TEMPLATE PROTOCOL INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)"if this is an investigator-initiated study where a protocol document has not already been provided to you with relevant information for each applicable section listed in the Table of Contents (below).*
- *Depending on the nature of the research, some sections may not be applicable. If a section is not applicable, mark as "NA" or delete altogether. For example, research involving a retrospective chart review may have many sections marked as NA or deleted.*
- *When you create a protocol using this template, save an electronic copy with the protocol version date incorporated into the name of the document, e.g., LastName_Protocol_20160623.You will need to use the current electronic copy when making recommended changes and future modifications.*
- *Please note that underlined items in this document are hyperlinked to additional information.*

STUDY TITLE: Validation of a video teaching tool for Adolescent Self Administration of Subcutaneous depot-medroxyprogesterone

STUDY SPONSOR: Amanda French, M.D.
If there is a study sponsor, please specify. If the PI is taking on the responsibilities of the study sponsor, i.e., an investigator-sponsor, insert PI's name here.

PRINCIPAL INVESTIGATOR

Refer to PI Eligibility on the Tufts Health Sciences IRB website. List only one PI:
Name: Amanda French
Department: obstetrics and gynecology
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VERSION DATE: 7/4/21

Table of Contents – Click on the links below to go directly to the applicable section

A. Study Schema

Include a diagram that provides a quick "snapshot" of the study. For examples of study schemas, refer to the FDA and NIH's Study Schema Examples document available on the IRB website:

1. Prior to enrollment: Determine number of subjects to be enrolled, craft patient and doctor surveys.
2. Enrollment will occur at clinic sites by calling potential subjects in advance to assess interest in the study.
3. If subject expresses interest, doctor or nurse practitioner will call in the subcutaneous form of depot-medroxyprogesterone to pharmacy of patient's choice, patient will pick up medication prior to scheduled office visit and bring medication with them to the visit.
4. Once patient arrives in clinic with the medication in hand, informed consent / assent will be obtained (consent/assent will be age appropriate and involve parent or guardian if patient is under the age of 18). If subject declines enrollment at this time, doctor will administer the medication.
5. When patient checks into clinic, contact information for patient will be verified including phone number and email address.
6. If consent is obtained, patient will be given video to watch.
7. After video is watched, patient will then self-administer the medication injection while healthcare provider on research team is watching. If there is concern that medication is not being given correctly, doctor/healthcare provider will step in and give the injection to ensure subject gets the correct medication, regardless of the success or failure of the teaching video.
8. After injection is given, subjects will complete a survey in REDCap and study team members will input observational data into REDCap
9. Approximately 12 weeks after the injection, at the time of their next scheduled office visit, participants will be asked complete a secondary survey via REDCap to determine frequency of follow up self injection. This survey will be administered in person or emailed to the subject.
10. Data analysis will follow completion of patient enrollment.

B. Introduction

B.1 Background and Rationale

1. *Describe the relevant prior experience and gaps in current knowledge:* Although traditionally administered in the clinical space, injectable contraception has been shown to be effective and well tolerated by adolescents when subcutaneously self-administered (please see question 3 below for background). However, there is no current peer to peer teaching model available online, which may be a barrier to care and is particularly applicable during the COVID19 pandemic when a large proportion of medical care was abruptly moved online.
2. *Describe any relevant preliminary data:* none
3. *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge:*

Means of providing health education are rapidly evolving. Telemedicine has become an important modality to provide healthcare and improve access, and will likely be increasingly utilized beyond the COVID-19 pandemic. Telemedicine can effectively provide care and counseling to all age groups, including adolescents (1). Studies have demonstrated that over 80 percent of adolescents between the ages of 11 and 18 spend one to four hours a day online (2); searches for health-related information are common (3). Nevertheless, adolescents may face obstacles when previously familiar aspects of their medical care are abruptly moved online, particularly when discussing contraception. Although traditionally administered in the clinical space, injectable contraception has been shown to be attractive, effective and well-tolerated by adolescents when subcutaneously self-administered, and can lead to

improved continuation rates (4, 5, 6). We found that remotely teaching a patient how to self-administer a subcutaneous injection is challenging. The provider may be in a home office, and may not have access to the actual medication or the supplies to demonstrate technique. The patient may struggle to understand verbal instruction without a visual demonstration, resulting in ineffective medication administration. Instructional videos currently available online are not specific to adolescents who use self-administered injectable contraception. Peer education can be relatable and effective for adolescent patients (7). We propose that self-administration of subcutaneous injectable contraception may be taught using a peer-to-peer video as a synchronous or asynchronous adjunct to consultation with the healthcare professional. Adolescents may be instructed to watch the video demonstration to help inform them about proper technique and ensure safe administration of their medication while at home. This study aims to validate an existing video as an effective teaching tool by assessing metrics such as clarity of the instructions, rate of error, and satisfaction with the video teaching method to our target population. The video was filmed in accordance with Tufts Medical Center department of Marketing and Communications policies and the adolescent participant in the video was appropriately consented by a parent/guardian. The video was presented as an oral abstract at the North American Society for Pediatric and Adolescent Gynecology Annual Meeting in March 2021.

3. *Describe the relevance and usefulness of the objectives:* The primary objective of this study is to determine the validity of this teaching video for adolescents wishing to learn how to self-administer depot-medroxyprogesterone as an alternative to receiving all injections in a medical office. Having a video option for a teaching tool gives an alternative to in person office visits for teaching and gives more flexibility for patients and providers when in person visits are limited. The secondary outcome is to determine if patients will continue to use the self-administration technique for future injections.
4. *Specify whether or not this is the first time the study drug, device, or intervention/procedure will be used in humans. If there has been experience with the study drug, device, or intervention/procedure in humans, detail the experience to date:* or ☒N/A, this is not the first time the study drug, device, or intervention/procedure will be used in humans
5. Is there an active control group?

   ☐ **Yes** ☒ **No**

   If **Yes**, respond to all of the following:
   a. ☐*Check to confirm that the active control is an established effective intervention. If it is not, clarify how it is ethically justified to use this control in the study:*
   b. *Describe any potential bias in the selection of the active control such that there will be an unfair advantage for the investigational intervention. For example, is the active control treatment known to be significantly less effective in this study population than another treatment:* or ☐N/A
   c. ☐*Check to confirm that the sample size and the randomization ratio for this active control study is ethically justified with regard to the number of participants who will be exposed to the risks of the study.*

B.2 Risks to Subjects

1. *List the reasonably foreseeable risks, discomforts, hazards, and/or inconveniences to the subjects related to their participation in the research, including risk of unintentional loss of confidentiality. Include a description of the probability, magnitude, duration, reversibility, and potential consequences of the risks. Consider physical, psychological, social, legal, and economic risks:* This study aims to enroll subjects who have already been counselled on risks and benefits of depot medroxyprogesterone, have chosen to receive this medication, and have had at least one previously administered injection by a healthcare provider. For these reasons the only intervention will be that their medication is self-administered rather than given by a medical provider. The risks of incorrect self-injection include bruising at the injection site, bleeding at the injection site, infection at the injection site, a broken needle, pain, and inadvertent injury. These risks are minimal and as the self-injection will be

witnessed by the study healthcare provider, any additional medical care deemed necessary as a result of incorrect self-injection will be immediately administered. The healthcare provider will also intervene if there is reasonable assumption based on the healthcare provider's clinical judgement, that harm is about to occur when watching the patient self-inject. If only a portion of the medication is given, an additional injection will be provided (which is standard practice and considered safe). All subjects will continue to receive the same routine health care as if the doctor had given the injection including instructions to call the office or come into the office to be evaluated if any questions or concerns arise between appointments. Unintentional loss of confidentiality is a minimal risk as exit questionnaires will be done directly through a coded REDCap survey link. Each patient will be given a number in the survey which will be linked to a list with the patient name and date of birth. This list with identifiers will be saved into a HIPAA compliant Box account approved by Tufts Medical Center and only accessible by password by the PI and members of the research team. This identified list will be destroyed by the research team after surveys have been completed per the protocol by Tufts Medical Center.

2. *State which study interventions may have unknown risks:* or ☒N/A
3. *State which study interventions may have risks to an embryo or fetus (if a subject is or becomes pregnant) or to a nursing infant of a study subject:* or ☒N/A
4. *Describe risks to people other than the participating subject, e.g., risks to family members, friends, others or risks to the community:* or ☒ N/A
5. Are there any risks to study investigators or staff performing the study procedures due to research with high risk populations (e.g. prisoners, intravenous drug users, patients with major psychiatric issues, etc.):?
   ☐ **Yes** ☒ **No**
   If **Yes**, respond to all of the following:
   a. *Describe these risks:*
   b. *Describe the procedures that will be put in place to minimize these risks:*
   c. *Describe how these procedures are adequate for the location where study procedures will be performed:*
   d. ☐*Check to confirm that you have contacted research administration to clarify whether additional approvals (e.g. Security, Risk Management, etc.) are needed for the performance of this study with high risk populations.*

B.3 Potential Benefits to Subjects

1. *Describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits:* If the video is successful and the subject learns how to self-inject, it gives the option of not coming into the doctor's office for every injection which may be more convenient.
   Note: Payments and incentives are not considered benefits in the IRB's risk-benefit assessment; payment and incentives should be addressed in the payment section.
2. ☐*Check if there is no direct benefit.*
3. *Describe any benefit to the population from which the subject is drawn:* If this teaching video is deemed to be successful in teaching adolescents to self-administer the subcutaneous depot-medroxyprogesterone, it may be shared on other medical forums and thus benefit a larger audience who then also will have more flexibility and choice about how they receive depot medroxyprogesterone. or ☐ N/A
4. *Describe any benefit to science, society, and humanity in general:* Please see answer to #3 above. or ☐ N/A

B.4 Alternatives

1. *Describe alternatives to participating in this research study (e.g. to decide not participate in the study, alternative treatments, no treatment (palliative care), etc.):* Alternative is to not participate in the

study and instead receive depot medroxyprogesterone administered by the healthcare provider.

2. *Describe the standard clinical care that may be an alternative:* Receiving the same medication by injection administered by a health care provider. or ☐ N/A
3. *Describe how the subject can receive the research procedures/drug/device used in this study in a non-research setting:* or ☒ N/A

C. Objectives

1. *Describe the purpose, specific aims, or objectives of the study (i.e. the reason for performing the study in terms of the scientific question to be answered):* Primary aim of this study is to validate that this video, filmed specifically for an adolescent population, is effective at teaching adolescents how to self administer subcutaneous depot medroxyprogesterone. Secondary aims are to determine if the video is deemed satisfactory to the intended viewing audience and to determine if adolescents who watch this video will continue to self administer subcutaneous depot medroxyprogesterone in the future.

   Note: Specify which are the primary or secondary aims or objectives of this study as applicable. The primary objective is the main question. Secondary objectives are goals that will provide further information for the study.

D. Enrollment and Withdrawal

D.1 Inclusion Criteria

1. *Describe the criteria that define who will be **included** in the study as a numbered list:*

   Subjects receiving the injection:

   1. Assigned females at birth 19 and younger seen at Tufts Medical Center or Tufts Children's Hospital that have previously received at least one injection of depot medroxyprogesterone

   Include age eligibility including upper and lower limit.

   Indicate specifically whether you will include any of the following special populations: (You may not include members of the populations listed below as subjects in your research unless you indicate them in your inclusion criteria.)

   a. Adults unable to consent (cognitively impaired adults)
   b. Pregnant women
   c. Pregnant minors
   d. Minors, i.e., individuals who are not yet adults (neonates, children, teenagers)
   e. Wards of the state
   f. Non-Viable neonates
   g. Neonates of uncertain viability
   h. Prisoners

   If during the course of the study you identify a potential subject who cannot read, write or has some impairment that hampers consent process or documentation, follow the Policy on Subjects who Cannot Read, Write, or Have Some Impairment that Hampers Consent Process or Documentation. If such subjects will be excluded from the study, you must specify that in the "Exclusion Criteria" section below and specify the rationale for their exclusion.

D.2 Exclusion Criteria

1. *Describe the criteria that define who will be **excluded** in the study as a numbered list:*

   Subjects receiving the injection:

   1. Any patient who has never received a prior dose of depot medroxyprogesterone.
   2. Any patient who has ever self administered any injectable medication (either intramuscular or subcutaneous)
   3. Any patient who cannot understand written or spoken English (as the video is currently in English with English subtitles)
   4. Any patient under the age of 18 who does not have a parent or guardian to sign the consent form.
   5. Subjects who are unable to watch the video due to any circumstances (such as device unavailability or poor wifi signal) will be excluded.

6. Subjects who are cognitively impaired
7. Subjects who are pregnant
8. Wards of the state, prisoners

2. *Describe in detail how the eligibility criteria will be assessed and satisfied (e.g., medical record review, physical examination):* Study team members will review the clinic schedule ahead of time to find patients who are scheduled for depot-medroxyprogesterone injections and perform chart review to preliminarily determine if patients meet inclusion criteria. These patients will be called via telephone and, using the script provided, will then be asked if they have interest in the study. Inclusion and exclusion criteria will be further clarified with verbal discussion when patients arrive in the office (for example, device availability, wifi signal).
3. *State who will determine eligibility. Note that those who are designated to determine eligibility must have appropriate training, expertise, and oversight, for example a physician PI or Co-I on a biomedical study:* Study team members Dr. French (PI), Dr. Fee and Dr. Bojko are gynecologists who currently provide care to patients receiving depot medroxyprogesterone and are trained to take care of these patients already. These physicians are also trained to administer both subcutaneous and intramuscular injectable medications. Any study team member added in the future must be a provider trained to care for patients receiving depot medroxyprogesterone injections.
4. *Can study subjects participate in another research study while participating in this research study:* ☒Yes ☐ No

D.3 Withdrawal of Subjects

1. *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent:* There is no anticipated circumstance in which subjects would be withdrawn without consent. If the questionnaire is not filled out by the subject, this will be noted, as the provider will still be expected to fill out a separate questionnaire. If the medication is not given by self administration after watching the video, the study data will reflect that outcome as a failure of the video to successfully teach technique.
2. *Describe procedures that will be followed when subjects withdraw or are withdrawn from the research, including the possibility of partial withdrawal from study intervention with continued data collection:* Patients will revert to usual care, which is, receiving depot medroxyprogesterone administered by the healthcare provider. Data collected before the point of withdraw will be retained.
3. *Describe any necessary safety precautions to be applied to subjects who withdraw or are withdrawn (tapering drug doses, evaluative x-ray, etc.):* or ☒N/A

D.4 Recruitment and Retention

D.4.1 Local Recruitment Methods

Describe the following attributes of the recruitment plan for the local Tufts site:

1. *When, where, and how potential subjects will be recruited:* subjects will be identified in the medical records and screened for eligibility, then receive a telephone call to offer participation prior to scheduled visit
    a. *If potential subjects will be **recruited by telephone**, describe how many times the research team will attempt to call / leave a voice message:* 2
        i. ☒*Check to confirm that a script for **both** the telephone conversation and the voice message is included with the submission.*
    b. *When subjects respond to recruitment material, describe the information that will be provided to them about the study and the information that will be collected from subjects (e.g. name, telephone number, etc.). Describe also, how many times you will attempt to respond to*

call the subject back / leave a voice message: Subjects will be offered participation in the study on the telephone. Two attempts to call will be made. If subject expresses interest, their pharmacy details will be collected and a prescription for the subcutaneous version of depot medroxyprogesterone will be sent to their pharmacy. Subject will be instructed to pick up the medication at the pharmacy and bring it to their previously scheduled appointment. Subjects will receive basic education from pharmacy as per SOP, so they will have some prior instruction on how to administer the shot on their own. Subjects will be told on the phone that the doctor will discuss the consent process in person once they are in the office and they are free to proceed or not proceed with the study at that time, but if they decline, the medication will be administered as per standard of care. No additional recruitment calls or materials will be provided or sent.

   i. ☒*Check to confirm that a script for **both** the telephone conversation and the voice message is included with the submission.*

2. *Source of subjects (for example, patient population, local community, etc.):* Subjects will be drawn from the existing patient population of healthcare providers on the research team
3. *Methods that will be used to identify potential subjects:* Review in advance the schedule of the health care providers on the research team to identify subjects who are known users of depot medroxyprogesterone
4. *If print and media advertisements will be used, specify when, where, how long and frequency of the advertisements that will be published/aired:* or ☒ N/A
   a. ☐*Check to confirm that any necessary permission will be obtained for posting/airing these (for example, permission to post a flyer on a bulletin board).*
5. *If recruitment material is being mailed or otherwise distributed, submit the proposed material and describe where/how the distribution list will be obtained:* or ☒ N/A
6. *Describe how the recruitment methods described will be effective in attracting the targeted subject population:* Patients will be asked if they want to participate, and the number of patients needed to complete this study is low compared to the high volume of patients already receiving this medication in an intramuscular form. As there is general interest noted online and by anecdotal discussion in being able to give oneself medication, it is expected that simply asking patients if they are interested would be sufficient to obtain the number of subjects targeted for the study.
7. Reminders:
   a. Refer to the Tufts Health Sciences IRB Policy on Direct Advertising Material for Recruitment for additional requirements when recruiting through social media.
   b. Submit a copy of each recruitment-related document to the IRB (including flyers, web ads, screening interview/questionnaires or screening scripts) for review & approval.
   c. For advertisements, submit the proposed final copy of the print advertisement. When advertisements are audiotaped or videotaped for broadcast, submit the proposed final audio/video. It is recommended that you submit a script of the proposed audio or video advertisement for IRB review before taping the final version in case revisions are needed. Once recommended changes are made, the final version is to be submitted to the IRB for review and approval.
   d. Postings to the Tufts Medical Center Clinical Trials website do not need to be submitted to the IRB for review and approval as long as information in these postings is restricted to the fields listed in the form.

D.4.2 Study-Wide Recruitment Methods

Is this is a multicenter study where subjects will be recruited by methods not under the control of the local Tufts site (e.g., call centers, national advertisements)?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

1. *Methods of recruitment not under the control of the local Tufts site:*
2. *When, where, and how potential subjects will be recruited:*
3. *Methods that will be used to identify potential subjects:*
4. *Materials that will be used to recruit subjects:*
5. Reminders:
    a. Refer to the Tufts Health Sciences IRB Policy on Direct Advertising Material for Recruitment for additional requirements when recruiting through social media.
    b. Submit a copy of each recruitment-related document to the IRB (including flyers, web ads, screening interview/questionnaires or screening scripts) for review & approval.
    c. For advertisements, submit the proposed final copy of the print advertisement. When advertisements are audiotaped or videotaped for broadcast, submit the proposed final audio/video. It is recommended that you submit a script of the proposed audio or video advertisement for IRB review before taping the final version in case revisions are needed. Once recommended changes are made, the final version is to be submitted to the IRB for review and approval.
    d. Postings to the Tufts Medical Center Clinical Trials website do not need to be submitted to the IRB for review and approval as long as information in these postings is restricted to the fields listed in the form.

D.4.3 Payment

Will subjects receive money, gifts, or any other incentive for participating in this study?

This does not include reimbursement for expenses, which is considered in the next section.

