TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Obstetrics and Gynecology

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Validation of a video teaching tool for adolescent self-administration of subcutaneous depot-medroxyprogesterone

Principal Investigator: Amanda French, MD
Co-Investigators: Erin Fee, MD and Areta Bojko, MD
Study team telephone number: 781-897-0240

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

A person who takes part in a research study is called a research subject. This consent form is used to document the permission of a parent(s) or guardian(s) to allow a minor to take part in a research study. In this consent form "you" refers to the minor who will take part in the research study.

In this study, we will ask you to watch a short video that teaches you how to give yourself a shot of medicine you already get from the doctor. After you watch the video, you will give yourself the shot while the doctor watches you to make sure you do it correctly. After you give yourself the shot, you will be asked to answer a few questions. You will also be asked to answer a few more questions at the time of your next scheduled shot (in about 12 weeks from now).

Why am I being invited to take part in a research study?
We are inviting you to be in the study because you are under the age of 20 years old and you are already receiving depot-medroxyprogesterone injections given by the doctor or nurse in your medical office.

What should I know about a research study?
- Someone will explain this research study to you.
- Please also read all of the following information carefully.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can decide to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide. Do not sign unless you understand the information in this consent form and have had your questions answered to your satisfaction.

- If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers that you may wish to refer to.

Why is this research being done?

This study will help us learn more about how well this video works for teaching adolescents to give themselves this shot. During the COVID pandemic, many kids had a hard time getting to the doctor's office for this medicine but there are no videos online to show kids how to give themselves this shot. We made a video and would like to see if it does a good job teaching kids how to give themselves this shot.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 12 weeks (two visits, about 12 weeks apart).

If you agree to take part this study, we will ask you to watch an instructional video today that lasts about three minutes, then give yourself the medication as instructed by the video. While you are giving yourself the shot, the doctor or nurse will watch you. After you give yourself the shot you will be asked to take an online survey of less than five questions. You may be asked to complete another survey in about 12 weeks, after your next depot-medroxyprogesterone shot.

More detailed information about the study procedures can be found under the **"Procedures to be Followed"** section.

Is there any way being in this study could be bad for me?
There is a small chance that we may not be able to protect your private information, but we ask that you not enter any information into the study questions that could identify you. We will keep track of the names of people who participated in the study, but the list of names will be kept secure by the research team and destroyed when the study is completed. The risks of giving yourself an injection are bleeding, bruising, infection, inadvertent injury, a broken needle, or not administering a complete dose of the medication.

More detailed information about the risks of this study can be found under the **"Risks"** section.

Will being in this study help me in any way?
If you learn how to give yourself the shot, you may be able to give yourself the medication instead of coming to the doctor's office every 12 weeks. This may save you some time and be a more convenient way for you to get your medicine. If we can prove that this video helps teach kids how to give themselves this shot, we can share it with other kids your age and help them in the same way.

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. The alternative to not participating in this study is to get your medicine from the doctor in the usual way.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

PURPOSE OF STUDY

This is a study to see if a teaching video we have made can be successfully used for adolescent patients to teach themselves, and then give themselves, this medicine (depot-medroxyprogesterone).

This study will be conducted at Tufts Medical Center and Tufts Children's Hospital.

We expect up to 50 people will be enrolled in this study at Tufts Medical Center in order to have 30 people complete the study.

PROCEDURES TO BE FOLLOWED

You will be asked prior to your appointment if you are interested in participating in this study. The overall study procedures will take less than half an hour for each visit. If you are interested, you will be given a link for a video. You will watch this four-minute video. You can watch the video as many times as you want to. After that, you will then give yourself the shot. The doctor or nurse will watch you give yourself the shot to make sure you get the medicine. If you do not give yourself the shot, the doctor or nurse will give you the shot, so that you will get your medicine either way. If the doctor or nurse feels you are not doing it properly, they will either correct you or take over and they will give you the shot, themselves. After the shot is given, you will be asked to answer a few questions into an electronic survey. At the time of your next shot (about 12 weeks from now), you will be asked to answer a few more questions either in person or through a link that is emailed to you. You will not be asked to share any private information. The information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifying information is removed.

The shot is being given for standard medical care; only the video and you choosing to give the shot to yourself are part of this research study. You will get your shot whether or not you participate in this study. You will be participating in this study for about 12 weeks total, with 2 study visits during this time.

WITHDRAWAL

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if she thinks it is in your best medical interest. You can also leave the research at any time and it will not be held against you. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

RISKS

The risks of this study are minimal. There is a small risk that the confidential list of study participant names will not be kept private, but the list of names will be kept in a separate location with access only by the research team, so this risk is very small. There are additional small risks of giving yourself an injection: bleeding, bruising, infection, inadvertent injury, a broken needle or incomplete administration of the medicine.

RESEARCH RELATED INJURY

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

COST

There are no costs associated with participation.

PAYMENT

You will not be paid for your participation in this study.

PRIVACY AND CONFIDENTIALITY

If you decide to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities. We will make every effort to keep your information private, but it cannot be completely guaranteed. The only private information collected during the study will be a list of the names of participants. This list will be kept in a separate secure location from the study data and only the research team will have access. This list will be destroyed at the end of the study.

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

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

If you sign this document, you give permission to the Principal Investigator named above and research staff at Tufts Medical Center as well as other individuals at Tufts Medical Center who may need to access your information to do their jobs (such as for treatment, payment (billing) or

health care operations), to use or disclose (release) your health information that identifies you for the research study described above.

The parties listed in the preceding paragraph may disclose the health information described below to the following persons and organizations for their use in connection with the research study:

- Individuals or organizations working under the direction of the Principal Investigator(s) for the study,
- Outside individuals or entities that have a need to access this information to perform activities relating to the conduct of this research, such as analysis by outside laboratories on behalf of Tufts Medical Center
- Other researchers and institutions that are conducting or participating in this study,
- The Office for Human Research Protections in the U.S. Department of Health and Human Services, the United States Food and Drug Administration (FDA) and other federal and state agencies that have the right to use the information as required by law, and
- The members and staff of any Institutional Review Board (IRB) that oversee this study.

The health information that we may use or disclose (release) for this research study includes all information in your medical record related to the diagnosis and management of using depot-medroxyprogesterone, including the record of your care, as well as any information collected or created during the course of this study.

Tufts Medical Center is required by law to protect your health information. By signing this document, you authorize Tufts Medical Center to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You may not be allowed to see or copy the information described on this form as long as the research is in progress, but you have a right to see and copy the information upon completion of the research in accordance with hospital policies.

Tufts Medical Center may not withhold or refuse to provide you with clinical care based on whether or not you sign this form.

This authorization does not have an expiration date. You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, this site's clinical, administrative and research staff may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must write to: HIPAA Privacy Officer for Research, 800 Washington Street, Box 5100, Boston, MA 02111. If you revoke this authorization, you may no longer be allowed to participate in the research described in this form.

WHOM TO CONTACT

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team:
During business hours, Amanda French, MD 781 897 0240
After hours and on weekends, Erin Fee MD through the Tufts hospital paging system

If you have questions about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress. This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

Documentation of Consent

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study. I understand that by signing this form I do not give up any of my legal rights.

_____ _____
Participant's Signature Date

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____
Date Principal Investigator or Representative's Signature

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.

_____ _____
Parent/Legal Guardian's Signature Date

_____ _____
Parent/Legal Guardian's Signature Date

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient.
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

_____
Child's Assent (7 years and older)

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature