University of Illinois at Chicago (UIC)
Research Information and Consent, Parental Permission, and Authorization for Participation in Social, Behavioral, or Educational Research

Patient Navigators for Children's Community Mental Health Services in High Poverty Urban Communities

CAREGIVER CONSENT AND PERMISSION FORM

You and your child are being asked to participate in a research study to help researchers and social service agencies learn more about the role of patient navigators, whose job is to support and guide families through their use of the mental health service system. Researchers are required to provide a consent form such as this one to tell you and your child about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you and your child to make an informed decision. You and your child should feel free to ask the researchers any questions you both may have.

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Sponsor: National Institutes of Health (NIH)

About this research study

You and your child are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Why am I being asked?

You and your child are being asked to participate in a research study about the roles of navigators, the services they provide, and families' experiences with navigation so that we can better understand and support navigators' work with Black and Latinx families within children's community mental health systems. We are asking Black and Latinx caregivers who have a child between the ages of 5 to 12 and who are on the waitlist at this agency, if they are interested in participating in this research. You and your child are being asked to participate because your child has been placed on the waitlist for services at [NAME OF AGENCY], meet these criteria, and were assigned a navigator by the agency.

This consent form will give you and your child information about the research study to help you decide whether you and your child want to participate. We ask that you read this form and ask any questions you or your child may have before agreeing to participate.

Three-hundred-and-seventy-eight caregivers will be enrolled in this research study over the course of 5 years.

Taking part in this study is voluntary

Your and your child's participation in this research study is voluntary. You and your child may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you and your child are entitled and will not affect your relationship with [NAME OF AGENCY] or with the University of Illinois at Chicago (UIC). **If you and your child decide to participate, you both are free to withdraw at any time without affecting these relationships. Additionally, deciding to not participate will not affect any services offered by [NAME OF AGENCY].**

Important Information

This information gives you and your child an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We are interested in learning more about the roles of patient navigators who work with Black and Latinx families within children's community mental health systems, the services they provide, and families' experiences with navigation.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	If you and your child decide to participate, you will be asked to complete questionnaires at four timepoints: when you and your child enroll in the study (baseline), at 6 months after you and your child begin the study, at 12 months, and finally, at 18 months. At each of these timepoints, you will be asked to complete questionnaires online, on a secure web-based application called REDCap. You will have the option of providing information with assistance from a research assistant, either in-person at [AGENCY NAME] or via a secure video platform (phone or video), or on your own via a secure link which will be sent to you. These questionnaires ask about your experiences with and beliefs about children's mental health services, you and your child's health, and your social support network. Your child is not being asked to do any research tasks.

	Information from your child's electronic medical record (EMR) maintained by the agency will be shared with our research team as needed throughout the duration of the study. EMR data to be shared will include child and caregiver name, demographic information, insurance type, therapist report of child progress, diagnosis, service use and attendance information, and record of staff outreach and contacts with families. This information will be used for data analysis in the present study.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The entire duration of your and your child's participation would be 18 months. The demographic questionnaire (completed once at baseline) will take approximately 5-10 minutes. The total time estimated to complete all online questionnaires will be approximately 60 minutes at each time point (baseline, 6 months, 12 months, 18 months), for a grand total of approximately 4 hours filling out questionnaires across the entire duration of the study.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Taking part in this research study may not benefit you and your child personally, but we [researchers] may learn new things that will help others. This study will be used to further develop mental health services and support staff on how to best engage with the families they serve.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The primary risks presented by this research study are breaches of privacy (others outside of the study may find out you are a subject) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you and your child during the study). Agency staff will know you and your child are participating in this study. Although we will work very hard to protect your and your child's privacy, it is possible that people may find out that you both are research participants, even if you and your child don't want them to know. We ask many questions about your child's behavior and your attitudes towards mental health services, so at times you may feel uncomfortable sharing information about yourself and your family with our staff. However, we will be very careful to keep this information private and you will not need to answer any questions that you don't want to answer. Data will be protected to the extent technologically possible, as substantial data will be collected electronically. Beyond this, to the best of our knowledge, the things you and your child will be doing have no more risk of harm than you would experience in everyday life.

DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You and your child have the option to not participate in this study.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Tara Mehta, Ph.D. and her staff. You and your child may ask any questions you both have now. If you or your child have questions later, you may contact the researchers at (312) 996-3910 or tmehta@uic.edu. If you and your child have questions about your rights as study subject; including questions, concerns, complaints, or if youfeel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you and your child have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you and your child should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.

What will happen with my information used in this study?

Your and your child's identifiable private information collected for this research study will be used to maintain contact with you during the course of the study. Identifiable information will be removed from all data and replaced with codes. After data analysis, when the master list with the code key is destroyed, the information cannot be withdrawn from further use.

What about privacy and confidentiality?

Efforts will be made to keep your and your child's personal information confidential; however, we cannot guarantee absolute confidentiality. For example, others within the clinic may know that you and your child are participating in the study. In general, information about you and your child, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and state university rules might require us to tell certain people about you or your child. For example, study information which identifies you and your child and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health

To help us protect you, your child, and the information and documents we will be collecting from you, this research has been given a Certificate of Confidentiality by the National Institutes of Health (NIH). This Certificate means that researchers cannot be forced, even by courts or the police, to disclose information or documents that may identify you or your child. However, your information may be given to personnel of the United States Government to audit or evaluate projects that are federally funded or to meet the requirements of the National Institutes of Health (NIH).

The Certificate does not stop you or a family member from disclosing, or agreeing in writing to allow researchers to disclose, information or documents about you and your child, including your participation in this research. For example, if you would like an employer or insurer to know something about you and your child that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

Even if the research has a Certificate, the researcher or any member of the study staff must report (even if it is without your consent) evidence of harm to self or others, including actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult. In addition, if the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.

A possible risk of the study is that your and your child's participation in the study or information about you both might become known to individuals outside the study. All information collected during this project will be kept private. All information that the project obtains will have a code so that no one will know your name or your child's name unless you give permission for this information to be used on your behalf or your child's behalf. A master list linking you and your child's name to your code will be securely stored and separated from all data. Information given by you or agency staff will be coded, stored on a password protected computer, and stored in a secure web application called REDCap. Any paper documents will be kept in a locked file cabinet to prevent people from seeing it.

As a study funded by the National Institute of Mental Health (NIMH) we are required to submit de-identified data to the National Data Archive, so some of you and your child's de-identified data will be shared with the National Data Archive. You or your child will not be asked for additional consent if only de-identified data or coded data without access to the code key are shared, for example, with other investigators.

Your and your child's individual data will be stripped of all direct and indirect identifiers after analysis.. The master list will be destroyed after data analyses. Your contact information used for gift card compensation will be destroyed after full compensation for all parts of the study are completed.

When the results of the research are published or discussed in conferences, no information will be included that could reveal your identity or your child's identity. Data will be reported in aggregate (with identifiers removed). All information we get about you or your child that can be identified with you or your child will remain secret. We can only give out information that identifies you or your child with your permission.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your and your child's health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your child's protected health information in this research study. By signing this form you are authorizing Dr. Tara Mehta and her research team to create, get, use, store, and share protected health information that identifies you and your child for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your child's medical record that is needed for the research and that specifically includes:

- Personal identifiers (your name; your child's name, address, phone number, date of birth, medical record number), dates of service, and demographic information (your child's race, gender, ethnicity, age)
- Mental Health information: service use at agency (attendance information), record of staff outreach and contacts with family (dates and contact notes), insurance type, child's diagnosis, therapist and caregiver reports of child's progress (questionnaire), caregiver report of personal physical and mental health (questionnaire). The categories of mental health information listed above may be drawn from EMR data or research data, depending on agency protocol, as some questionnaire data may be considered elements of standard care data

During the conduct of the research, the researchers may use or share your and your child's health information:

- With each other and with other researchers involved with the study.