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following*:*

1. *Describe any proposed payment or incentive for subjects (e.g. money, gifts cards, water bottles, tote bags, pill boxes, etc.). Include a specific description of the incentive and its value both in US and local currency (if international). The payment/incentive value must not be so great that it could cause undue influence*[1]*:*
2. *Payment amount:*
3. *How payment will be made (e.g., cash, check, Greenphire ClinCard). Please note, if Greenphire ClinCard will not be used to pay subjects, you must use a payment log to track payments to subjects and you must retain financial records of payments to subjects, as payments are subject to audit:*
4. *To whom payment will be made (subject, parent [which one],legally authorized representative):*
5. *Payment schedule:*
    a. *When payment will occur*

The payment schedule (amount at each time point), including details about the payment schedule and amount for subjects who withdraw or are withdrawn from the study:

D.4.4 Reimbursement

Will subjects be reimbursed for their expenses, such as travel, parking, meals, or any other study related costs?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following*:*

1. *What qualifies for reimbursement and whether pre-approval is needed:*
2. *How subjects will be required to document expenses for reimbursement (e.g., provide receipts):*
3. *How and how often subjects may request reimbursement:*
4. *How reimbursement will be made (e.g., cash, check, Greenphire ClinCard). Please note, if Greenphire ClinCard will not be used to provide reimbursement, you must use a log to track reimbursements to subjects, as these reimbursements are subject to audit:*
5. *The reimbursement schedule (when will subjects be reimbursed):*

E. Costs to Subjects

Does the research involve any costs to subjects?

[1] **Undue influence**, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

☐ **Yes** ☒ **No**

If **Yes**, describe any costs that subjects might be responsible for due to participation in the research:

F. Study Design

F.1 Study Timelines

1. *Describe the duration of an individual subject's participation in the study:* Approximately 3 months (two separate clinic visits approximately 12 weeks apart)
2. *Describe the duration anticipated to enroll all study subjects at the Tufts study site:* Approximately 6-12 months
3. *Describe the estimated date for investigators to complete this study (complete primary analyses):* Approximately 12-18 months

F.2 Procedures

1. *Summarize the research design and sequentially identify all procedures to be performed to accomplish the specific aims of the project. Clearly identify and distinguish procedures that are considered experimental, procedures that are performed exclusively for research purposes (including "extra" routine tests), and procedures that would occur regardless of the research (i.e., standard of care). Point out any procedures, situations, or materials that may be hazardous, and the precautions to be exercised to maintain subject safety:* 1. Clinic schedules for the medical providers on the research team will be reviewed in advance and any patient that is under the age of 20 and receiving depot-medroxyprogesterone will be contacted by telephone in advance to offer participation in the project. 2. The telephone call will follow the attached script. Two attempts will be made to call patients. 3. If subject is interested in participating, a prescription for the subcutaneous version of depot-medroxyprogesterone will be sent to their pharmacy to be picked up by the subject prior to the office visit. 4. Subjects under 18 will be instructed that they must be accompanied by a parent or guardian. At the office visit, written consent/assent will be obtained. 5. Subject will be shown the instructional video, which is approximately 3 minutes long (video submitted in attached word document with a link, Consent on file for actor in video). They may view as many times as they want. 6. Once ready, the healthcare provider from the research team will observe, without giving verbal instruction, the patient give themselves a subcutaneous depot-medroxyprogesterone injection. 7. If at any point the provider feels that the subject is not performing the injection safely or correctly the healthcare provider will intervene to ensure that the medication is given correctly, and this will be recorded within the REDCap survey. 8. After the injection is given, the subject will fill out the REDCap survey and study team member administering injection will input observational data into REDCap. 9. Subject will be asked to repeat another questionnaire in REDCap at the time of the next injection which will be scheduled for 12 weeks later. The next visit is as per standard of care scheduling (this medication is routinely administered at approximately 12 week intervals). If the subject comes into the same office for the injection, the survey will be filled out in person. If the subject does not come in to the same office, a link to the follow up REDCap survey will be emailed to the subject with instructions on how to access the survey. Email addresses will be confirmed at the time of the first visit, as is routine for medical care.

   Please also describe the following concerning procedures:

   a. *How individuals will be screened for eligibility. Specify screening that will take place prior to informed consent and screening that will take place after informed consent:* Initial screening will be via review of medical charts in advance of appointments, followed by asking

subjects about inclusion and exclusion criteria verbally prior to enrollment and consent process.

b. *Procedures being performed to monitor subjects for safety or to minimize risks:* All injections will be self administered in the presence of the healthcare provider on the research team. If the provider feels that the subject is not following safe or proper technique, in their clinical opinion, the subject will be stopped and the injection will be administered by the trained healthcare provider.

c. *All drugs and devices used in the research, their regulatory approval status, and the purpose of their use:* Depot-medroxyprogesterone will be the medication given, but only in the setting of patients who have already been counselled and agreed to treatment with this medication, which is FDA approved for contraception in this patient population. The medication is not being given for the purposes of this research, but rather for standard of care. Only the method of administration is being changed for this study.

d. *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.):* Will attach telephone scripts that will be used to talk to patients. Chart reviews to determine eligibility. A REDcap survey will be built (attached in a word document)

2. Is there a placebo control arm?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

d. *Describe the scientific, methodological, and medical reasons to use a placebo:*

e. *Describe the care that will be given to subjects who receive placebo. If this is local standard of care, specify that:*

f. *Describe all potential risks to the placebo group and how the risks will be minimized.*

3. *Describe the following concerning pregnancy testing and birth control:*

a. *What type of pregnancy testing and how frequently will be conducted on women of reproductive potential. If testing will not be conducted provide the reason:* Depot medroxyprogesterone is a form of contraception and has been used in both subcutaneous and intramuscular form effectively and safely. Subjects will only be tested for pregnancy for routine care reasons that are not related to the study.

b. *What birth control methods **women** of reproductive potential will be instructed to use. If women will not be instructed about acceptable methods of birth control, clarify why:* Depot medroxyprogesterone is a form of contraception. Subjects will receive the same counselling regarding contraception as all non study participants seen in the research team's medical practices.

c. *What birth control methods **men** of reproductive potential will be instructed to use. If men will not be instructed about acceptable methods of birth control, clarify why:* n/a - people who are not menstruating will not be enrolled in this study

4. *Describe the data that will be collected during the study and how the data will be obtained:* Survey data will be entered directly into REDCap links by study participants and the healthcare provider on the research team. For the purpose of administering secondary surveys of patients that do not come into the same clinic for the second visit, the key will be consulted for patient names, and these charts will be accessed to obtain email addresses for contact purposes. Email addresses will not be otherwise recorded or collected.

a. If there are plans for long-term follow-up (once all research related procedures are complete), describe the data will be collected during this period: or ☒ N/A

5. *Specify which procedures, tests, visits, etc. described above are part of usual standard of care at Tufts and which are performed solely for research purposes:* Administration of the medication is part of standard of care, the survey and self-administration (if done) is for research.

6. *Specify which tests are routinely performed for clinical care, but are providing data for the research, and which tests are only performed for research purposes:* n/a
7. *For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.* or ☒ N/A

F.3 Evaluations

Will you perform any laboratory tests for this study?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

1. *List all laboratory tests to be done as part of the study (e.g., hematology, clinical chemistry, urinalysis, pregnancy testing)as follows:*
   a. Differentiate screening laboratory test(s) from those taken after enrollment.
   b. Include specific test components and estimated volume and type of specimens needed for each test.
   c. List special assays or procedures required to determine study eligibility or assess the effect of the intervention (e.g., immunology assays, pharmacokinetic studies, images, flow cytometry assays, microarray, DNA sequencing). For research laboratory assays, include specific assays, estimated volume and type of specimen needed for each test. For procedures, provide special instructions or precautions.
2. *Describe laboratory methods to provide for appropriate longitudinal and cross-sectional comparison (e.g., use of consistent laboratory method throughout study, use of single, central laboratory for multi-site studies):*
3. *If more than one laboratory will be used to perform study tests, specify which evaluations will be done by each laboratory:*
4. ☐*Check to confirm that laboratory tests that will be performed are in compliance with Clinical Laboratory Improvement Amendments (CLIA) of 1988. If not, explain why:*
5. *If samples will be stored for the purpose of this study, describe the preparation, handling, and storage of specimens, including specific time requirements for processing, required temperatures, aliquots of specimens, where they will be stored, how they will be labeled, and what will happen to the samples after the study is over (e.g. will be destroyed):* or ☐ N/A

F.4 Collection and Storage of Human Biological Specimens (Tissue Banking)

Will biological specimens be stored for **future, unspecified**, research?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

1. *Where specimens will be stored, how long they will be stored, how specimens will be accessed, and who will have access to the specimens:*
2. *List the Protected Health Information (PHI) to be stored or associated with each specimen. If PHI will be gathered in the future and associated with the specimen, describe the frequency of gathering such PHI:*
   or ☐ N/A, PHI will not be stored or associated with each specimen.
3. *Procedures to release specimens, including: the process to request a release, approvals required for release, who can obtain specimens, and the PHI to be provided with specimens:*
4. *Risks to subjects and their families associated with this collection and storage for future research use:*
5. *Risks to groups or populations associated with this collection and storage for future research use:*
6. *The mechanism by which the research subject can withdraw permission to use the stored specimens and associated PHI for future research. Indicate what will happen to the specimens and related research data if permission is withdrawn:*

Refer to the IRB's Policy for Research Involving Collection and Storage of Human Biological Specimens for Future Research to ensure that all relevant information is included in the protocol.

G. Ethics and Protection of Human Subjects

G.1 Informed Consent Process

Will subjects be required to provide informed consent?

☒ **Yes** ☐ **No**

If **Yes**, respond to all of the following:

1. *Where the consent process will take place (e.g. a private clinic room):* Privately, in the medical clinic prior to watching the instructional video.
2. *Anticipated amount of time a potential subject will have to make a decision about participation in the study:* Subjects will be aware of the study approximately 1-2 days prior to their scheduled appointment. They will be given the consent / assent forms in person once they arrive in the office. They will be given as much time as they prefer to ask questions and make a decision prior to their appointment so as not to disrupt the flow of the clinic.
3. *Processes to ensure ongoing consent throughout the study:* Research team members will ensure consent forms are signed just prior to watching the video.
4. *Role of each research team member involved in the informed consent process (Please note, in general, for studies designated by the IRB as greater than minimal risk, a physician PI or Co-I must perform the informed consent process with subjects. A study coordinator/clinical research associate may not consent subjects. A study coordinator/clinical research associate may assist with this process; however, the PI or Co-I should be present to discuss the study with the subject and answer questions, and the PI or Co-I should sign the ICF documenting that s/he has performed the informed consent process with the subject and the subject understands the study.):* Consents will be signed with the PI/Co-Is on the research team only.
5. ☒ *Check to confirm you will follow "SOP: Informed Consent Process for Research (HRP-090)". If **not**, answer all of the following:*
    a. *Steps that will be taken to minimize the possibility of coercion or undue influence:*
    b. *Steps that will be taken to ensure subjects' understanding:*
    c. *Describe in detail any other changes that differ from the SOP:*
6. ☐ *Check to confirm that Non-English speakers will be enrolled using interpreters and IRB approved Short Forms per the IRB's Short Form policy. If IRB approved Short Forms will not be used, describe which languages the consent will be fully translated into, who will conduct the consent interview, use of interpreters, use of IRB approved translated documents, etc.:*
7. *If non-English speakers are not eligible (excluded from enrollment) for this study, provide the ethical and scientific justification, including whether this would be equitable. For example, if non-English speakers are eligible for the study and could potentially benefit from participation, it would not be equitable to exclude them:* Our video at this time is in spoken English with English subtitles only. Providing different languages for the video prior to validation as a teaching tool is not practical. If the video is validated in English, newer versions in different languages may be considered with the assistance of medical interpreters to ensure the verbiage is appropriate.

    Refer to the IRB Short Form Policy on the IRB website for information about enrolling non-English speakers including how to reach medical interpreters.
8. ☒*Check to confirm you will follow "SOP: Written Documentation of Consent (HRP-091)". If **not**, describe how consent will be documented in writing:*
9. ☐*Check to confirm you will follow "SOP: Remote Consent Process (HRP-092)" if there is ever a situation where consent will **not** be obtained in person. If you will follow a different process if there is ever a situation where consent will **not** be obtained in person, describe:* or ☒ N/A.

G.2 Waiver or Alteration of Consent Process

This applies for studies where informed consent will not be obtained, required information will not be disclosed, or the research involves deception.

1. Is a waiver or alteration of the consent process being requested for this study?
   ☒ **Yes** ☐ **No**

If **Yes**, respond to all of the following:

a. *Provide the rationale for the waiver:* Patient charts will be reviewed to determine eligibility for the study, but this screening step will not alter medical care. It is necessary to determine eligibility in order to contact appropriate candidates for the study, and to ensure that the subcutaneous form of depot medroxyprogesterone is prescribed so that when patient arrives in the office, the choice to participate in the study is available. If charts cannot be prescreened, it cannot be guaranteed that the appropriate medication will be available and this will limit the enrollment process. Having a preliminary consent for the screening process is unduly onerous to potential study subjects as there is no alteration in clinical care regardless of which form of depot medroxyprogesterone they bring to the office. Patients receiving depot medroxyprogesterone administered by the doctor are already being called routinely in advance of their appointments to confirm pharmacy information and to confirm they will be bringing the correct medication to the appointment.

b. *How the waiver or consent alteration will **NOT** adversely affect the rights and welfare of subjects: Determination of eligibility criteria only by pre-screening charts will not alter medical care in any way. Having the subcutaneous form of depot medroxyprogesterone does not commit the subjects to participation in the study.* The subcutaneous and intramuscular forms of the medication can be given interchangeably by the doctor.

c. *How the research could **NOT** practicably be carried out without the waiver or alteration:* It is not practical to consent for chart review to determine eligibility as patients are at home and the phone call prior to an appointment to confirm pharmacy information is already routinely performed.

d. *How, subjects will be provided with additional pertinent information after participation. If subjects will not be provided this information after participation, explain why:* Complete consent for the actual study will be reviewed while the potential subjects are physically in the office space and at that time all questions will be reviewed. Any additional information will be provided at this time, prior to signing of the consent and assent forms

2. Is a waiver of the consent process being requested for parents for research involving children?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *The rationale for this waiver:*
b. *How the research could **NOT** practicably be carried out without the waiver or alteration:*
c. *How this waiver is an appropriate substitute to parental consent for protecting the children who will participate as subjects in the research:*
d. ☐ *Check to confirm that the waiver is consistent with Federal, State, and local laws.*

3. Is a waiver of the consent process for planned emergency research being requested?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *How the subjects are in a life-threatening situation:*
b. *How available treatments are unproven or unsatisfactory*:
c. *How the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions:*
d. *Clarify how the appropriate animal and other preclinical studies that have been conducted, and the information derived from those studies and related evidence that supports the potential for the study drug, device, or procedure to provide a direct benefit to the individual subject:*
e. *How the research could not practicably be carried out without the waiver:*
f. *How obtaining informed consent is not feasible because:*

i. *Subjects will not be able to give their informed consent as a result of their medical condition (describe why):*
ii. *The study drug, device, or procedure must be administered before consent from the subjects' legally authorized representatives can be obtained (describe why):*
iii. *There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research (describe why):*

g. *The length of the potential therapeutic window based on scientific evidence:*
h. ☐*Check to confirm that the research team will attempt to contact a legally authorized representative for each subject within that window of time and, if feasible, ask for consent within that window rather than proceeding without consent. Note that at continuing review, you will need to report to the IRB the efforts made to contact legally authorized representatives or subject's family member if a legally authorized representative is not available.*
i. ☐*Check to confirm that if the subject dies before a legally authorized representative or family member can be contacted, information about the research will be provided to the subject's legally authorized representative or family member, if feasible.*
j. ☐*Check to confirm that if a legally authorized representative or family member is told about the research and the subject's condition improves, the subject will also to be informed as soon as feasible.*
k. *The consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn:*
l. *The public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of the plans for the investigation and its risks and expected benefits:*
m. *The public disclosure following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results:*

n. *The procedures to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the investigation and other information contained in the ICF, and that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled:*

G.3 International Research

Refer to the IRB's International Research Checklist and International Research Guidance and include all relevant information described in those documents in this protocol: N/A

G.4 Confidentiality

Data and specimens should be stored in a secure location only accessible by the research team. The PI must ensure that study documents are stored in a manner that protects the privacy of subjects and the confidentiality of study data.

1. *State where the study records, both electronic and/or paper documents including signed ICFs/assent forms, will be retained during the study (state the location for original document plus any copies that are made, e.g., if a copy of the ICF will be retained in the subject's medical record):* A key containing the link between coded REDcap responses and patient names will be kept separately in a password protected HIPAA compliant Box account set up through Tufts Medical Center. The REDCap does not collect any identifiers and each subject will have a unique sequential code attached to their survey. This will only be accessed by the study team and will be destroyed at the completion of the study. The Key and any downloaded REDCap coded data will have two different passwords. Paper consent forms will be stored in a folder in a locked cabinet in a locked office that will only be accessible by Dr. Fee and Dr. French (PI).

2. *State where study records will be retained when the study has been closed (long-term storage):* The paper consent forms will be stored in the locked cabinet in the locked office following Tufts data retention policies. Identifiable data that is entered into the HIPAA compliant Box account will not be stored long term and will not be accessed by anyone other than the research team. Data will be destroyed at the culmination of the study.
3. *State who, in addition to the research team, will have access to the study files, data, and/or specimens:* Only Dr. French and Dr. Fee will have access to the consent forms. Study files in Box will be accessed only by the research study team for the duration of the study. Nobody other than the research team will have access to this data.
4. *Will data (or specimens) be sent outside of Tufts Medical Center or Tufts University **and/or sent between Tufts Medical Center and Tufts University**?*
   ☐ **Yes** ☒ **No**
   If **Yes**, respond to all of the following:
   a. *Describe the nature of the data/specimens to be transferred:*
   b. *State to whom or what entity the data/specimens will be transferred:*
   c. *Confirm that you have consulted with Tufts MC Research Administration or Tufts University Technology Transfer to determine whether an agreement is needed to permit the transfer of data/specimens, and one of the following is true:*
      i. ☐ *An agreement (e.g. contract, Clinical Trial Agreement, Collaboration Agreement, Data Use Agreement (DUA), or Material Transfer Agreement (MTA)) has been or will be established that will cover any transfer of data/specimens, and the agreement will be executed **prior** to any transfer.*
      ii. ☐ ***Research Administration or Technology Transfer has determined** that an agreement is not needed for this research. (Research Administration/OVPR should make this determination, not the Investigator.)*
      iii. ☐ *A determination from Research Administration/Technology Transfer is still pending. (The study cannot be approved by the IRB until Research Administration/Technology Transfer makes a determination, but it can be approved prior to the execution of an agreement.)*
5. *Explain how data and/or specimens will be transported (e.g. fax, mail, delivery, email, etc.):* REDCap data will be de-identified and kept within the REDCap tool. Box data will be kept electronically and in separate password protected files accessible only by study team members through online access. Paper consent forms will be transported by study team members to the locked cabinet detailed above. No data will leave Tufts Medical Center.
6. *Explain how data and/or specimens will be coded. Specify if there is a key to the code that matches the subjects' study identification number with their name and who, in addition to the research team, will have access to it:* The key with patient names will have a number assigned to each name that corresponds to the number in the REDCap survey. This key will be kept in a password protected Box account set up through Tufts Medical Center and nobody aside from the research team will have access.
7. *Explain whether confidential genetic information will be collected from subjects:* or ☒ N/A
8. *Explain whether audio/videotapes and/or photographs of subjects could potentially identify the study subject. If so, indicate who will have access to (be able to view) these item, in addition to the research team, and how long the videotapes or photographs will be retained for the study and what the plan is for their destruction:* or ☒ N/A
9. ☒*Check to confirm that study records will be retained for the timeframe described in the record retention policy of the "SOP – Records Retention Timeframe – Investigators". If they will not, describe the record retention plan for this study:*
10. ☒*Check to confirm that you will follow the "Confidentiality and Data Security Guidelines for Electronic Research Data" for electronic data. If not, describe how your plan differs from these guidelines:*
11. *A Certificate of Confidentiality will be issued (for NIH studies) or obtained:* ☐Yes ☒N/A

CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. NIH funded researchers are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research, i.e., research involving collection of information that, if disclosed, could have adverse consequences for subjects or damage financial standing, employability, insurability, or reputation. For more information, refer to refer to the NIH website.

G.5 Screening Data Collection Form/Screening Log

This section specifically refers to data collected about potential subjects who are screened, but have not signed consent, for example potential subjects whose medical record is reviewed to see if they are potentially eligible, potential subjects who respond to a telephone screening call where the research team records information about the potential subject, etc. In this section "Screening Data / Screening Log" refers to any form of data collection on potential subjects who have not yet signed consent. For more information, refer to https://privacyruleandresearch.nih.gov/clin_research.asp.

Will a screening data/screening log be used in this research study?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

1. ☐ *Check to confirm you have submitted the Screening Data Collection Form / Screening Log to the IRB.*
2. *Review the following and provide information about the Screening Data / Screening Log and how it will be used (**check all that apply**):*
   a. ☐ *De-identified Screening Log will be provided to and/or viewed by the Study Sponsor (the log does not record any HIPAA identifiers or contain protected health information (PHI)).*
      i. *Explain how the Screening Log will be "distributed to" or viewed by the study Sponsor, i.e., how the Screening Log be e-mailed, sent to and /or viewed by the study Sponsor:*
   b. ☐ *Identifiable Screening Log that will **not** be distributed or viewed outside of the institution (although the Screening Log will record HIPAA identifiers, the Screening Log will **not** leave the institution.)*
      i. *Specify the identifiers that will be collected (e.g. date of admission or clinic visit, medical record #, and reason the person was not eligible for the study):*
   c. ☐ *Identifiable Screening Log that will be distributed or viewed outside of the institution. Consider whether these identifiers could be removed from the Screening Log. It might be possible to eliminate HIPAA identifiers or use a screened subject identifier code and maintain a separate key to the code so no PHI will leave the institution.*
      If it is necessary to include HIPAA identifiers in the screening log, address the following:
      i. *The rationale for including HIPAA identifiers in the Screening Log:*
      ii. *A plan for protecting the privacy and confidentiality of screened subjects. Screened subjects might or might not be enrolled in the research study, and since screened subjects will not have consented to the use of their PHI for research purposes, it is especially important to protect their privacy and confidentiality. The plan should include keeping identifiers to a minimum, and keeping the Screening Log in a secure location (password protected computer location only accessible by the research team or a locked file cabinet in a locked office, only accessible by the research team):*

Note: A Screening Data Collection Form / Screening Log that contains identifiers and/or PHI must NOT be sent to the study Sponsor UNLESS the IRB has granted a waiver of consent/authorization for this component of the study (or unless the investigator has obtained IRB approved consent and research authorization from each study subject whose name is on the log.)

G.6 Provisions to Protect the Privacy Interests of Subjects

In this section, "privacy" refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interests, people want to control:

- The time and place where they give information
- The nature of the information they give
- The nature of the experiences that are given to them

- Who receives and can use the information

Persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building. What is private depends on the individual and can vary according to gender, ethnicity, age, socioeconomic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual's relationship to the researcher. Protecting the privacy interests of a young child might mean having a parent present at a session with a researcher. Protecting the privacy interests of a teenager might mean having a parent absent.

1. *Describe the steps that will be taken to protect subjects' privacy interests (e.g. ensuring that discussion of the study will take place in a private area where subjects cannot be overheard):* The consent for the study will be done in a private clinic room where medical care is provided. Watching the video and completing the questionnaire will also be done in a private clinic room. Subject and guardian/parent will have the room to themselves while answering REDCap. The study doctor will be present during drug administration.
2. *Describe the steps that will be taken to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might or might not experience in response to questions, examinations, and procedures (e.g. ensuring that subjects are comfortable with the research team members performing the study procedures):* Patients will be given a choice between participating in the study to perform self injection, or to get the injection from the healthcare provider which is their usual care. The choice to participate or to receive usual care will be entirely up to the patients, as the medication is the same and the health care plan overall does not change depending on who gives the injection (patient or healthcare provider).

G.7 Provisions to Monitor the Study to Ensure the Safety of Subjects

1. *Describe the plan to periodically evaluate the data regarding both harms and benefits to assess subject safety as follows:*
   a. *The data that will be reviewed, including safety data, untoward events, and efficacy data:* As there is no new medication being given, untoward side effects or issues regarding safety with this medication during the study are not anticipated. Self administered subcutaneous injections are also widely accepted as safe practice. If unexpected issues arise, the PI will assess. Data will be collected on failed attempts at self injection as part of the REDCap survey. Failed self administered attempts at injection will be followed immediately by provider injection so as to ensure that the patients get the medication appropriately.
   b. *Who will review the data:* Dr. Bojko, Fee and French.
   c. *How the safety information will be obtained and documented (e.g., case report forms, by telephone calls with participants, printouts of laboratory results, etc.):* telephone or in person discussion with patients
   d. *The frequency of data collection, including when safety data collection starts:* Data collection will be ongoing
   e. *The frequency or periodicity of review of cumulative data:* Data collection will be reviewed every 3 months
   f. *The statistical tests for analyzing the safety data to determine whether harm is occurring:* There is no anticipated harm from this study (see a above). If an adverse event is reported the study PI will do a root-cause analysis to assess the nature of the event and why it happened. Any event will be reviewed so there is no need for statistical testing.
   g. *Any conditions that trigger an immediate suspension of the research or other action for the research:* none

   The plan might include establishing a data monitoring committee which addresses all the above.
2. *Describe the entity responsible for monitoring the data, and their respective roles (e.g., the investigators, the research sponsor, a coordinating or statistical center, an independent medical monitor, a Data and*

Safety Monitoring Board (DSMB) /Data Monitoring Committee (DMC), and/or some other entity, and the timeframe for reporting events to this entity: The PI and study team

3. *A copy of the DSMB/DMC Charter if the study is enclosed with the submission:* ☐Yes ☒N/A

G.8 Vulnerable Populations

If the research involves individuals who are vulnerable to coercion or undue influence, describe the rationale for their inclusion and the additional safeguards included to protect their rights and welfare.

1. Can or will pregnant women be enrolled?

   ☐ **Yes** ☒ **No**

   If **Yes**, respond to all of the following:

   a. *Describe any preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, that have been conducted that provide data for assessing potential risks to pregnant women and fetuses:*
   b. *Are there any risk to the fetus from the study interventions or procedures. If yes, describe:* or ☐No*, there are no risks to the fetus from the study interventions or procedures*
   c. *Do the study interventions or procedures hold out the prospect of direct benefit for the woman or the fetus. If yes, describe:* or ☐No*, the study interventions or procedures do not hold out the prospect of direct benefit for the woman or the fetus.*
   d. *If there is no prospect of benefit to the fetus, clarify whether the risk to the fetus is NOT greater than Minimal Risk, and whether the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means: or* ☐ N/A
   e. *The biomedical knowledge that is expected to result from this research for this population:*
   f. *How any risk of this research is the least possible for achieving the objectives of the research:*
   g. *How mothers providing consent are informed of the reasonably foreseeable impact of the research on the fetus or neonate:*
   h. ☐*Check to confirm that no inducements, monetary or otherwise, will be offered to terminate a pregnancy and that in the case of a fetus, the fetus is not the subject of a planned abortion.*
   i. ☐*Check to confirm that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy or in determining the viability of a neonate.*

2. Can or will the research involve neonates of uncertain viability or non-viable neonates?

   ☐ **Yes** ☒ **No**

   If **Yes**, respond to all of the following:

   a. *Any preclinical and clinical studies that have been conducted that provide data for assessing potential risks to neonates:*
   b. *The important biomedical knowledge that will be developed from this research and why it cannot be obtained by other means:*
   c. *Whether there will be added risk to the neonate resulting from the research:*
   d. *How individuals providing consent are informed of the reasonably foreseeable impact of the research on the neonate:*
   e. *No person shall perform or offer to perform an abortion where part or all of the consideration for said performance is that the fetal remains may be used for experimentation or other kind of research or study:* ☐Yes ☐ N/A
   f. *No person shall knowingly sell, transfer, distribute or give away any fetus or neonate for a use which is in violation of Massachusetts General Laws Chapter 112 Section 12J:* ☐Yes ☐ N/A
   g. *Individuals engaged in the research will have no part in determining the viability of a neonate:* ☐Yes ☐ N/A
   h. *For non-viable neonates, the vital functions of the neonate will not be artificially maintained and that the research will not terminate the heartbeat or respiration of the neonate:* ☐Yes ☐ N/A

i. *For neonates of uncertain viability, the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective:* ☐Yes ☐ N/A

3. Can or will subjects who are not yet adults (neonates, children, teenagers) be enrolled?
   ☒ **Yes** ☐ **No**
   If **Yes**, respond to all of the following:
   a. ☒*Check to confirm that you will follow "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to determine whether a prospective subject has or has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (e.g., individuals under the age of 18 years). If this SOP will not be followed, describe how this (attainment of legal age for consent or not) will be determined:*
   b. *How permission to participate in the study will be obtained from the parents or legal guardians:* Written consent forms will be signed in person by parent/guardian as well as assent forms will be reviewed and signed in person by the subject.
   c. *The assent process of children as follows:*
      i. *Any waiting period available between informing the prospective subject and obtaining the assent:* no
      ii. *Any process to ensure ongoing assent:* Subjects may opt out of the study anytime. Assent will be confirmed before both the first and second visit.
      iii. *Research team members involved in the assent process:* PI/Co-Is
      iv. *How long children will have to consider study participation:* They will be notified several days prior to their appointment and will be able to ask questions and consider participation on the day of the appointment prior to signing assent. They can opt out anytime during the study.
      v. *Steps that will be taken to minimize the possibility of coercion or undue influence:* Patient will have the choice to opt out at any time.
      vi. *Steps that will be taken to ensure the subjects' understanding:* Assent forms will be given and healthcare provider will explain verbally, with ample opportunity for subjects to ask questions.
      vii. *If assent will not be obtained from children, specify why:* n/a
      viii. *If children reach 18 years of age while in the study describe the following:*
         1) *The plan to obtain written informed consent from the subject at age 18 years:* There is a consent form for those 18 and over – subjects will be re-consented if they turn 18 between their two appointments.
         2) *Who will be responsible for managing the plan:* Healthcare providers on the research team.
         3) *Where the consent discussion will take place:* In the clinical office space at the time of their medical appointments.
         4) *What will happen if the subject cannot be located to provide consent at age 18 years:* n/a

4. Can or will minors who are:
   i) married, widowed, divorced; or
   ii) the parent of a child; or
   iii) a member of any of the armed forces; or
   iv) pregnant or believes herself to be pregnant; or
   v) living separate and apart from his/her parent or legal guardian, and is managing his/her own financial affairs

   be approached for study participation for either themselves or their child?
   ☒ **Yes** ☐ **No**
   If **Yes**, respond to all of the following:

a. *How will it be determined that this population has the capacity to consent for this study. Please note that the circumstance of parenthood, pregnancy, etc. may not mean that the person has the same capacity of an adult who can understand the risks, benefits, and alternatives for indicated care. Thus, sound and sensitive clinical judgment that is attentive to both the minor's rights* and *the minor's actual competence and needs must be considered, and is to include a determination as to whether involvement of family or other adults familiar to the minor is necessary and appropriate:* The subjects will only be approached if they are already receiving this medication and have already consented to using it. The only intervention in this study will be the patient's choice about self administration of the medication which will be explained verbally and with written consent forms with the opportunity to ask questions and opt out any time. Study doctor is observing application of shot, so subject will be stopped from self-administering if doctor feels subject cannot administer safely.

b. *How informed consent will be executed with this population in a way that allows for independent and thoughtful decision-making:* Consent will be approached in the same way as for all subjects. If parent or guardian signature is required due to age of patient, and is not available, then the patient may not participate in the study.

c. *Any additional steps or procedures that will be used when performing informed consent with this population:* no

Refer to Massachusetts state law (MGL Chapter 112, Section 12F) for more information about this population. Please note, the statute applies to clinical care and should be applied to research only as applicable.

5. Can or will wards of the state and/or children at risk of becoming wards of the state be enrolled (this includes foster children or any child that is in state custody)?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *Justification for recruiting and enrolling this population:*
b. *Any additional details about the recruitment methods to be used. If the same recruitment methods previously described in the protocol will be used, then state that:*
c. *Any additional details about the informed consent process to be used. If the same informed consent process for enrolling minors previously described in the protocol will be used, then state that:*
d. *How it will be ensured that the appropriate person(s) grants permission for each ward to participate in the research:*
e. *How the research team will know if there has been a change in guardianship status during the course of the research and how permission will be obtained from the new guardian:*
f. ☐*Check to confirm that documentation of review by the Department of Children and Families (DCF) for this study has been submitted to the IRB.*
g. *If the study is greater than minimal risk, describe the following* or ☒ N/A, study is not greater than minimal risk:
    i. *Whether the research is related to their status as wards OR if the research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards:*
    ii. *How an advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis:*
    iii. *The background and experience of the advocate to act in the best interests of the child for the duration of the child's participation in the research:*
    iv. ☐ *Check to confirm that the advocate will not be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.*

Refer to the IRB's Wards of the State policy for additional information on enrolling wards of the state.

6. Can or will cognitively impaired adults (adults with impaired-decision making capacity) or adults who may lose the capacity to consent be enrolled?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *Whether the research holds out a prospect of direct benefit to the individual subject that is unavailable outside the research context:*
b. *Why the objectives of the study cannot be met by enrolling subjects who are able to give consent:*

c. ☐*Check to confirm that this study is NOT prohibited by law.*
d. *The process to determine whether or not the individual is capable of consent:*
e. *Who will determine if the subject is able to provide informed consent:*
f. *How it will be determined whether the subject is able to provide informed consent:*
g. *When and how often (even after obtaining informed consent) it will be determined whether the subject is able to provide informed consent:*
h. *List the individuals from whom permission will be obtained if the subject cannot provide informed consent. Prioritize the list (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.):*
    i. ☐*Check to confirm that for research conducted in MA, you have reviewed "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" and are aware of which individuals in MA meet the definition of "legally authorized representative."*
    ii. *For research conducted outside of MA, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol regarding the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)":*
i. *If it is possible that subjects may regain capacity to provide informed consent during the study, describe how frequently this will be assessed and state that subjects will be consented to the study in the event that they regain capacity to provide informed consent:* or ☐ N/A
j. *Describe the process for assent of the subjects as follows:*
    i. *Whether assent will be required of all, some, or none of the subjects. If some, specify which subjects will be required to assent and which will not:*
    ii. *If assent will not be obtained from some or all subjects, an explanation of why not:*
    iii. *Whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents:*
k. *Provide a description of how the patient will be informed of the potential risks and benefits of the study and any procedures associated with its use:*
l. ☐*Check to confirm that subjects will be withdrawn if they appear to be unduly distressed at any time during the study.*

7. Can or will prisoners be enrolled?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *Any possible advantages accruing to the Prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired:*
b. *Whether the risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers:*
c. *Procedures for the selection of subjects within the prison which are fair to all Prisoners and immune from arbitrary intervention by prison authorities or Prisoners. Unless the Principal Investigator provides to the Board justification in writing for following some other procedures, control subjects*

must be selected randomly from the group of available Prisoners who meet the characteristics needed for that particular research project:

d. ☐*Check to confirm that parole boards will not take into account a Prisoner's participation in the research in making decisions regarding parole, and each Prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.*
e. ☐*Check to confirm that a letter of support from the Prison this research will be conducted in has been submitted to the IRB.*
f. *If follow-up examination or care of subjects after the end of their participation is required, describe the provision for such examination or care, taking into account the varying lengths of individual Prisoners' sentences, and for informing subjects of this fact:*

8. Can or will students and/or employees be **targeted** for enrollment in this research?
   ☐ **Yes** ☒ **No**
   If **Yes**, respond to all of the following:
   a. *Justification for specifically targeting recruitment efforts to enroll students and/or employees:*
   b. *How potential coercion will be eliminated:*
   c. *Recruitment methods to be applied specifically to students and/or employees. If the same recruitment methods previously described in the protocol will be used, then state that:*
   d. *Additional safeguards included to protect the rights and welfare of students and employees:*
   e. *Protections to ensure that a subject's decision about participation and/or early withdrawal from the study will not affect his/her status as a student or employee:*
   f. ☐*Check to confirm that you have submitted a letter from the appropriate institutional official (e.g., Department Chair, Dean, Vice-President) who oversees the students and/or employees attesting to the fact that the employee's or student's participation in the research is acceptable and that coercion has been minimized.*

9. Transgender Subjects: Are you recording sex or gender for your study?
   ☐ **Yes** ☒ **No**
   a. Is there a scientific and/or safety rationale for collecting information on whether a subject is transgender? ☐ Yes ☐ No
      If **Yes**, respond to all of the following:
      i. *Provide the scientific/safety rationale for collecting information on whether a subject is transgender*:
      ii. Are transgender individuals eligible for participation in this study? ☐ Yes ☐ No
      If **No**, *Provide the scientific or safety rationale for excluding transgender or gender nonconforming individuals*:
      Note: Transgender subjects may not be excluded unless there is a scientific or subject safety rationale for doing so.
      iii. ☐ *Check to confirm that relevant questions for transgender and gender nonconforming individuals have been incorporated into relevant study documents (i.e. protocol eligibility, screening forms, demographic questionnaires, surveys), per the website guidance.*

   If **no**, there is no scientific or safety-related rationale for needing to identify sex or gender for your study, and you will not collect information on transgender and gender nonconforming people's identification.

H. Adverse Event Monitoring

H.1 Definitions

Define adverse events (AEs), serious adverse events (SAEs), and unanticipated problems for your study: No serious adverse events are anticipated. The only intervention in the study is to self administer an injection versus receiving the same injection from a healthcare provider. There is a risk that the subject may not properly give themselves the injection, but this is a minor risk that may also occur when a healthcare provider gives injections and is easily remedied by having the healthcare provider give an additional injection. If an additional injection is given, the risk of side effects from the medication is minimal, and the therapeutic

benefit is the same as if a single injection is given. This practice of repeating an injection on the same day at the same clinic appointment if there is concern for incomplete administration of medication for depot medroxyprogesterone is common and accepted practice when this medication is administered by healthcare providers. Risks of administering an injection include bleeding, bruising, unintentional injury, broken needle, infection. All of these are minor risks that will be attended to with routine medical care.

