# Parental Consent Form

**Title of Research Study:** Lisdexamfetamine for the Treatment of Severe Obesity in Children Aged 6 to 12 Years

### Investigator Team Contact Information

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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| Investigator Name: Claudia Fox, MD<br>Investigator Departmental Affiliation: Pediatrics<br>Phone Number: (612) 626-6616<br>Email Address: lusc0001@umn.edu | Study Staff: Patti Laqua<br>Phone Number: (612) 624-2151<br>Email Address: laqua001@umn.edu |

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## *Key Information About This Research Study*

The following is a short summary to help you decide whether or not to allow your child to be a part of this research study. More detailed information is listed later on in this form.

### What is research?

Doctors and investigators are committed to your child's care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. Your child, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help your child get better or to improve your child's quality of life. Doctors can make changes to your child's clinical care plan as needed.

### Why is my child being asked to take part in this research study?

We are asking your child to take part in this research study because your child is between the ages of 6 and 12 and has difficulty maintaining a healthy weight.

### What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not your child takes part is up to you.
- You can choose not to have your child take part.
- You can agree to have your child take part and later change your mind.
- Your decision will not be held against you or your child.
- You can ask all the questions you want before you decide.

## Why is this research being done?

This study is being done to see if children aged 6 to 12 years who carry extra weight might benefit from taking a medication called lisdexamfetamine. Lisdexamfetamine (also called Vyvanse) is a medication that is used to treat attention deficit hyperactivity disorder (ADHD) in children and it is used to help decrease binge eating behaviors in adults. This study will use lisdexamfetamine in children to see if it can assist with weight loss. This study will be using lisdexamfetamine in an investigational manner, which means that it is not approved by the FDA.

## How long will the research last?

We expect that your child will be in this research study for about 28 weeks. There will be a total of 14 visits for the study, 8 of them will be conducted in person and 6 will be conducted by phone or Zoom. For the first and the last visits, your child will be asked to come to the research unit after not having had anything to eat or drink (except water) for 12 hours.

## Is there any way that being in this study could be bad for my child?

The risks to this study include the following:

Risks of Lisdexamfetamine: The most common side effects of lisdexamfetamine in children aged 6 to 12 are broken down by frequency:

Seen in more than 10% of children:

Decreased appetite
Upper abdominal pain

- Insomnia (sleeplessness)

Seen in 6-10% of children:

- Irritability
- Decreased weight
- Vomiting

Seen in 1-5% of children:

- Dry mouth
- Affect lability (mood swings)
- Fever
- Tic
- Anxiety
- Nausea
- Fast heartbeat
- Dizziness
- Rash
- Drowsiness
- Anorexia
- Diarrhea
- High blood pressure

The use of Vyvanse carries a high potential for abuse and dependence. Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Abuse is characterized by impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving higher priority to drug use than other activities and obligations), and possible tolerance or physical

dependence. Both abuse and misuse may lead to addiction, and some individuals may develop addiction even when taking Vyvanse as prescribed.

Using Vyvanse may lead to psychiatric symptoms such as hallucinations, delusional thinking, or mania. Taking Vyvanse may also lead to peripheral vasculopathy (the reduced circulation of blood to a body part, other than the brain or the heart, due to a narrowed or blocked blood vessel. If your child has diabetes, obesity, smokes or has a sedentary lifestyle, the risk of peripheral vasculopathy might be increased.

Vyvanse is part of a class of drugs that may suppress linear growth, though it appears that final adult height is not impacted.

A potentially life-threatening problem called serotonin syndrome (having too much serotonin in the synapses of the brain) may happen when Vyvanse is taken with certain other medicines. You should have your child stop taking Vyvanse and call your child's healthcare provider or go to the nearest hospital emergency room right away if your child develops any of the following signs or symptoms of serotonin syndrome: agitation, flushing, coma, loss of coordination, dizziness, seeing or hearing things that are not real (hallucination), high body temperature (hyperthermia), fast heartbeat, seizures, sweating, confusion, tremors, still muscles or muscle twitching, changes in blood pressure, vomiting or diarrhea.

Risks of DXA scans and wrist x-rays: As part of this study your child will undergo 2 DXA scans and 2 bone age x-rays. DXA scans provide information about body composition (lean mass versus fat). The bone age x-ray provides information about whether your child is done growing and developing. These procedures involve exposure to ionizing radiation. The radiation exposure is not necessary for your child's medical care and is for research purposes only. The average amount of radiation that the average person would receive from these procedures is less than 1% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired.

