

**Piloting a Clinical Decision Support tool to identify and refer patients
with social needs to community based organizations**

Approved May 23, 2024

NCT05574699

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

COMBINED RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Piloting a Clinical Decision Support tool to identify and refer patients with social needs to community based organizations

Application No.: IRB00354803

Sponsor/Supporter/Funded By: National Institute on Minority Health and Health Disparities (R01MD015844)

Principal Investigator: Elham Hatef, MD, MPH
2024 E Monument Street, Baltimore, MD, 21205
Room 1-103
shail1@jh.edu
443-927-3004

You are being asked to join a research program. Participation in this research program is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the research program are listed in the sections below. If you are considering participation in the research program, the entire document should be discussed with you before you make your final decision. You can ask questions about the research program now and at any time in the future.

- We are asking you to volunteer for a research program looking to assess the impact of tool in the electronic health records in the clinic on workflow and patient care in the clinic. We want to learn if the electronic tool that provides information on some of the needs a patient may have (such as food problems, housing issues, and lack of transportation services to attend medical appointments) and a referral system to community-based social services organizations improve the health of our patients.
- If you join, we will ask you to attend your regularly scheduled doctor's visit. After you consent to the research program, you will be randomly (by chance, like a flip of a coin) assigned to the intervention or control arm. Providers will then either access the new tool or provide the standard of care to determine your individual social needs (if any). If needed the providers may contact you to

assess your need and assist in referring you to appropriate social services. A member of your provider team will follow up approximately 3 months later in a telephone interview that will take approximately 15-20 minutes.

- There is nothing you will need to do beyond following your providers' advice about your care and needs.
- There is a risk that information being discussed in the social needs score may be sensitive and cause some personal discomfort.

2. Why is this research program being done?

This research program is being done to test an electronic tool and referral system that identifies an individual's social needs and connects them to relevant social service organizations. The tool will provide information on some of the needs a patient may have (such as food problems, housing issues, and lack of transportation services to attend medical appointments) and allow the providers to determine what follow-up screening to do and refer to social services organizations as needed.

We want to see if this tool and referral system to community-based social services organizations can more efficiently identify individuals with social needs and decrease the social needs of patients when compared to the standard of care (providers' decision for screening and referrals).

Who can join this research program?

Adults (18+ years old) of any race/ethnicity who were seen at Johns Hopkins facilities in the past year and live in a neighborhood with some social challenges such as a food desert, housing issues, or lack of transportation services may join.

3. What will happen if you join this research program?

If you agree to be in this research program, we will ask you to do the following things:

- You will be randomly (by chance, like a flip of a coin) assigned to either the intervention or control arm of the research program by clinic staff.
 - For those in the intervention arm, your provider will access the tool in your electronic health records. The provider will use that to determine if further screening around social needs is required.
 - For those in the control arm, you will receive a standard of care that consists of your provider screening, assessing, and addressing your social needs on an as-needed basis based on the information you provide during your visit.
- Attend your scheduled doctor's visit as normal
 - For those in the intervention arm, if your provider identifies a social need they may perform a more in-depth assessment of your needs and find a community-based social services organization that can provide support services.
 - Someone from the community-based organization will reach out and provide you with further information on obtaining services.
- A member of the program team will call you approximately 3 months after your initial office visit for a 20-30 minute telephone interview.

Will research test results be shared with you?

This research program involves using information you provide to your clinic and is used to determine your social needs. This information will be shared with you at your doctor's visit. If your provider thinks it is necessary they will perform more in-depth assessment of your social needs and refer you to an outside organizations to help address your social needs.

How long will you be in the research program?

You will be in this research program for 3 months. Your participation includes your provider visit, potential interaction with a community-based organization to address your social needs, and a telephone call 3 months after your initial visit

4. What happens to data that are collected in the research program?

If you join this research program, your data will be used to answer the research question and publish the findings of this research program. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data collected in this research program for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this research program. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data-sharing agreements and review by oversight groups within Johns Hopkins.

If data are used or shared with types of information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time and may continue after the research program ends.

The use and sharing of your data are required for participation in this research program. **If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this research program.**

5. What are the risks or discomforts of the research program?

- Information being discussed in this research program may be sensitive and cause some personal discomfort to individuals.
- You may be uncomfortable or feel embarrassed to answer questions around your social needs.
- The program team will do its best to approach these topics with sensitivity and respect for you and your needs.

- There is small risk for unintended consequences including social risk profiling that could lead to bias and stereotyping in the delivery of your care. In order to minimize the risk, clinical providers and clinic staff will receive training on how to use this information in their communications with you.
- There is the risk that information about you may become known to people outside this research program.

6. Are there benefits to being in the research program?

You may or may not benefit directly from enrolling in this research program. If a provider and you identify a specific social need that can be addressed by an outside social services organization you will be referred to those services. The services provided will be covered by this research program.

If you take part in this research program, you may help others in the future. Your involvement will help determine the feasibility of using electronic health data to identify the social needs of patients and test how to develop a referral system for other patients to access services to address their social needs.

7. What are your options if you do not want to be in the research program?

You do not have to join this research program. If you choose to not join the research program your care and access to your care team at the clinic will not change. You will continue to receive care and be screened through the standard of processes. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this research program?

There is no cost to you to be in this research program

9. Will you be paid if you join this research program?

You will receive a \$20 gift card upon completion of the research program. Your participation includes your provider visit, potential interaction with a community-based social services organization to address your social needs, and a telephone call 3 months after your initial visit.

You may be required to provide your social security number to be paid for taking part in this research program. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed \$600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the research program early?

- You can agree to be in the research program now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this research program early will not stop you from getting regular medical care.

If you leave the research program early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this research program or any follow-up activities.

11. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the program team believes it needs to conduct the research program. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of the Johns Hopkins Health System, Johns Hopkins University, or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example, if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the research program you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the research program and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the research program, data managers, and other agents and contractors used by the program team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your healthcare providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the research program.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the research program, or information that has already been shared with others before you canceled your authorization.

How will your information be protected?

All information collected during this research program will be protected to the best of our ability. We will use HIPAA compliant servers and electronic folders to store and analyze information collected for this research program. Your name and contact information will not be directly linked to the information

collected for this research program. It will be kept in a separate secured folder in order to maintain confidentiality. Your name will not be directly associated with any of your survey answers, rather we will assign a study ID to your answers. This will be used to help link your medical records and survey responses.

12. What is a Certificate of Confidentiality?

Your research program information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this research program or future research. Disclosures that you make yourself are also not protected.

13. What does a conflict of interest mean to you as a participant in this research program?

One of the researchers on this research program is an inventor of technology being evaluated in the research program.

If you have any questions about this inventorship, please talk to Jonathan Weiner at (410) 955-5661. This person is a member of the research program but is not an inventor of the technology being evaluated in the research program. You may also contact the Office of Policy Coordination (410-361-8667 or policy@jhmi.edu) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

14. What other things should you know about this research program?

During the research program, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on <http://www.ClinicalTrials.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. If you would like to review the information for this research program, or a summary of the results, ask the program team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?

This research program has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research program. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the research program?

Call the principal investigator, Elham Hatef, MD, MPH at (443) 927-3004. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

15. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the research program. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
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Signature of Person Obtaining Consent	(Print Name)	Date/Time
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Signature of Interpreter/Witness to Consent Procedures	(Print Name)	Date/Time
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(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).