H.2 Reporting Procedures

1. *Describe the protocol-specific reporting procedures, including who will be responsible for each step (e.g., PI, Data Coordinating Center, Medical Monitor), which forms should be completed, timeframes for reporting, how reports will be distributed, and what follow-up is required:* If medication is not correctly self administered this data will be entered into the REDcap survey by the healthcare provider and is part of the data being collected. In addition, this will be documented in the patient's medical record as part of routine medical care.
2. *Include specific details of reporting procedures for:*
   a. *Deaths, life-threatening events, pregnancies:* not anticipated
   b. *Other SAEs:*
   c. *Other AEs:*
   d. *Other UPs:*

Ensure that the reporting procedures meet the reporting requirements of the FDA, NIH, OHRP, sponsor, study leadership and any other regulatory body that applies to the study, as applicable.

H.3 Reportable New Information

☒*Check to confirm that reportable new information will be reported to the IRB per the Tufts Health Sciences IRB's Reportable New Information policy. If your reporting plan to the IRB differs from the IRB's policies, please describe it in detail or specify where this information is in the protocol:*

I. Statistical Considerations

I.1 Study Endpoints

1. *Describe the primary and secondary study endpoints:* The primary outcome for this study is successful or not successful (i.e.,1/0) self administration of depot-medroxyprogesterone by study participants. A secondary outcome is understanding whether or not study participants will continue to use self administered injections in the future. In addition to these quantifiable outcomes, the study will also collect feasibility information, such as ease of identifying eligible study participants, potential participants willingness to consent, or participants willingness to pick up the prescribed medication prior to an in-person appointment.
2. *Describe any primary or secondary safety endpoints:*

I.2 Sample Size Justification Statistical Analyses

1. *Describe the statistical analyses that will be performed for this study:* This is a pilot study, designed to understand the feasiblity of larger scale studies, including those with a comparisong group, in the future. Key questions include the statistical properties of the dependent variables, including response rates for survey items and the injection success rate. The analysis will be descriptive, looking at the completeness of the survey data, correlation among survey items, and the injection success rate (to help inform future power analysis, among other things). We will also assess concordance between the observing physician and the patient on the success of the injection using a kappa statistic. Finally, we will compare injection success based a patient's assesement of willingness to continue using self injection in the future. After the initial survey, a

second survey will be given to participants approximately 12 weeks later, to see if participants self inject a second time.

2. *Provide a sample size justification:* Since this is a treatment group-only pilot study, formal power analysis was not conducted. We are targeting 30 participants to better understand how many teenagers complete all steps in the study process (i.e., meet study criteria, consent, pick up medication, attend appointment, attempt injection, complete surveys). The team will make efforts to understand study drop-out at each stage. We also want to better understand the relationship between key covariates, such as convinence of home injection, and the outcome.

I.3 Number of Subjects

1. *Specify the number of subjects to be enrolled in total across all sites:* or ☒ N/A this is not a multicenter study.
2. *Specify the number of subjects to be enrolled at the Tufts site. Subjects who sign an ICF are considered "enrolled". For studies that have a separate screening ICF, this number is the number of subjects who sign a screening ICF:* 50
    a. *Provide the rationale for enrolling this number of subjects at the Tufts site:* it is anticipated that 50 will need to be enrolled to achieve 30 to complete the study
    b. *Estimate the number of subjects expected to be enrolled at the Tufts site (i.e. sign the screening or study ICF) as well as the number needed to complete the study at the Tufts site:* 50 enrolled, 30 complete
    c. *If a large number of withdrawals and/or dropouts is expected, explain why:* not expected

I.4 Data Management

1. *Describe the data analysis plan, including descriptions of the data:*
   The data are survey results, collected and stored in the Tufts instance of RedCAP. Each encounter will result in two surveys: one from the patient and one from the clinician. Each survey will have a unique identifier for the provider and an encrypted identifier for the patient.

   Descriptive analysis will start with data completeness. Next, we will look at the frequency of all variables, including the patient's self-assessment of a complete injection with the provider's assessment of the injection. We will look at the correlation between self-perception of a successful injection and age, assessment of the video and self-reported intent to do self-injection in the future. We will also assess the degree to which patients and providers agree on the quality of the injection (kappa statistics to assess concordance on injection success).
2. *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission:* All data entered into REDCap will be coded. Subjects will be given numbers by the REDCap survey, and these numbers will be assigned in the sequential order the subjects complete the surveys. These numbers will be linked to their names, and the key will be kept in a password protected online file in a HIPAA secure Box file created by Tufts Medical Center. Only research team members will have access to this file. The file will be destroyed at the end of the study. Consent forms will be kept in a locked cabinet in a locked office accessible only by Dr. Fee and Dr. French.
3. *Describe any procedures that will be used for quality control of collected data:*
   One challenge with data collection is making sure the provider survey and patient survey are correctly linked. To test this, the team will review a random 5 cases and make sure the date, time and provider match. During the analysis, we will see if any surveys are incomplete. If yes, we'll seek to understand any patterns. For example, are teens in a specific age group leaving items blank? Are patients see at a particular time of day or by a specific clinician skipping items. This type of information will be used to decide if incomplete surveys can be used in the analysis.

To ensure data integrity, downloads from RedCAP will be dated and carefully managed to make sure incomplete data sets are not used for analysis. Only members of the study team will have access to the analytic file and results will be reviewed by multiple team members. All final tables will clearly show the number of cases involved in the analysis and identify the analytic data set used to generate results.

4. *Describe how data and specimens will be handled study-wide as follows:*
   a. *What information will be included in that data or associated with the specimens:* Each survey will be given a number by REDCap, and this number will be recorded and linked to the patient's name. The key that has the names and numbers will be stored in a HIPAA compliant password protected Box account for the PI and only research team members will have access to this Box account.
   b. *Where and how data or specimens will be stored:* There will be no specimens. Data will be stored electronically in the REDCap surveys which are coded. The key matching survey numbers and patient names will be stored in a HIPAA compliant Tufts Medical Center Box account. Paper consent forms will be kept in a locked cabinet in a locked office accessible only to Dr. Fee and Dr. French.
   c. *How long the data or specimens will be stored:* Paper consent forms will be stored for at least 7 years. REDCap surveys will only contain de-identified information. The key linking survey numbers to patient names will be in a secure Box account that will be destroyed at the completion of the study and data analysis.
   d. *Specify who will have access to the data or specimens:* only members of the research team
   e. *Specify who is responsible for receipt or transmission of the data or specimens:* Dr.s Fee, French and Bojko
   f. *Specify how data and specimens will be transported:* study data will not be transported and will not leave Tufts.
   g. *Specify the plan for study data retention and storage (accounting for research team turnover):* Electronic data will be stored online with password protection. If the specified locked cabinet becomes unavailable for storage of the paper consent forms, plans will be made with Ms. Iyer to obtain a different secure locked location within the obstetrics and gynecology department for storage.

I.5 Randomization

Will subjects be randomized?

☐ **Yes** ☒ **No**

If **Yes** respond to all of the following:

1. *Describe the randomization procedures, including the ratio of subjects randomized to each study arm:*

2. *Describe the blinding procedures* or ☐N/A the study will not be blinded.

J. Drugs or Devices

1. Will the research involve drugs?

   ☐ **Yes** ☒ **No**

   If **Yes**, respond to all of the following:

   a. *If the drug is investigational (has an IND) identify the holder of the IND:*
   b. *Describe your plans to store, handle, and administer study drugs so that they will be used only on subjects and be used only by authorized investigators* (if the control of the drugs used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section)*:*
   c. *Who on the research team, in addition to the Principal Investigator, will be accountable for drug(s):*

   d. *Who will interface with the pharmacy:*

e. *If pre-printed orders will be created to obtain study drug(s) from the pharmacy, describe the procedures for reviewing and verifying the accuracy of the pre-printed orders prior to their being implemented:* *or* ☐N/A, there are no pre-printed orders

f. *If computerized order sets are created and/or infusion devices need to be programmed to administer an investigational drug, indicate the mechanism to pre-review and verify their accuracy, including who will be involved in this process from the research team, pharmacy, and nursing:* or ☐N/A, there are no computerized orders sets and/or infusion devices.

g. *The study drug or procedure (including beneficial health care procedures) will be available to subjects after participation in the study:* ☐Yes ☐N/A

h. *There are medications or other substances that should not be taken while participating in the study. A list of these are incorporated into the ICF or submitted to the IRB as a subject handout:* ☐Yes ☐N/A

i. *Handouts or instructions sheets that will be given to subjects on how to administer study drug(s) have been submitted to the IRB:* ☐Yes ☐N/A

2. Will the research involve devices?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

a. *If the device has an IDE or a claim of abbreviated IDE (non-significant risk device) identify the holder of the IDE/Abbreviated IDE:*

b. *Describe your plans to store, handle, and administer study devices so that they will be used only on subjects and be used only by authorized investigators* (if the control of the devices used in this protocol will be accomplished by following an established, approved organizational SOP, please reference that SOP in this section)*:*

c. *Specify who will be responsible for the costs of implantation or placement of the device in subjects' bodies?:* *or* ☐N/A, the device will not be implanted or placed in the body.

d. *Specify who will be responsible for the costs of removing the device from subjects' bodies?* *or* ☐N/A, the device will not be removed from the body.

e. *Specify the cost of the device and who will be responsible for the cost*: *or* ☐N/A, the device will be *provided free of charge*.

f. *Who on the research team, in addition to the Principal Investigator, will be accountable for device(s):*

g. *Who will interface with the sponsor:*

h. *The study device or procedure (including beneficial health care procedures) will be available to subjects after participation in the study:* ☐Yes ☐N/A

i. *Handouts or instructions sheets that will be given to subjects on how to use study device(s) have been submitted to the IRB:* ☐Yes ☐N/A

K. Study Administration

K.1 Setting

1. *Describe the sites / locations where your research team will conduct the research:* Sites will be where the healthcare providers in the research team currently see patients and include Tufts Medical Center, Boston MA. Tufts Pediatric Specialty Centers in Woburn, Chelmsford and Lawrence.
2. *The research will take place at an international site, and the International Research Guidance and International Checklist were utilized:* ☐ Yes ☒ N/A

K.2 Registration

1. *Describe the steps the research team will take to ensure that a subject is appropriately enrolled or registered in the study prior to receiving any study intervention (e.g. describe and submit any protocol eligibility checklist that will be used, specify who on the research team will confirm eligibility and that*

consent was documented, etc.): Eligibility criteria and consents will be reviewed on the same day as the video is shown and the medication is given.

K.3 Resources Available

1. *Describe the roles/tasks of each research team member here (or alternatively, you may submit any current Delegation of Authority Log you may have which already has this information completed):* Members of the research team Dr.s Fee, French and Bojko will all be responsible for reaching out to patients, reviewing consent, watching patients administer the injections, ensuring study participants fill out the surveys and filling out surveys themselves. In addition they will be responsible for keeping data and analyzing data. Ms. Iyer will assist with administrative support, such as assistance in building a REDCap survey, and may assist with data analysis.
2. *Describe the qualifications (e.g., training, experience) of the PI and research team to perform their roles. Provide enough information for the IRB to determine the PI and research team are qualified to conduct the proposed research. Alternatively, you can submit the current CVs for the research team instead:* Dr.s Fee, French and Bojko are all trained in gynecology care including administration of subcutaneous and intramuscular injections as well as trained to counsel and care for patients taking depot medroxyprogesterone.
3. *Describe the coverage plan to address any issues (including subject safety issues) that occur while the PI is away and/or unavailable. The research team member designated to serve as the acting PI in the PI's absence should have similar training and expertise as the PI:* The PI will be available, in case of emergency, Dr. Fee is a fellow receiving advanced training in pediatric and adolescent gynecology and will be able to contact the PI.
4. *Describe the process to ensure the research team members have adequate oversight and are adequately trained regarding the protocol, study procedures, and their roles and responsibilities:* See above.
5. *Medical or psychological resources that subjects might need, such as for emergencies or medical issues, are available for the study:* ☐Yes ☒ N/A

K.4 IRB Review

1. ☒*Check to confirm that an appropriate IRB registered with the OHRP, will review and approve this study.*
2. ☒*Check to confirm that any amendments to the protocol or informed consent documents will be reviewed and approved by the IRB prior to use, unless required to eliminate an apparent immediate hazard to subjects.*

K.5 Multi-Site Research

Is this a multi-site study where Tufts is the sponsor, primary grant recipient, or coordinating site?:

☐ **Yes** ☒ **No**

If **Yes**, describe the Study Management Plan, including:

You can also provide corresponding sections from Manual of Operations in the below.

1. *Complete the following for each site:*

List the name of each site	Address	Name of Site PI	Name of IRB overseeing the research at each site	Telephone # of IRB Contact Person (if Tufts is not the IRB of record)	Site's FWA #	Research Activity that will occur at each site (if they will do all the activities described in the protocol state that)

a. ☐*Check to confirm that documentation of each site's IRB approval letter will be submitted to the Tufts Health Sciences IRB prior to initiating any research activity at that site.*
b. ☐*Check to confirm that Tufts Health Sciences IRB is serving as the IRB of record for any site, and a Form 10 (IAA/IIA) has been submitted for each site to request Tufts Health Sciences IRB assume IRB oversight for the research* or ☐N/A, Tufts Health Sciences IRB is not serving as the IRB of record for any site
    i. ☐ *Check to confirm Tufts Health Sciences IRB will serve the HIPAA Privacy Board for this study. If no, please clarify:*
    ii. ☐ *Check to confirm that Conflict of Interest (COI) management plans from relying intuitions will be provided to Tufts Health Sciences IRB when applicable.*
    iii. ☐ *Check to confirm that Local Context Survey was completed by each relying site and included with this submission.*
    iv. *If there are additional state laws and/or local requirements that should be considered by the Reviewing IRB (e.g., mandatory reporting to state health authorities, child abuse reporting, child pregnancy results), please provide details* or ☐N/A
c. ☐*Check to confirm each site will be provided with all relevant sIRB policies.*
d. ☐*Check to confirm each site will complete the File Review Checklist and Participant File Checklist self-audit tools as part of the annual continuing review. If they will not, describe the mechanism for review / audit of sites:*
Refer to the Tufts Health Sciences IRB website for more information about requests to cede/assume IRB review.

2. *The plan for preparing and submitting the study materials for continuing review, submitting modifications and submitting site specific materials to the sIRB:*
3. *The plan for tracking IRB approval of documents and consent forms for each site:*
4. *Name of the sponsor and Contract Research Organization (CRO):* or ☐N/A, there is no sponsor or CRO for this study.
5. *The training that will be provided to the enrolling sites' staff prior to protocol implementation at that study site and throughout the course of the study. Include the type of training, e.g., study meetings, teleconferences, etc., as well as who will provide the training and how it will be documented:*
6. *The plan for ensuring:*
    a. *All sites have the most current version of the protocol and consent forms:*
    b. *Amendments to the Coordinating Center's template protocol and template consent forms will be communicated to all sites:*
7. *The plan for collection and management of data from all sites. Specify if Tufts' data will be shared outside of Tufts (e.g., with other investigators, sponsor, etc.) and how the data will be shared (e.g. how data will be received from and distributed to other sites as needed). If available, please provide the Data Sharing Plan or Policy; if not, describe how each will safeguard data, including secure transmission of data, as required by local information security policies:*
    a. ☐*Check to confirm all local site investigators will conduct the study in accordance with applicable federal regulations and local laws.*
8. *The plan to manage and/or monitor each site's study conduct including enrollment, research events, withdrawals and protocol deviations:*
    a. *Describe how the Coordinating Center will monitor each site's study conduct during the different phases of the study (e.g. remotely, in-person visits, reports, etc.):*
    b. *Describe whether monitoring visits will be conducted. If so, how often? What will the site monitoring visits entail?:*
9. *The plan for processing, reporting and evaluating interim results, unanticipated problems, protocol violations, deviations, and serious adverse events from all sites to the IRB, funder, and federal agencies (e.g. FDA):*
10. *The plan for handling of the investigational product (drug/device/biologic) at each site (if applicable) as follows:*
    a. *Describe how they will be provided to each enrolling site:*
    b. *Describe how dispensing will be monitored:*

c. *Describe what investigational product accountability procedures will be implemented:*

11. *The procedures for study closures and early site termination:*
    a. *Describe any collaborations not described above, such as Tufts investigators with multiple affiliations that would engage other institutions in research (e.g., Tufts is paying another institution for the research, the research is being conducted on behalf of another institution):* or ☐N/A

K.6 Community-Based Participatory Research

Note: "Community-based Participatory Research" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Can or will this study involve community-based participatory research?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following

1. *Describe the communities that will be involved in this research:*
2. *Describe the composition and involvement of any community advisory board:*
3. *Describe the involvement of the community in the design, protocol development, informed consent process, access to data and samples, and conduct of the research*
4. *Describe the plans on dissemination and publication of study results which are in agreement with the community:*

K.7 Sharing Results with Subjects

Will results (overall study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) be shared with subjects or others (e.g., the subject's primary care physician or the subject's treating physician)?

☐ **Yes** ☒ **No**

If **Yes**, respond to all of the following:

1. *Rationale for sharing these results:*
2. *How results will be shared:*
3. *For individual subject results, specify if subjects have the option to opt-in or opt-out of receiving these results or allowing these results to be shared with others:*
4. *Any referral policies (i.e. for confirmation of any individual subject results):*
5. ☐*Check to confirm that testing of research specimens is being conducted in a laboratory certified (CLIA-approved) to conduct diagnostic testing. If patient-specific research results are reported from the laboratory and those results will or could be used for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings, the laboratory must be CLIA certified.*
6. *If the research tests are experimental or of unknown or unproven clinical significance and the results will be provided to the source individual or physician or placed in the source individual's medical record, provide the rationale for this:*

L. References

Provide a list of references for all citations included in the protocol

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3. Park E, Kwon M. Health-Related Internet Use by Children and Adolescents: Systematic Review. J Med Internet Res. 2018 Apr 3;20(4):e120. doi: 10.2196/jmir.7731. PMID: 29615385; PMCID: PMC5904452

4. Kennedy CE, Yeh PT, Gaffield ML*, et al.* Self-administration of injectable contraception: a systematic review and meta-analysis. *BMJ Global Health* 2019;**4:**e001350.
5. Williams RL, Hensel DJ, Fortenberry JD. Self-administration of subcutaneous depot medroxyprogesterone acetate by adolescent women. Contraception. 2013 Sep;88(3):401-7. doi: 10.1016/j.contraception.2012.11.019. Epub 2013 Jan 4. PMID: 23294549; PMCID: PMC3745808.
6. Cameron ST, Glasier A, Johnstone A. Pilot study of home self-administration of subcutaneous depo-medroxyprogesterone acetate for contraception. Contraception. 2012 May;85(5):458-64. doi: 10.1016/j.contraception.2011.10.002. Epub 2011 Nov 12. PMID: 22079602.
7. Patton GC, Sawyer SM, Santelli JS, Ross DA, Afifi R, Allen NB, Arora M, Azzopardi P, Baldwin W, Bonell C, Kakuma R, Kennedy E, Mahon J, McGovern T, Mokdad AH, Patel V, Petroni S, Reavley N, Taiwo K, Waldfogel J, Wickremarathne D, Barroso C, Bhutta Z, Fatusi AO, Mattoo A, Diers J, Fang J, Ferguson J, Ssewamala F, Viner RM. Our future: a Lancet commission on adolescent health and wellbeing. Lancet. 2016 Jun 11;387(10036):2423-78. doi: 10.1016/S0140-6736(16)00579-1. Epub 2016 May 9. PMID: 27174304; PMCID: PMC5832967.