Your child may not be eligible for this study if they have participated in another study within the last 12 months in which they received research related radiation exposure. You are responsible for informing the study team of such involvement prior to the beginning of the study.

Risks of blood sampling: There is a minimal risk of bruising, fainting and infection associated with blood draws.

Risks of indirect calorimetry: This test, which measures how fast a body is burning energy by measuring the air that we exhale. For the test, your child will be asked to lie down on a flat surface and have a mask or hood placed over their head for a period of time, Your child may feel claustrophobic from wearing the mask/hood for the test.

Risks of accelerometry: This test will measure how active your child is. This will be done by wearing a device called an accelerometer. Potential risks include emotional distress from wearing the device 24 hours per day.

Risks of lifestyle therapy: potential risks related to lifestyle therapy are sadness or frustration related to difficulty adhering to dietary and activity plans. Participants may experience injury related to increased physical activity.

Risks of neuropsychological assessments and eating questionnaires: emotional distress and possible "test fatigue." If the questionnaires about depression or suicide show that your child is experiencing significant depression or thoughts of harm, we may need to tell others outside of the study team in order to help keep your child safe. We will tell you if your child is experiencing worsening depression or thoughts of harm.

### Will being in this study help my child in any way?

We cannot promise any benefits to your or others from participating in this research. However, possible benefits include a better understanding of healthy food choices and weight loss. It is hoped that the information that is learned from this study might help others in the future.

### What happens if I do not want my child to be in this research?

You do not have to allow your child to participate in this research. Instead of being in this research study, your child may have lifestyle therapy to help control their weight that is conducted in a clinic setting. There are other medications that your child may be able to take that may assist with weight loss. The study doctor can talk to you about other options available to your child.

## *Detailed Information About This Research Study*

### How many people will be studied?

We expect about 44 people will be in this research study.

### What happens if I say "*Yes, I want my child to be in this research*"?

If you are interested in having your child participate in this research, this is what will happen at each visit.

Screening Visit (in person):

- Review of inclusion/exclusion criteria
- Basic information about your child and family (such as age, gender, education level, nationality and ethnicity).
- Review your child's medical history including chemical dependency history
- Height, weight, blood pressure and heart rate
- Physical exam
- Tanner staging (puberty assessment)
- EKG
- Dietary recall
- Blood draw after your child has been fasting for 12 hours to look at how their body is functioning and to look at the amounts of fat, sugar and insulin in their blood
- Pregnancy test (either urine or serum) if your child is female

- Questions about depression and suicide
- If your child has difficulty swallowing capsules, your child may be given a sample pill (with no medication) to see if they can swallow the capsule that will be used for the study. If your child is unable to swallow the capsule, they will be allowed the opportunity to practice swallowing items (such as tic tacs) at home in order to become more accustomed to swallowing the capsule that will be used in the study. Your child would need to return within 14 days to demonstrate the ability to swallow the test capsule.

An accelerometer will also be worn for one week (7 days x 24 hours/day) between the screening and baseline visit. You will be provided with a small reward (such as stickers, pens or markers) to give to your child when they complete wearing the accelerometer. You will be asked to complete a sleep diary.

Baseline/Randomization (in person):

- Height, weight, blood pressure and heart rate
- Bone age x-ray
- Indirect calorimetry. Your child should not engage in intentional activity or consume caffeine the day prior to the visit.
- DXA scan (with urine pregnancy test for females of childbearing potential)
- Suicide and depression screening
- Dietary recall
- Questionnaires for both you and your child
- Medication/placebo dispensed
- Review your child's health history and medication history and how s/he has been feeling
- In-person lifestyle therapy visit

At this visit your child will be chosen at random (like the toss of a coin) to receive the study medication, lisdexamfetamine, or placebo. A placebo is a pill that looks like lisdexamfetamine but has no medication in it. Neither you, your child, or the study staff will know if your child is taking the lisdexamfetamine or the placebo, but this information is available in the event of an emergency. Your child will gradually increase the dose of the study medication over the next several visits. You will be asked to keep a diary of the times you give your child the study medication. You will also be provided with a portion plate which may be helpful in teaching your child about portion sizes.

Week 2 (virtual visit):

- Compliance check
- Review of how your child has been feeling and the medicines s/he has been taking
- Dose escalation (if tolerated)
- Virtual lifestyle therapy visit

Week 4 (in person visit):
- Height, weight, blood pressure and heart rate
- Urine pregnancy test for females
- Suicide and depression screening
- Compliance check and return of unused study medication
- Review of how your child has been feeling and the medicines s/he has been taking
- Dose escalation (if tolerated) and study drug dispensing
- In-person lifestyle therapy visit

Week 6 (virtual visit):
- Compliance check
- Review of how your child has been feeling and the medicines s/he has been taking
- Dose escalation (if tolerated)
- Virtual lifestyle therapy visit

Weeks 8 (in person visit):
- Height, weight, blood pressure and heart rate
- Urine pregnancy test
- Suicide and depression screening
- Review of how your child has been feeling and the medicines s/he has been taking
- Compliance check
- Dose escalation (if tolerated) and study drug dispensing
- Review of how your child has been feeling and the medicines s/he has been taking
- In-person lifestyle therapy visit

Weeks 10, 14, 18 and 22 (virtual visits):
- Compliance check
- Dietary recall (at Week 22 only)
- Review of how your child has been feeling and the medicines s/he has been taking
- Virtual lifestyle therapy visit

Week 12 (in person visit):
- Height, weight, blood pressure and heart rate
- Urine pregnancy test
- Suicide and depression screening
- Compliance check and return of unused study medication
- Study drug dispensing
- Review of how your child has been feeling and the medicines s/he has been taking
- In-person lifestyle therapy visit

Weeks 16 and 20 (in person visits):

- Height, weight, blood pressure and heart rate
- Urine pregnancy test
- Suicide and depression screening
- Compliance check and return of unused study medication
- Study drug dispensing
- Review of how your child has been feeling and the medicines s/he has been taking
- In-person lifestyle therapy visit

An accelerometer will also be worn for one week (7 days x 24 hours/day) between the visits at Week 20 and Week 24. You will be provided with a small prize to give your child (sticker, pen or markers) at the completion of wearing the accelerometer. You will be provided with an envelope to return the accelerometer or you can return it in person at the Week 24 visit.

Week 24 (in person visit):

- Height, weight, blood pressure and heart rate
- Tanner stage (puberty assessment)
- Bone age x-ray
- Indirect calorimetry. Your child should not engage in intentional activity or consume caffeine the day prior to the visit. Your child should not take their study medication in the morning before the visit.
- DXA scan (with pregnancy test (either urine or serum) for females of childbearing potential)
- Suicide and depression screening
- Dietary recall
- Fasting blood draw for fats, sugars and insulin in your child's body and a metabolic panel to look at how their body is functioning
- Questionnaires for you and your child
- Compliance check and return of unused study medication
- Review of how your child has been feeling and the medicines s/he has been taking

| | Screening | Randomization/ Baseline | Week 2 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 14 | Week 16 | Week 18 | Week 20 | Week 22 | Week 24 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **In-person visits** | | | | | | | | | | | | | | |
| Review of eligibility | X | | | | | | | | | | | | | |
| Demographics | X | | | | | | | | | | | | | |
| Review of medical history including chemical dependency | X | | | | | | | | | | | | | |
| Height, weight, blood pressure and heart rate | X | X | | X | | X | | X | | X | | X | | X |
| Physical exam | X | | | | | | | | | | | | | |
| Puberty staging | X | | | | | | | | | | | | | X |
| ECG | X | | | | | | | | | | | | | |
| Blood draw after 8-10 hour fasting | X | | | | | | | | | | | | | X |
| Pregnancy test for females | X | X | | X | | X | | X | | X | | X | | X |
| Depression and suicide screening | X | X | | X | | X | | X | | X | | X | | X |
| Bone age | | X | | | | | | | | | | | | X |
| Indirect calorimetry | | X | | | | | | | | | | | | X |
| DXA scan | | X | | | | | | | | | | | | X |
| Diet recall | X | X | | | | | | | | | | | X | X |
| Accelerometry | X | | | | | | | | | | | X | | |
| Questionnaires for child and parent | | X | | | | | | | | | | | | X |
| Planned dose escalation | | | | X | | X | | | | | | | | |
| Dispense study medication | | X | | X | | X | | X | | X | | X | | |
| Compliance check | | | | X | | X | | X | | X | | X | | X |
| Review of your child's health | | X | | X | | X | | X | | X | | X | | X |
| Lifestyle therapy | | X | | X | | X | | X | | X | | X | | X |
| **Phone Visits/Virtual Visits** | | | | | | | | | | | | | | |
| Lifestyle therapy | | | X | | X | | X | | X | | X | | X | |
| Compliance check | | | X | | X | | X | | | | | | | |
| Planned dose escalation | | | X | | X | | | | | | | | | |
| Review of your child's health | | | X | | X | | X | | X | | X | | X | |

## What are my responsibilities if my child takes part in this research?

If your child takes part in this research, you will be responsible for attending the visits, ensuring your child is taking the study medication/placebo, completing questionnaires and keeping us up to date about how your child is feeling and the medicines they are taking.

