enforcement officer. All patients who express any suicidal thoughts will be referred for follow-up mental health counseling.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

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

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. If you are assigned to the active study drug group, the possible benefits you may experience from this research study include faster recovery from eating disorder. If you are assigned to the placebo group, you are not expected to benefit from this research.

4b. What are the possible benefits to others?

The results of this research may guide the future treatment of eating disorders

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

You may choose not to be in this research study. You do not have to take part in this study to be treated for your condition. If you choose not to participate, you will still be offered standard treatment at the partial hospital program, which includes completing other clinic questionnaires.

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

You will be enrolled in the study for six months. This does not change how long you will be in our eating disorder program. You will be given study medication or placebo weekly while you are in programming or for six weeks, whichever happens first. You will be asked to visit the research site once after you finish PHP.

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.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: name/initials, electronic mail address, and medical record numbers.

- A list that matches your name with your code number, which is a unique number used to identify you in the research record, will be kept in a locked drive in Dr. Roden's computer. No physical list will be kept.
- Your research records will be labeled with your study code number and will be kept in a safe area in Dr. Roden's research office.
- Results of some of the research-related clinical tests (including but not limited to liver function tests and pregnancy tests) will be kept in your PSH medical record. Results of your urine drug screen will not be in the medical record.
- Results from this study will be provided upon request. The status and available results of the study are visible to the general public on clinicaltrials.gov, and are updated on a regular basis.

7b. What will happen to my research information and/or samples after the study is completed?

We will not be storing any of your information or biological samples for use in future studies. Your information and biological samples will not be shared with any other investigators for use in future studies.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

No biological specimens will be used for commercial profit.

No biological specimens will be used for genomic sequencing.

7c. How will my identifiable health information be used?

In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use, and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and

disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- The PSH/PSU pharmacy
- The sponsor(s) of this study, monitors and auditors, and other people or groups it hires to help perform this research

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

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

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

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

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The naltrexone or placebo will be provided by the Children's Miracle Network at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

PSH/PSU compensation for injury

- There are no plans for PSH/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

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

You will receive a $25 Greenphire Clincard at enrollment and six months for your participation in this research study for a total of $50. If you do not complete the study for any reason, you will be paid for the visits you have completed. This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, and date of birth.

10. Who is paying for this research study?

The institution will be reimbursed by the research sponsor, the Children's Miracle Network, for use of this site's facilities and for the work the research staff does to conduct this research. No one on the research team will receive a direct payment or an increase in salary for conducting this study.

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.

If you decide to leave the research, you may still participate in PHP. If you decide to leave the research, contact the investigator so that the investigator can stop the pharmacy from preparing more medication for you.

If you participate in this study and you feel the study medication helped you, you can ask the healthcare provider in the clinic to prescribe it for you again.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the

research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects, or you need treatment with opioid medications for any reason.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

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. Rosemary Claire Roden at (717) 531-7235 or the Adolescent Medicine doctor on 24-hour call at (717) 531-8521 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 research protection advocate in the PSH Human Subjects Protection Office (HSPO) at (717) 531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- 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.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

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.

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INFORMED CONSENT AND AUTHORIZATION 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	Time	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	Time	Printed Name

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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 Time 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.

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 will have a urine drug test, and it must be negative to participate in this research study. If you are 13 years of age or younger at the time this consent/assent form is signed, and your urine drug test comes back positive, your parents will be notified of this information. If you are 14 years of age or older at the time this consent/assent is signed, and your urine drug test comes back positive, your parents will not be notified of this information without your consent. However, your parents may find out that you are using drugs as you will not be able to take part in this research. If you are a female capable of becoming pregnant you will be tested for pregnancy. The results of your test will not be shared with your parent/guardian without your permission. However, your parents may find out if you are pregnant because you will no longer be able to take part 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