- With the sponsor/funding agency of the research, The National Institutes of Health, as required to conduct the research and/or confirm the results of the research.
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and National Institutes of Health (NIH).

If all information that identifies you and your child is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your and your child's participation in this research, you will not have access to the research records or information that is not usually kept in your and your child's medical record. However, this information is available to your and your child's provider in the case of an emergency. The researcher may provide you and your child with access to the research records or information related to this research once the study is done.

How will your and your child's health information be protected?

The researchers and The National Institutes of Health agree to protect your and your child's health information and will only share this information as described within this research consent/authorization form.

When your and your child's health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your and your child's information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study expires at the end of the study, but can be canceled sooner if you decide to withdraw your permission. If you decide to cancel this authorization, a research team member will communicate with [NAME OF AGENCY] data team and the research Data Management Core responsible for extracting data from agency medical records to halt data extraction of your data.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Tara Mehta, Ph.D.
1747 W. Roosevelt Rd
Chicago, IL 60608

If you cancel this Authorization, you and your child may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose

health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you and your child.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your child's health information is required for research participation, you and your child cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you and your child cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your and your child's eligibility for other medical benefits.

What are the costs for participation in this research?

There are no costs to you or your child for participating in this research. Your health insurance will not be charged for any aspect of the research. However, following agency procedures, agencies can bill health insurance for the services they provide as appropriate.

Will I be reimbursed for my participation in this research?

You will receive $25 in cash or gift card for each completed assessment at the four time points. If you and your child do not finish the study, you will be compensated for the visits you have completed. If you and your child complete the study, you will receive a total of $100. You will receive your payment within approximately 30 days after each completed time point by email, mail, or in-person. If you decide to receive a gift card, your contact information will be shared with the issuer of the gift card for compensation purposes only.

Can I withdraw or be removed from the study?

If you decide to participate, you and your child are free to withdraw your consent and discontinue participation at any time. To withdraw, simply let the researcher know that you and your child would like to discontinue participation. Participants may withdraw by informing the investigator by email (tmehta@uic.edu). You and your child can do this at any time during a study session or between study sessions.

The researchers [and/or sponsor] also have the right to stop your participation in this study without your or your child's consent if they believe it is in our best interest.

In the event you and your child withdraw or are asked to leave the study, you will still be compensated as described above.

What other things should I know?

Near the end of your 18-month participation in this study, a member of our research team may reach out to you to ask if you are interested in participating in focus groups about your

experience with navigation. If you are contacted about focus groups at that time, you will have the opportunity to learn more about the focus groups, what they involve, and decide whether or not you would like to participate. If you decide to participate at that time, you will be asked to sign a separate consent form to participate in the focus group.

Future recruitment for research studies

Our research team may conduct future research studies that may be of interest to you and your child.

May a member of the research team contact you to invite your participation in future research studies? If you mark "yes" under an option below, you consent for us to retain your name and contact information beyond the current research study solely for this purpose. This information will be securely stored and maintained separate from any study data.

A) Future phases of this protocol

____Yes ____No

B) Future studies conducted by the investigators involved in the current protocol

____Yes ____No

Remember:

Your and your child's participation in this research is voluntary. Your and your child's decision whether or not to participate will not affect your or your child's current or future relations with the University or [NAME OF AGENCY]. If you and your child decide to participate, you are both free to withdraw at any time without affecting that relationship.

You will be given a copy of this form for your information and to keep for your records.

Signature of Participant or Legally Authorized Representative

I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this form.

My signature below indicates that I am providing consent to participate in the research study.

_____ _____

Signature Date

_____
Printed Name

Permission for Data to be Collected About Minor

My signature below indicates that I am providing permission for the research team to collect information about my child.

_____
Printed Name of Minor

_____ _____
Signature of Parent, Guardian, Legal Representative Date of Signature

_____
Printed Name of Parent, Guardian, Legal Representative

Describe relationship to subject including the legal authority this individual has to act on behalf of the subject. (Check one below)
☐ Parent
☐ Legal guardian
☐ Other; specify
_____

_____

[Required]

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent