University of Illinois at Chicago (UIC)
Consent for Participation in Social, Behavioral, or Educational Research

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

NAVIGATOR CONSENT FOR PARTICIPATION IN RESEARCH

You 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 about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

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Sponsor: National Institute of Health (NIH)

About this research study

You 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 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 families within children's community mental health systems. You have been asked to participate in the research because you are a navigator at [NAME OF AGENCY]. Researchers from the University of Illinois at Chicago are working with community agencies to study patient navigation in child mental health services. The information we learn from this study will help us better understand how navigation contributes to families' engagement with mental health services. This consent form will give you information about the research study to help you decide whether you want to participate. We ask that you read this form and ask any questions you may have before agreeing to participate.

All navigators within the participating community social service agencies are invited to participate in this research. Twelve to eighteen navigators will be involved in this research.

Taking part in this study is voluntary

Your participation in this research study is voluntary. You 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 are entitled and will not affect your relationship with [NAME OF AGENCY] or the University of Illinois at Chicago (UIC). None of the information you share about yourself with us will be shared with [NAME OF AGENCY]. **If you decide to participate, you are free to withdraw at any time without affecting these relationships.**

Important Information
This information gives you 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, the services they provide, and families' experiences with navigation so that we can better understand and support navigators' work with families within children's community mental health systems.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	At the beginning of your participation, you will be asked to fill out an online demographic questionnaire and a survey on REDCap, which is a secure web application used for data collection. We will also be collecting the forms and/or navigation contact notes (from the child's electronic medical records) used to track navigation services for each of your clients who consent to participate in the study in order to gauge family engagement and attendance. The research study is comprised of 3 phases of caregiver recruitment (3 cohorts) across 4 years. You will be asked to track your navigation contacts for 5 to 10 caregivers per cohort, for a total of 15 to 30 caregivers across the 4 years.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	Your participation takes place across 4 years of the research study. The demographic questionnaire and survey collected at baseline will take approximately 20-30 minutes.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Taking part in this research study may not benefit you personally, but we [researchers] may learn new things that will help others. This study will be used to further develop navigation 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 during the study). A possible discomfort is the time spent completing measures. Beyond this, to the best of our knowledge the things you 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 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 may ask any questions you have now. If you have questions later, you may contact the researchers at (312) 996-3910 or at tmehta@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel 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.

Please review the rest of this document for details about these topics and additional things you 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 identifiable private information collected for this research study will be used to maintain contact with you during the course of the study. In addition, your social security number will be used solely to provide you with compensation. Identifiable information will be removed from all data and replaced with codes. After data analysis, when the the master list with the code key is destroyed, the information cannot be withdrawn from further use. You will not be asked for additional consent. Also, additional consent will not be asked if only de-identified data or coded data without access to the code key are shared.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, 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. For example, study information which identifies you 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
- [NAME OF AGENCY] (No identifiable data will be shared with the agency. However, aggregated data may be shared.)

To help us protect you 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. 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, including your participation in this research. For example, if you would like an employer or insurer to know something about you 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 research 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.

The people who will know that you are a research subject are members of the research team and the agency. Other staff at your agency might hear about your participation in this research. However, the information you share with us will remain confidential. Otherwise information about you will only be disclosed to others with your written permission, or if necessary to protect your rights or welfare (for example, when the UIC Office for the Protection of Research Subjects monitors the research or consent process).

All information that the project obtains will have a code so that no one will know your name unless you give permission for this information to be used on your behalf. A master list linking your name to your code will be securely stored and separated from all data.

A possible risk of the research is that your participation in the research or information about you might become known to individuals outside the research.
When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Data will be reported in aggregate (with identifiers removed).

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 your de-identified data will be shared with the National Data Archive. You 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 individual data will be stripped of all direct and indirect identifiers or destroyed 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.

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. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs for participation in this research?

There are no costs to you for participating in this research.

Will I be reimbursed for my participation in this research?

You will receive $10 for filling out demographic information and a survey at baseline. You will receive $25 each month for completing your navigation contact tracking. If you complete the baseline measures and the monthly tracking for the maximum duration of 48 months, you would receive a total of $1210. If you do not finish the study, you will be compensated for the visits/tracking you have completed.
You will receive your payment in the form of cash, gift card, or check approximately within 30 days after each completed time point by email, mail, or in-person. Participant's contact information will be shared with either UIC (for a check) or the issuer of a gift card for compensation purposes.

Per the University of Illinois System policy regarding payment of human subjects, we will collect participants' social security number (SSN) or tax identification number (TIN) when an individual's payment exceeds $200 per calendar year. SSN and/or TIN are collected solely in

accordance with this policy, in order for the System to fulfill its tax reporting responsibilities to the IRS. Based on annual compensation amounts for navigators, we will collect your SSN/TNN.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time. To withdraw, simply let the researcher know that you would like to discontinue participation. Participants may withdraw by informing the investigator by email (tmehta@uic.edu). You 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 consent if they believe it is in our best interest.

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

What other things should I know?

At three time points during the study, all navigators will be invited to participate in a 1-2 hour focus group. There is a total of three navigator focus groups that you may participate in across the duration of the study. These focus groups are group discussions with other navigators. A UIC research member will ask a series of questions aimed to understand navigators' experiences with supporting families, perceptions and experiences over the course of the study, and to gather feedback about the feasibility of their role, their supports, their needs, and their strengths. When you are contacted about focus groups at the aforementioned times, 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.

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 the study detailed in this form

____Yes ____No

B) Future studies conducted by the investigators of the study detailed in this form

____Yes ____No

Remember:

Your participation in this research is completely voluntary. Your decision whether or not to participate will not affect your current or future relations with the University or [NAME OF AGENCY]. If you decide to participate, you are 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

I have read (or someone has read to me) 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 signed and dated form.
Your signature below indicates that you are providing consent to participate in the research study.

_____ _____
Signature Date

_____
Printed Name

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

_____
Printed Name of Person Obtaining Consent