Principal Investigator: **James A. Feinstein, MD, MPH**
COMIRB No: **22-2423**
Version Date: **03/03/2023**
Study Title: **Optimizing the Clinical Management of Polypharmacy for Children with Medical Complexity: The Pediatric Medication Therapy Management (pMTM) Trial**

You are being asked to be in a research study. "You" as used in this consent form means "you" or "your child" if you are consenting on behalf of your child. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

Sometimes children need to use many different medications to treat their medical conditions and symptoms. But sometimes medications can also cause unwanted symptoms or problems. This study plans to learn more about ways to keep children who use many different medications healthy and safe.

You are being asked to be in this research study because you have a complex chronic medical condition, you take 5 or more medications (including as needed and over-the-counter medications), and you have an upcoming primary care appointment in the Children's Hospital Colorado Special Care Clinic.

A parent and their child's medical provider must decide what to do if they think a medication is causing an unwanted symptom or problem. This can be a difficult decision to make, especially for a child who takes many different medications.

We plan to study whether a system called Pediatric Medication Therapy Management (pMTM) might make it easier to figure out what to do when medications are causing unwanted symptoms or problems.

Other people in this study:

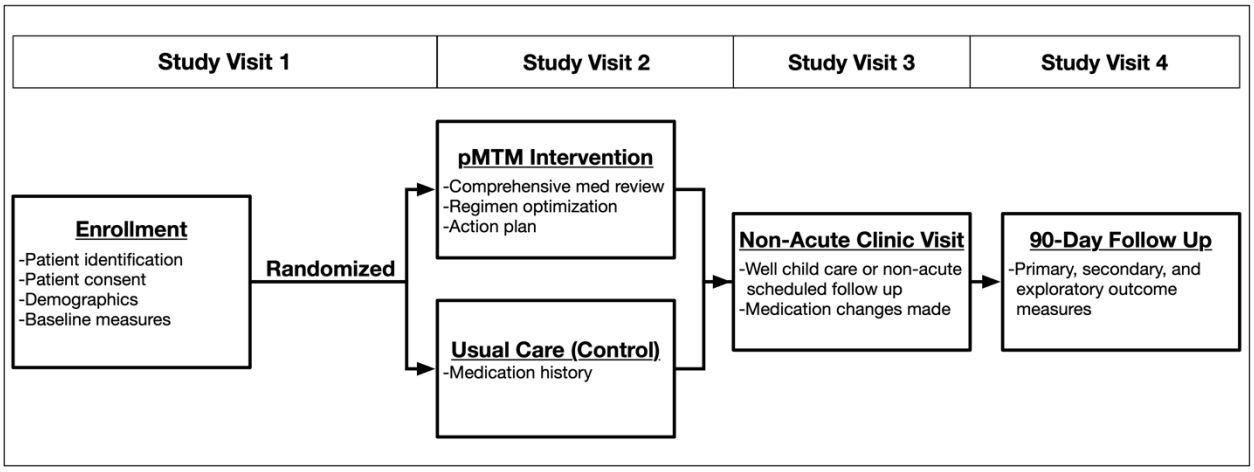
Up to 371 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will randomly be assigned to either the pMTM intervention group or to the usual medical care group. You will not know to which group you were assigned.

All study participants will be asked to participate in up to 4 visits over a period of 90 days (see figure below). Study-related activities will include surveys, questionnaires, and structured conversations about your current medications and symptoms. This study does not involve any

physical exams or painful procedures. Some study visits may be audio recorded and you can ask to stop the recordings at any time. All study-related activities will be conducted by trained study team members.



Study Visit 1: This study visit will occur up to 14 days before your Special Care Clinic appointment. After you enroll, you will be asked to complete baseline study-related activities. This study visit will occur by phone or by video and the visit will take up to 60 minutes.

Study Visit 2: This study visit will occur up to 3 days before your Special Care Clinic appointment. If you are randomized to the pMTM Intervention group, you will meet with the study pharmacist before your Special Care Clinic appointment. If you are randomized to the Usual Care group, you will undergo medication history review performed by study personnel prior to your Special Care Clinic appointment. This study visit will occur by phone or by video and the visit will take up to 60 minutes.

Study Visit 3: This study visit is your routine Special Care Clinic appointment. You will have the opportunity to talk with your medical provider about your medications. Together, you will decide whether any medication changes should be made, including any medication-related recommendations made as part of the pMTM study intervention. This visit will occur in person and the visit will take the amount of time you scheduled for your routine Special Care Clinic appointment.

Study Visit 4: This study visit will occur 90 days after your Special Care Clinic appointment. You will be asked to complete follow-up study-related activities. This visit will occur by phone or by video and the visit will take up to 60 minutes.

Your participation in the study will end after you complete study visit 4.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include needing to repeat information collected during study visits 1 and 2 to your medical provider during your upcoming Special Care Clinic appointment (study visit 3).

There is a risk that while completing study-related activities (for example, a questionnaire that asks about any medication-related symptoms you may have experienced in the past 7 days), you may identify a medical problem that needs immediate attention. However, the information collected during the study is not a communication with your medical provider. If you feel that you are having a medical problem, you will need to contact your medical provider immediately.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

You will be assigned to the pMTM study intervention group by chance, and the pMTM study intervention you receive may prove to be no more effective than usual clinical care.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about ways to improve medication effectiveness and safety for children who take multiple medications. Participants may receive benefit from study participation if the pMTM intervention improves the identification and management of medication-related problems compared to usual medical care.

Who is paying for this study?

This research is being sponsored by the Agency for Healthcare Research and Quality, through a grant made to Dr. James Feinstein (R01 HS028979-01A1).

Will I be paid for being in the study?

You can be paid for being in this study. Children's Hospital Colorado pays you using a debit card system. The cash value will be loaded onto a debit card when you finish certain study procedures. The Internal Revenue Service (IRS) requires that we report as income when we pay you. A research team member will ask you to provide your social security number or tax identification number to meet these IRS requirements. Without this number, we can't pay you for being in this study.

You will be paid $50.00 after completing study visit #3 and $50.00 after completing study visit #4. This will add up to a total of $100.00 if you complete all of the visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study except your time to complete the 3 study visits.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study medical provider.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study medical provider may decide to stop your participation without your permission if the study medical provider thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. James Feinstein immediately. His phone number is 303-724-4186.
In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. James Feinstein. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. James Feinstein at 303-724-4186. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. James Feinstein with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Children's Hospital Colorado (Children's Colorado)
- Other: Children's Colorado shares a medical record system with the Barbara Davis Center and PedsConnect; therefore, it is also possible that other healthcare professionals could view your information.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. James Feinstein
University of Colorado Denver
1890 N. Revere Court, Mail Stop F443
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study medical provider and the rest of the study team.
- The Agency for Healthcare Research and Quality who is paying for this research study and its agents who perform services in conjunction with the study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

What will happen to my recorded information?

In this study we may record portions of the study visit. We will use digital audio recording equipment. We will keep this information secure and private. We will store it for 5 years. At the end of that time, we will destroy it.

Certificate of confidentiality:

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Authorization for optional additional study procedures:

In this form, you were given the option to agree to additional, optional research procedures (such as completion of survey and interview questions). You must also give us your permission, under HIPAA rules, to contact you for the additional procedures and to use and disclose the information collected from these optional procedures, as described above, to your health care providers.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

___I **give** permission to be contacted for the optional additional study procedures and for information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

___I **do not** give permission to be contacted for the optional additional study procedures and for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data:

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

----------Use the following only if applicable----------

Signature: _____ Date:_____
(Child Subject 13-17 years old; ***In addition*** to Parent Signature)

Print Name:_____

Person in Charge of the Study: **James A. Feinstein, MD, MPH**
COMIRB No: **22-2423**
Version Date: **03/03/2023**
Assent Form for Ages 7-12: **Optimizing the Clinical Management of Polypharmacy for Children with Medical Complexity: The Pediatric Medication Therapy Management (pMTM) Trial**

What is this study about?

You are being asked if you want to be in this research study. The goal of this study is to learn about ways to keep children who use many different medications healthy and safe.

Why are you asking me?

You are being asked to be in the study because you take 5 or more medications.

What do I have to do or what will happen to me?

If you are in the study, you will:

- Participate in 4 short study visits over a period of 90 days
- Answer questions about your medications and symptoms
- Talk with your medical provider about your medications

You don't have to answer any questions that you don't want to, and you can stop at any time.

Will this hurt?

If you are in the study, there is nothing done in the study that will hurt you or cause pain.

What will happen to my recorded information?

In this study, we may audio record portions of the study visits using digital recording equipment. You can ask to stop the recordings at any time. We will keep all of your information secure and private. We will store it for 5 years. At the end of that time, we will destroy it.

Can I ask questions?

You can ask any questions that you have now about the study. If you have a question later, you can ask and get an answer. If you want to, you can call Dr. James Feinstein at 303-724-4186.

Do I have to do this?

You do not have to be in this study. No one will be mad at you if you say no. You can choose to stop at any time. Just tell the researcher if you want to stop.

Do you want to be in the study at this time? (Check one box)
☐ Yes ☐ No

You will get a copy of this form to keep.

Child's Signature:_____ Date:_____
(Child Subject 7-12 years old)

Child's Printed Name:_____

Consent Form Explained By:_____
(Print name)

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent*:* _____ Date:_____