## What happens if I say "Yes", but I change my mind later?

If your child takes part in this research study, and wants to leave, you should tell us. Your choice not to have your child be in this study will not negatively affect your child's right to any present or future medical care.

We will make sure that your child stops the study safely. We will also talk to you about follow-up care, if needed.

If you decide to stop your child's participation in the study, no new data will be collected. However, any data that has already been collected will be kept in the study record.

## Will it cost me anything to have my child participate in this research study?

Taking part in this research study will not lead to any costs to you.

## Notification of Significant New Findings

You will be told of any important new information that is learned during the course of this research study, which might affect your child's condition or your willingness to allow your child to continue participating in this study.

## Important information for females

The iDXA and the wrist x-ray use radiation to help generate their picture. Radiation can be very harmful to an unborn baby. If your child is a female, she will need to have a pregnancy test at the visits where these tests are done and at other study visits. The results of the pregnancy test will not be disclosed to you without your child's permission. But if the doctor believes that being pregnant may cause serious problems for your child's health, they may tell you about the pregnancy test results.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your child's information include the Food and Drug Administration (FDA), the US Department of Health and Human Services (DHHS), the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)).

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

A description of this clinical trial will be available at http://www.clinicaltrials.gov, as required by U.S. Law or other guidelines. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

**Certificate of Confidentiality**

To help protect your child's privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify your child, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your child or your child's involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

## Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care and will not be shared with you. The results of the blood tests done on your child will be posted to their medical record and can be available to you via MyChart.

## What will be done with my child's data when the study is over?

We will use and may share data for future research. Data collected in this study may be made available for others to use, including future research studies on similar or different topics, teaching, or other purposes. This could include for profit companies. Our goal is to make more research possible. We will not ask for your consent before using or sharing your child's data. We will remove identifiers from your child's data, which means that nobody who works with them for future research will know who your child is. Therefore, neither you nor your child will receive any results or financial benefit from future research done on your children's data.

## Will anyone besides the study team be at my child's consent meeting?

You may be asked by the study team for your permission for an auditor to observe the consent

meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g., name, date of birth) or confidential information about you or your child. The auditor will not observe your consent meeting without your permission ahead of time.

### Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

### Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

### Can my child be removed from the research?

The person in charge of the research study or the sponsor can remove your child from the research study without your approval. Possible reasons for removal include not attending the study visits or not taking the study medication.

### What happens if my child is injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that your child has suffered a research related injury let the study physicians know right away.

### Will my child be compensated for their participation?

If you agree to allow your child to take part in this research study, they can earn up to $725. Payments will be made for completed visits as follows:

- Baseline visit: $75 for the visit and $25 when the accelerometer is returned
- Week 4: $75
- Week 8: $75
- Week 12: $75
- Week 16: $75
- Week 20: $75
- Week 24: $100 for the visit and $50 when the accelerometer is returned

Participants who complete all of the virtual lifestyle therapy visits will receive a $100 bonus at the Week 24 visit.

Payment for the study earnings will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give the debit card to you (not your child) and each time your child receives a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

Payment, you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

## Use of Identifiable Health Information

We are committed to respect your child's privacy and to keep your personal information confidential. When choosing to allow your child take part in this study, you are giving us the permission to use your child's personal health information that includes health information in his/her medical records and information that can identify your child. For example, personal health information may include your child's name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

***How will my child's information be used in publications and presentations?***
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. We may also share this information with the National Institutes of Health or other researchers. Information that makes it easy to identify your child (such as their name and contact information, SSN and medical records number) will not be part of any publication, presentation or sharing. If your child has an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your child's identity even without these identifiers.

**Optional Elements:**
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| **Yes, I agree** | **No, I disagree** | |
|---|---|---|
| _____ | _____ | The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Claudia Fox or the Center for Pediatric Obesity Medicine. |

## Parental Consent Form

**Signature Block for Capable Adult:**

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____

Name of Participant

_____ _____

Signature of Parent Date

_____ _____

Printed name of Parent Relationship to Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent