

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to Community-Based Organizations

CPHIT-NIMHD-RCT Protocol

V.06.04.2024

NCT05574699

Table of Contents

Background	4
Study Goals.....	4
Objectives	4
Study Team and Collaborating Sites.....	5
Coordinating Site - Center for Population Health Information Technology (CPHIT)	5
Primary Care Clinics	5
Hopkins Community Connection (HCC)	6
Community-Based Organizations	6
RCT Study Procedure.....	7
Study Overview	7
Patient Enrollment - Identifying Eligible Patients.....	7
Consenting Process	9
Patient Enrollment - Randomization	10
Planned Intervention	10
Intervention arm.....	10
Control arm	11
Sample Size	11
Analysis plan	11
Usability and Acceptability Assessment - Study Procedure	12
Participant Enrollment for Focus Groups.....	12
Conducting Focus Groups	12
Sample Size	12
Data Management Plan	13
Responsibilities of the DSMB.....	13
Organization and Interactions.....	13
DSMB Members	13
Scheduling, Timing, and Organization of Meetings.....	14
Recruitment, Adverse Events, and Alert Reports.....	14
Adverse Event (AE) Reporting.....	14
Plan for Reporting Unanticipated Problems or Study Deviations	15
Appendix	16
MyChart Communication Content.....	16

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs
PI: Hatef and Weiner

Recruitment email/letter content for Aim 2	18
Recruitment email/letter content for Aim 3	19
Recruitment Opt-out card.....	20
Epic Smart Phrase Template document.....	21
Graphic Summary	22
Staff Messaging Template	23
Telephone Screening Script for Aim 2	24
Telephone Screening Script for Aim 3	26
Patient Consent Documents	28
Waiver of Documentation of Consent Script.....	29
Hopkins Community Connection Work Process Diagram	30
CDS Tool Explanation Sheet	31
Patient Follow-up Telephone Survey.....	34
Data Collection Form for Secondary Data Analysis	36
Outline for Focus Group Discussion Points.....	37

Background

Social needs and social determinants of health (SDOH) significantly outrank medical care when considering the impact on a person's length and quality of life. Challenges related to social needs and SDOH disproportionately impact minority populations such as African Americans with low income and are critical factors in explaining many health-related disparities, ultimately leading to higher mortality among minority populations and those with low income. Thus, integrating social needs and SDOH challenges along with clinical risk information within operational clinical decision support (CDS) systems built into electronic health records (EHRs) is an essential approach to addressing health disparities.

Presently, the US health system is undergoing rapid change towards "value-based" care models which require the incorporation of social needs and SDOH challenges contexts and frameworks to ensure that these programs equitably address the needs of minority and disadvantaged communities. Furthermore, it will be critical that clinical and social interventions are aligned, and that no financial disincentives are imposed on providers who disproportionately serve minority and disadvantaged patients. To address health disparities and provide equitable healthcare, applied research is needed to: (1) identify optimal solutions for the effective collection and application of social needs and SDOH information within EHRs; (2) link provider-based data to community-level data describing the characteristics of patients' neighborhoods; and (3) develop EHR- integrated CDS tools. Currently, many sources of social needs and SDOH challenges can be found within a typical EHR and some vendors have started adding specific data fields for collecting information on social needs and SDOH challenges. However, no universally accepted or standardized format exists for documenting social needs and SDOH information. Furthermore, delivery systems can now take advantage of recent health information technology advances in offering automated integration of new sources of relevant social needs and SDOH information.

Study Goals

The overarching goal of this project is to leverage health information technology (HIT) to integrate available digital information on social needs to improve care for racial and ethnic minorities and socially disadvantaged populations with chronic diseases. In the previous phases of this project, we developed a social risk score to identify medically underserved patients with a higher probability of having social needs (JHSPH IRB #00014124). We also developed a clinical decision support (CDS) tool in the Johns Hopkins Health System (JHHS) EHR to present the social risk score and other relevant data at the point of care to clinical providers (JHSPH IRB #00021084).

This phase of the project will run a randomized clinical trial (RCT) study to pilot test the new risk score and CDS tool in selected primary care clinics within JHHS and in collaboration with selected community-based organizations (CBOs) (JHSOM IRB #00354803). This system will help identify, manage, and refer patients with both high levels of disease burden and modifiable social needs.

Objectives

1. Implement the CDS tool developed with the support of the Technology Innovation Center at JHHS (TIC) team. The CDS tool will utilize TIC's pre-developed EHR tool (i.e., Patient Insight) and integrate it into the JHHS-EHR (EPIC). It will help provider teams in primary care clinics identify patients with social needs and refer patients to relevant CBOs.

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs
PI: Hatef and Weiner

2. Using RCT study design, assess the impact of the social risk score/CDS tool on care processes and patient outcomes compared to the standard of care in pilot primary care clinics at JHHS and collaborating CBOs in Baltimore City.
3. Evaluate the acceptability of the social risk score/ CDS tool and its impact on the clinical workflow, patient care, and HIT Data quality through interviews and focus groups of the care teams at the various pilot primary care clinics, Hopkins Community Connection (HCC) staff, CBO staff, and others to determine satisfaction of users, and identify any facilitators or barriers to using the risk score and CDS tool.

Study Team and Collaborating Sites

Coordinating Site - Center for Population Health Information Technology (CPHIT)

- Elham Hatef – Principal Investigator (ehatef1@jhu.edu)
- Jonathan Weiner – Co-Principal Investigator (jweiner1@jhu.edu)
- Tom Richards – Data Analyst (tom.richards@jhu.edu)
- Talan Zhang – Biostatistician (tzhang45@jhu.edu)
- ICTR Research Coordinator Team (Sofia Hail and Osamah Alsaadi) – Research Project Manager (shail1@jh.edu, oalsaad1@jhu.edu)
- Lauren Tansky – Administrative Coordinator (ltansky@jhu.edu)

Contact Information:

Elham Hatef, MD, MPH, FACPM
Center for Population Health IT, Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health
624 N. Broadway, Room 502, Baltimore, Maryland 21205
Office Phone: 443-287-2284
Email: ehatef1@jhu.edu

Primary Care Clinics

The CDS tool will be implemented in the following five pilot primary care clinics:

- General Internal Medicine, Johns Hopkins Outpatient Clinic (GIM-JHOC)
- General Internal Medicine, Green Spring Station (GIM-GSS) Clinic
- Johns Hopkins Community Physicians (JHCP) at Remington,
- East Baltimore Medical Center (EBMC)
- Comprehensive Care Practice (CCP) at Bayview

We have identified the following provider champions at each clinic. Provider champions are primary care physicians with interest and expertise in assessing and addressing social needs and SDOH challenges. The provider champion will be the liaison for the study in the clinic and will inform other providers about the study. We will also seek their feedback on the necessary changes in the digital and clinical workflow for this project to make it a better fit for the providers in the clinic:

- Gail Berkenblit M.D., Ph.D. at GIM-JHOC (gberken1@jhmi.edu)
- Samantha Pitts M.D., M.P.H. at GIM-GSS Clinic (spitts4@jhmi.edu)

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs
PI: Hatef and Weiner

- Kendrick Gwynn M.D., M.P.H. at JHCP-Remington Clinic (kgwynn3@jhmi.edu)
- Katherine Shaw M.D. at EBMC (kshaw17@jhmi.edu)
- Sophia Purekal M.D. at CCP (spureka1@jhmi.edu)

Hopkins Community Connection (HCC)

For this RCT we will work closely with the HCC team. HCC is a group of social workers, community program coordinators, and patient navigators currently acting as a hub for social needs assessment, navigations services, and CBO referral at JHHS. Provider teams of different clinics across JHHS can refer their patients to HCC for further assessment of their social needs. We have identified the following HCC representatives as the study staff in each clinic;

- Natalia Camargo (ncamarg1@jhmi.edu), Jane Min (jmin17@jhu.edu), Caitlyn Ramdat (cramdat1@jhu.edu), and Arit Dogiparthi (adogipa1@jhu.edu) at GIM-JHOC
- Kristen Foreman (kforema2@jh.edu) and Zanya Jamieson (zjamies1@jhu.edu) at CCP, GIM-GSS Clinic, and JHCP-Remington Clinic
- Grace Goldman (ggoldm10@jhu.edu), Dalia Shawgi (dshawgi1@jhu.edu), Hanna Wu (wwu57@jhu.edu), and Jeremy Gu (jgu22@jhu.edu) at EBMC

We will also work with the HCC program manager Kristin Topel (ktopel1@jhmi.edu).

Community-Based Organizations

We have identified the following CBOs in Baltimore City, which are mostly equipped to address 3 major categories of social needs; residential instability, food insecurity, and transportation issues;

- Green & Health Homes Initiative: Ruth Ann Norton (ranorton@ghhi.org)

Works to create healthy homes and healthy lives with programs including reducing lead poisoning, asthma, and injury in low-income housing areas while improving energy efficiency in houses in Maryland.

- Civic works: Molly Wisniewsk (mwisniewsk@civicworks.com)

Strengthens Baltimore's communities through education, skills development, and community service.

- Moveable Feast: Sam Zisow-McClean (smcclean@mfeast.org)

Prepares and delivers medically tailored food to those who suffer from food insecurity and experience health-related issues due to this insecurity.

- Meals on Wheels of Central MD: Stephanie Archer-Smith (archersmith@mowcm.org) and Margo Coruzzi (coruzzi@mowcm.org)

Provides home-delivered meals and grocery assistance to eligible homebound Maryland residents.

- Action in Maturity: Laura Bristow (lbristow@actioninmaturity.org)

Offers senior-friendly and accessible transportation services across Baltimore City.

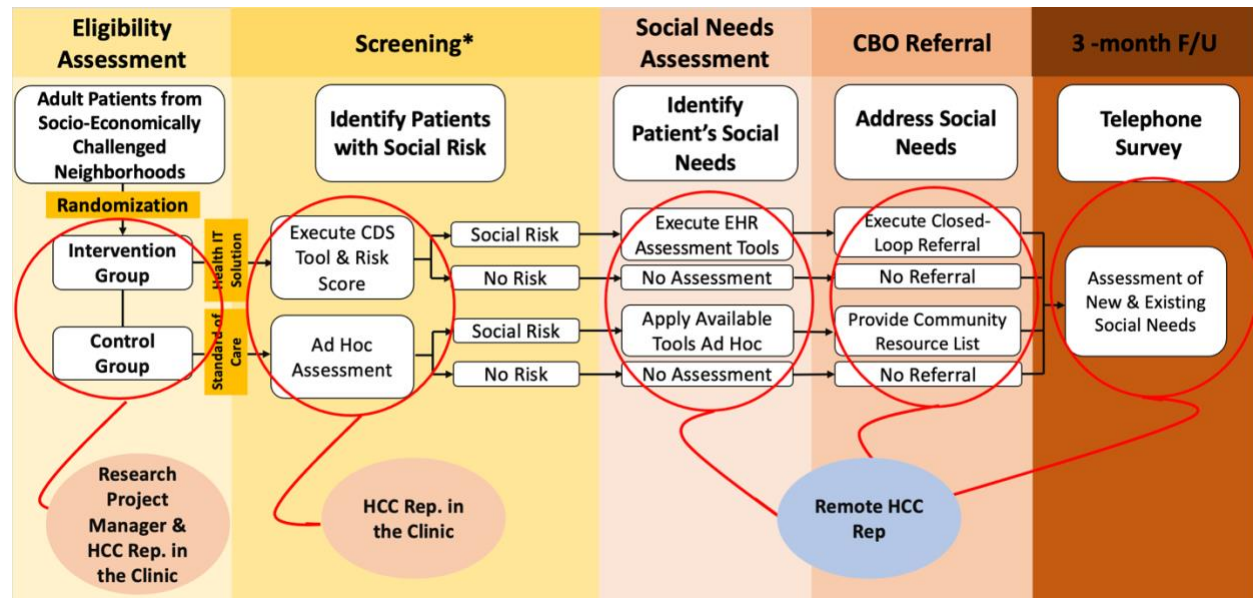
RCT Study Procedure

Study Overview

Figure 1 presents an overview of the RCT. In the following sections, we provide more details on each step of the process. The timing of the project is approximately 2 years. Patient enrollment will be conducted over 18 months, starting in June 2023. We may continue patient enrollment until the end of the grant cycle (March 2025) to reach the planned sample size.

Patient Enrollment - Identifying Eligible Patients

Figure 1. An Overview of the NIMHD-Randomized Clinical Trial to Identify and Refer Patients with Social Needs



CBO: Community-Based Organization, CDS: Clinical Decision Support, HCC: Hopkins Community Connection, EHR: Electronic Health Record, SDOH: Social Determinants of Health

To identify eligible patients, we will use the following inclusion/exclusion criteria:

Inclusion Criteria:

- Adult (18+ years old)
- Low income

First-generation immigrants may be non-English speaking and will be eligible for enrollment. The JHHS-EHR does not contain data on patients' income. Therefore, we will consider enrollment in Medicaid and living in a neighborhood with a high poverty level as proxies for low income. We will use the patient's address in the EHR to identify their neighborhood of residence and use the area deprivation index (ADI), a population-level composite measure that ranks the neighborhoods based on their poverty level, using data from U.S. Census American Community Survey (ACS). The ADI is currently calculated for all individuals in JHHS-EHR. We will consider ADI at the 80th percentile as a proxy for the most deprived neighborhoods.

Exclusion Criteria:

- Children

- Individuals with high levels of income
- Patients who have an HCC care team member assigned to them with a start date within the last 90 days and no end date

Every week, the data analyst (Tom Richards) will use the above inclusion/exclusion criteria and identify eligible patients who will have primary care appointments in 3 weeks in one of the pilot primary care clinics. The data analyst will have another list of eligible patients with a newly scheduled appointment (new refers to scheduled appointment after generated list 3 weeks before the appointment) and will identify those patients during the weekend before their appointments. The data analyst will share the list of eligible patients with the study team through OneDrive in a folder called NIMHD Recruitment Lists, Weekly Eligibility List. There will be an Excel sheet for each clinic each week (tagged with the name of the clinic) and an Excel sheet with all patients across clinics. The project manager will upload the list on REDCap (this list will be used for randomization assignment) and also add the weekly eligibility list to the enrollment list (Excel sheet on OneDrive called *Enrollment List*) to complete the outreach and documentation. After patients consent to participate in the study, they will be moved from this *Enrollment List* to the list of consented patients (Excel sheet on OneDrive called *Consent Patients Activities*) to document additional information.

The MyChart team at the Institute for Clinical and Translational Research (ICTR) will use MyChart as a tool for reaching out to eligible patients. During the patient enrollment period, the MyChart team will use the list generated by the data analyst to send a message to eligible patients to inform them about the project and to provide background information on the project. If patients agree to participate in the study, the research program manager will contact them to complete the consent process. The MyChart team will use the weekly list on the SAFE desktop folder called *CPHIT_NIMHD_MYCHART* uploaded by the data analyst to send the MyChart messages. The project manager will check the REDCap weekly to identify patients who agreed to participate in the study and will reach out to them by phone to complete the consenting process.

For patients who do not have an active MyChart account, the research project manager will reach out to them via email and paper mail to ask permission to contact them by phone. Printing and mailing of the outreach material will be outsourced to a company outside of Johns Hopkins. We have identified a company (House of Printing Inc.) with HIPAA-compliant servers. The data analyst will upload a weekly list of eligible patients' names and addresses on the company server for them to send the recruitment packages via US mail. The research program manager will contact patients who do not opt out to inform them of the study, provide information and obtain consent. Patients will be contacted approximately 1-2 weeks before their primary care appointment and consent will be acquired via email, fax, or paper mail. The research project manager will use the Excel sheet on OneDrive called *Enrollment List* and identify patients for calling using the information in the column called *Call due date*. They will then share the list of consented patients with HCC representatives in each clinic weekly.

For all eligible patients who have appointments during that week, the research project manager will contact providers via secure messaging in EPIC before their visit and inform them about the patient's eligibility for our study. The providers inform the patients about the study and if patients agree to participate will communicate this information with the project manager via secure

messaging. A one-page information sheet containing a summary of the project along with the contact information of the project manager will be added to the visit summary. This process will be completed using an Epic Smart Phrase (.NIMHDRCTPATLETTER) to populate a prefilled form containing all the necessary information. This one-page letter will be printed at the clinic or sent via email or MyChart to the patient.

We will also have a one-page graphic document summarizing the study process, which will be printed and distributed at the clinics and given to providers to hand out to interested patients. It will also be included at the end of the Smart Phrase. This document will contain a short summary of the steps involved in the study along with pictures for better comprehension. The templates used for the Smart Phrase, staff message, and flyer are included in the appendix.

We will use a OneDrive folder to share the ongoing list of eligible patients with different members of the study team (e.g., research project manager, MyChart team, and HCC representatives in primary care clinics).

Consenting Process

We will be using both teleconsent and in-person consent when possible to obtain informed consent from eligible participants. Teleconsenting will be done by DocuSign by the research project manager and in-person consent will be done by the research staff at the clinics.

We will use DocuSign, the Institution's approved and 21 CFR Part 11-compliant software, to obtain a secure electronic signature. We will use the IRB-approved consent form(s) as the base for the DocuSign template. The IRB-approved document will not be altered other than to overlay locations where signatures, initials, dates, or other DocuSign fields will be added to create the study-specific DocuSign template.

We will send the consent to the participant via DocuSign, providing a participant-specific code in advance of sending the document via DocuSign, which will be required when the participant accesses and signs the consent. The consent discussion may take place via phone or video conference (e.g. Zoom). Participants will be given adequate time to consider the research study and ask questions before signing the consent form. When ready to sign, the participant will enter their code, verifying that the person signing the consent is the person that we spoke with previously, and sign the consent within the DocuSign system. Once the participant has electronically signed, the research project manager obtaining informed consent will be notified that the electronic form is ready for his or her signature. Once signing is completed by all parties, both the research project manager and the participant can download the signed consent as a PDF. The research project manager will also have access to the audit log and the Certificate of Completion. They will then load the signed consent into Epic.

For in-person consenting, the following process will be used:

For patients who have not completed the consenting process through the method described above, in-person consenting will be done by the research staff present in the clinic (HCC staff) if patients indicate their desire to be enrolled in the study. The IRB-approved consent designees at the clinic will consent eligible participants who desire to be enrolled in the study and will inform the research project manager once consent has been obtained. Participants will be given

adequate time to consider the research study and ask questions before signing the consent form. The participant or their legally authorized representative (LAR) will sign and date/time the informed consent document. A copy of the signed consent form will be given to the patient and the informed consent documents will be sent to the research project manager for filing.

A physician/mid-level provider consent is not required for this study. After the Informed Consent process is completed, the IRB-approved study team member files the consent document in EPIC, including a note confirming the consent process. The entire consent document is also then filed in the research record.

For individuals participating in the focus groups to evaluate the acceptability of the CDS Tool consent will be done at the time of the focus group. The eligible individuals will receive information about the study via email before the day of their focus group. On the day of the focus group, they will be asked to orally consent to participate before the recording starts. The consent will be obtained over a video conference at the beginning of the virtual focus groups.

Patient Enrollment - Randomization

Our team has worked with the JHU-REDCap team to generate a randomization list for this study using stratified blocked sampling for each pilot primary care clinic. The computer-generated list will be available via a link to the JHU-REDCap website. The users of the REDCap website are required to enter their JHID to receive the assignment. The randomization will be completed for each participant after they complete the consent process. On the day of an eligible patient's visit, the research project manager will monitor the patient's arrival in the clinic through EPIC, and when the patient gets to the clinic the research project manager will use the REDCap randomization list to receive the randomization assignment for each patient and to record the patient's name and/or ID with their assigned group (i.e., intervention or control arm). The research project manager will communicate the randomization assignment with the HCC representative in the clinic through Epic secure messaging.

Planned Intervention

Once consented to and randomized into the intervention or the control arms, patients will be seen at their regularly scheduled visit to the clinic.

Intervention arm: For patients in the intervention arm the HCC representative in each clinic will use the CDS tool to review their social risk score. If the patient is identified as with medium to high social needs based on the risk score and other information provided in the CDS tool, the HCC staff will refer them to HCC remote staff for further in-depth assessment of their social needs. For patients with low risk, the HCC representative will review the social needs history and other items depicted in the tool and decide to refer or not based on their judgement. An explanation sheet is provided to HCC representatives as guide to all the details depicted in the CDS tool in order to help with their decision making. This explanation sheet can be found in the appendix. If the HCC representative decides to screen the patient, they will also leave a secure message for the clinical provider in the EHR, informing them about the risk score and the decision about a referral to HCC. The clinical provider will have the option of checking the risk score on the CDS tool and the summary of patients' previous social needs and other factors contributing to the social risk score.

The remote HCC staff will reach out to the patients over the phone and will perform an in-depth assessment of their social needs. This may be done on the day of the appointment or after the appointment. If any social needs are identified and the patient agrees to address those needs the HCC staff will refer the patient to CBOs. HCC uses FindHelp, a Health Insurance Portability and Accountability ACT (HIPAA) compliant database and referral platform for social needs, both for communications with provider teams (i.e., receiving patients with social needs for further assessment from provider teams in the pilot clinics) and with CBOs (i.e., referring patients with social needs to CBOs). We are working with a few CBOs in Baltimore City including “Green & Health Home Initiative”, “Moveable Feast”, “Meals on Wheels”, “Civic Works”, and “Action in Maturity” in this study, which are mostly equipped to address 3 major categories of social needs; residential instability, food insecurity, and transportation issues.

Depending on the type of social needs identified by the HCC staff we may consider engaging other CBOs that HCC is currently working with. After an in-depth assessment of the social needs the HCC staff will generate a summary report through FindHelp and alert the CBOs about the referred patients. CBOs will also have access to FindHelp and can review patients’ social needs assessment and summary reports. After meeting with the referred patient and identifying resources to address their social needs, CBOs generate a summary report, which will be accessible by HCC.

Control arm: The control arm of the study will be provided with the standard-of-care screening, assessing, and addressing of social needs. The assessment will not be automated with pre-collected information as is designed in our CDS tool. The assessment will be on an ad-hoc basis, which may include completing currently available social needs screening tools in the clinics and providing information to the patients about available community-based resources.

Follow-up: For patients in the intervention arm of the study who get screened by HCC, after their case has been closed (approximately 3 months after enrollment), the staff at HCC will conduct a telephone survey with the patients enrolled in the study to assess whether the social needs still exist, to what degree their needs were met, and satisfaction with the process for identifying and addressing the social needs as well as with the services they received. In addition to the telephone survey, we will conduct a secondary data analysis to assess the impact of the CDS tool and referral system.

Sample Size

We plan to enroll approximately 295 patients in each study arm. The calculation is based on addressing the primary outcome of the study, namely the change in the number of social needs identified during the visit at 3 months follow-up telephone survey compared to the baseline visit. Such a sample will provide 80% power in 2-sided tests with a type I error rate of 5% to detect standardized small effect sizes (Cohen d range, 0.17-0.20 as an estimated in similar studies of SDOH screenings and referral). Sample size estimates conservatively account for a 20% loss to follow-up.

Analysis plan

We will assess the impact of the CDS tool on care processes and short-term outcomes of care. Some outcomes we expect to assess: (1) change in the number of social needs identified during

the visit at the 3-month follow-up telephone survey compared to the baseline visit, (2) difference in the number of patients with social needs identified in the control and intervention groups. We will compare the number of patients in the intervention arm identified by using the CDS tool, risk score, and completed HCC assessment tools to the control arm whose social needs were identified through standard-of-care (clinical judgment of primary care providers using existing tools), (3) difference in the number of patients with social needs who receive services at a CBO, and (4) Change in the number of hospitalization events and emergency department (ED) visits between intervention and control arms.

Usability and Acceptability Assessment - Study Procedure

Participant Enrollment for Focus Groups

After the completion of the RCT, the study team will conduct an evaluation of the CDS and referral system from a health system perspective. We will conduct focus groups/interviews with provider teams such as physicians, nurses, social workers/ care managers/ community program coordinators or patient navigators in the clinic and at HCC, and staff of CBOs to determine the satisfaction of the users with the tool, determine if there are any facilitators or barriers to using the risk score, CDS tool, and closed loop referral, and generate ideas on who to improve the tools.

Our research program manager will identify individuals who interacted with our CDS tool in each pilot clinic, HCC, and CBOs and invite them to join the focus groups. We will work with the provider champion at each clinic site to inform other provider teams about the focus groups and invite them to the study. We will also work with the HCC program manager (Kristin Topel) and the CBO representatives (members of our advisory board) to identify qualified individuals for the focus groups. We will use a convenience sampling method to select and enroll qualified individuals.

Conducting Focus Groups

The focus groups will be 90 minutes each. Participants will be invited via email to join a focus group at a convenient date and time for their schedule and will be consented to this part of the study on the day of the meeting. The email will provide a summary of the study and the purpose of the focus group, the date/time, and duration of the focus group, as well as the contact information of the study PI (Principal Investigator) and the research program manager to answer any questions of the potential participants before they agree to participate. The focus groups will be conducted under the supervision of the study PI (Dr. Elham Hatef) and study co-investigators with expertise in qualitative research. Participants in the focus groups will be asked a variety of questions on their interaction with the tools, their perception of how it fits within the workflow, their satisfaction with the tool, and how it can be improved. Focus groups will be recorded using the automated transcription service via Zoom to transcribe the focus groups and allow the research team to analyze and review notes.

Sample Size

We aim to enroll and engage a variety of clinical providers (e.g., physicians and nurses), social workers/ care managers/ community program coordinators or patient navigators in pilot clinics and at HCC, and CBO staff in this aim. We will attempt to conduct six 90-minute meetings for 6 months to collect input on the potential challenges in the implementation and use of the CDS tool.

We hope to have 6-10 individuals at each meeting for a total of 36-60 individuals from a variety of positions within the health system.

Data Management Plan

We will convene a Data and Safety Monitoring Board (DSMB) to safeguard the interests of study participants, assuring safety and adherence to human subjects' protection policies, and for monitoring the overall conduct of the study. The following details are intended to be a living document. The DSMB may wish to review them at regular intervals to determine whether any changes in procedure are needed.

Responsibilities of the DSMB

The DSMB is an independent group advisory to the project PIs, Dr. Elham Hatef and Dr. Jonathan Weiner, and is required to review the safety of study participants during the study and provide recommendations on specific aspects of the research protocol as it pertains to safety, potential study alerts, and adverse events. In addition, the DSMB is asked to make recommendations, as appropriate, to the study team about:

- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Amendments to the study protocol and consent forms
- Performance of individual clinics and community-based organizations
- Participant safety, and
- Notification of and referral for abnormal findings

Organization and Interactions

Communication with DSMB members will be primarily through the PIs. It is expected that other study investigators will not communicate with DSMB members about the study directly, except when making presentations or responding to questions at DSMB meetings or during conference calls.

DSMB Members

The DSMB is an independent multi-disciplinary group consisting of biostatistical, research, and clinical experts who collectively have experience in the conduct of clinical trials exploring the application of health information technology among minorities and vulnerable populations with social needs and social determinants of health challenges. The members will have no apparent conflict of interest with the study including financial, scientific, or regulatory. DSMB members will be responsible for advising the PIs of any changes in their relationship and/or financial interests that occur during the trial. The DSMB and PIs will be responsible for deciding whether these changes create a conflict of interest. Any DSMB member who develops a conflict of interest during the trial will be asked to resign from the DSMB and another person with similar areas of expertise will be sought. Otherwise, DSMB membership is to be for the duration of the trial.

Scheduling, Timing, and Organization of Meetings

The DSMB will meet twice annually throughout the study. DSMB meetings are usually held by remote connections. More frequent meetings or teleconferences may be held to review serious adverse events from the trial at the discretion of the DSMB. The first meeting's purpose is to review and discuss this Charter, provide an overview of study activities, review and make recommendations about the protocol, and determine the frequency of interim analyses.

At this meeting, the DSMB will agree on whether there should be interim analyses of efficacy endpoints and, if so, the stopping rules and interim analysis plan that avoids potentially biasing the investigative team. Modifications to protocols based on the DSMB review will be made before entering the field. At subsequent conference calls, the DSMB will review the progress of the study (accrual rate, protocol deviations, and interim study analyses if recommended) and make recommendations. A representative of the research team will keep the minutes of these meetings. A copy of the minutes approved by the DSMB will be shared with the IRB of Johns Hopkins Medicine. The minutes will include recommendations from the DSMB and be provided to the NIH after each meeting. Meetings of the DSMB will be open unless the DSMB requests otherwise. A closed meeting of the DSMB may be requested if it is deemed necessary to review efficacy data. The DSMB chair or designate will take meeting notes of closed sessions.

Recruitment, Adverse Events, and Alert Reports

Reports presented to the DSMB will include data on enrollment (study accrual by month; comparison of expected to actual enrollment; the number of individuals screened, number eligible and number ineligible, number randomized by gender), adverse events (AEs), and alerts. Also, the DSMB will receive reports of the number of study participants who discontinue the treatment group and/or the study and the reasons for discontinuation. Reports will be provided to the DSMB twice yearly. However, the DSMB will decide upon the schedule of reports at their first organizational meeting. Also, the DSMB may request reports as needed. For the first meeting of the DSMB, members will receive and review the following materials: (1) Grant proposal, relevant appendices, and reviewers' comments; (2) Standard Quality control procedures; (3) IRB-approved consent forms for Aim 2; (4) Shell of an electronic database for management of enrollment information; (5) Subject tracking forms; (6) Alerts and Adverse event procedures and forms; (7) Intervention documentation forms; (8) Shell for reporting recruitment and enrollment; (9) Data shells for reporting tracking information and baseline characteristics.

Adverse Event (AE) Reporting

The DSMB is notified by the PIs of any serious AE within 48 hours of initial notification to the project team. All members of the DSMB will receive copies of all safety reports at the time of submission to the IRB of Johns Hopkins Medicine. In addition, a listing of all AEs and their attribution (e.g., study-related, intervention-related, or unrelated to study or treatment) will be provided to the DSMB monthly. We do not anticipate any adverse reactions to the intervention. Based on our previous work and studies in this area by others, there is only a small risk for unintended consequences, such as social risk profiling that could lead to bias and stereotyping in the delivery of care to patients. To address this, the study team will incorporate patients' preferences into the use of the clinical decision tool and social risk score and will provide primary care physicians and clinic staff training on how to use this information in their communications with patients. There might be some ethical concerns about identifying social needs and social

determinants challenges beyond the 3 major categories we have specified in this study (i.e., housing issues, food insecurity, and transportation) without addressing them. We refer to such events as alerts and have well-developed procedures for their management. All alerts are reported to the DSMB on a biannual basis. However, the reporting of alerts to the IRB of Johns Hopkins Medicine is not required (see the Chart below of potential alert events and plan for their management and reporting).

Plan for Reporting Unanticipated Problems or Study Deviations

There are only minimal risks associated with the trial. It is anticipated that participants will experience more benefits than risks from their participation in the trial. Details about specific alerts and actions taken are found in **Table 1**.

Table 1. Specific Alerts and Actions Taken	
Alert	Action Taken
Suicidal ideation, threats to hurt self	If a research staff (i.e., HCC representative) encounters a situation in which the person threatens to hurt themselves immediately, then the physician at the clinic site is informed and the person is referred to the emergency department for observation and psychiatry consult. If the person is not an immediate threat to self, then the physician at the clinic site is informed and the person is actively encouraged to make a psychiatry appointment, and/or the contact is made for the person if they choose. The research staff also informs the person that a member of the research team will be contacting him/her shortly to follow up. Immediately after the visit, the PIs will be notified of the situation. The PIs complete the Alert form and give the form to the study project manager (or designate) for filing.
Evidence of Abuse and intimate partner violence	Evidence of physical abuse is as follows: • Participant states to research staff that abuse occurs; • Research staff observes physical evidence (e.g., black eye, black and blue marks on arms/legs) Research staff member informs physician at the clinic site. The physician obtains further information from the participant and will contact Adult Protective Services. Immediately after the visit, the PIs will be notified of the situation. The PIs complete the Alert form and give the form to the study project manager (or designate) for filing. Note: The possibility of informing an agency about an abusive situation is stated in the informed consent.
<i>PI: Principal investigator, RC: Research Coordinator, HCC: Hopkins Community Connections.</i>	

Appendix

MyChart Communication Content



Hello,

In addition to providing high-quality medical care, Johns Hopkins supports research to improve health.

I am writing to you about a research program that may be of interest to you. This program wants to *identify people who might have needs such as food problems, housing issues, and lack of transportation services to attend medical appointments and help them get connected to community-based social services organizations to help with their needs.*

A computer search of information in the Johns Hopkins medical records found you might be eligible for this study. Specifically, we are looking to identify adults (18+ years old) 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.

If you agree to join this study, clinic staff may contact you to talk to you about some of your needs and to connect you to community-based social services. About 3 months after your doctor's visit, you will have a 30-minute phone call to talk about your experience with this research program and how your needs were addressed. **After completion of the interview, you will receive a \$20 gift card for your participation.**

Participation in this study is voluntary. If you decide not to be part of this study, it will not change the medical care you receive.

If you are interested in participating, please complete this brief survey and a member of our research team will contact you. [\[here will be inserted a unique REDCap study-specific link for tracking participant interest and follow-up\]](#)

Please feel free to contact our study team at shail1@jh.edu with any additional questions or concerns.

Sincerely,

Principal Investigator's Name: Elham Hatef, MD, MPH
IRB Number: 00354803

Daniel E. Ford, MD, MPH
Director, Institute for Clinical and Translational Research ICTR Research Recruitment Office

Participation in this study is voluntary. If you decide not to be part of the study, it will not change the medical care you receive. This message is not meant to be a diagnosis, and it may include information that does not pertain to your health. While we have tried our best to identify appropriate recipients, please accept our sincerest apologies if this message has reached you in error. If you would like to speak

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs
PI: Hatef and Weiner



Approved April 30, 2024

with one of our team members about this, please feel free to email [ehatef1@jhu.edu]. Thank you for your understanding.

You are receiving this message because you were identified by an automated computer search of information in the electronic medical record. For more information about how we protect your privacy and frequently asked questions (FAQs) related to research recruitment through MyChart, please visit <https://ictr.johnshopkins.edu/community-engagement/participate-in-clinical-research/mychart-messages>. To unsubscribe from all future MyChart research recruitment messages, please email research_recruitment@jhmi.edu. Provide feedback on MyChart messaging here: https://nursingjhu.qualtrics.com/jfe/form/SV_7V3vzTvDuAO5fwh

Recruitment email/letter content for Aim 2



Approved April 30, 2024

Hello,

In addition to providing high-quality medical care, Johns Hopkins supports research to improve health.

I am writing to you about a research program that may be of interest to you. This program wants to *identify people who might have needs such as food problems, housing issues, and lack of transportation services to attend medical appointments and help them get connected to community-based social services organizations to help with their needs.*

A computer search of information in the Johns Hopkins medical records found you might be eligible for this study. Specifically, we are looking to identify adults (18+ years old) 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.

If you agree to join this study, clinic staff may contact you to talk to you about some of your needs and to connect you to community-based social services. About 3 months after your doctor's visit, you will have a 30-minute phone call to talk about your experience with this research program and how your needs were addressed. **After completion of the interview, you will receive a \$20 gift card for your participation.**

Participation in this study is voluntary. If you decide not to be part of this study, it will not change the medical care you receive.

If you are not interested in participating, please send back the attached postcard indicating your desire to not be contacted by the study team. You can also send an email shail1@jh.edu or call 443-927-3004 and leave a message. If we do not hear back from you about opting out of future communications, one of our team members will then reach out to you by phone to set a call to discuss the study and provide more information.

Principal Investigator's Name: Elham Hatef, MD, MPH
IRB# 00354803

Please feel free to contact our study team with any additional questions or concerns.

Sincerely,

Elham Hatef, MD, MPH
IRB number

Recruitment email/letter content for Aim 3



Hello,

I am reaching out today regarding a research study that may be of interest to you. The purpose of this study is to evaluate satisfaction with a social risk score and the decision support tool we have developed to identify patients with social needs, assess their social needs, and refer them to community-based organizations, to determine any barriers to utilizing this tool, and provide thoughts on how to improve the tool and workflow.

You are being asked to participate in this study because you have been identified as a physician, nurse, social worker, care manager, community program coordinator, patient navigator in a primary care clinic and/or at Hopkins Community Connections, staff at a community-based organization, or other users of this social risk score and clinical decision support tool. If you agree to join this study, you will be invited to join a (virtual) focus group which will last about 90 minutes.

Participation is voluntary and none of your supervisors or co-workers will be informed about whether you have or have not elected not to participate.

If you are not interested in participating, please send back the attached postcard indicating your desire to not be contacted by the study team. You can also send an email to ehatef1@jhu.edu or call (410) 614-7409 and leave a message. If we do not hear back from you about opting out of future communications one of our team members will reach out to you by phone or email to provide more information on the study and the next steps to get involved in the study.

Please feel free to contact our study team with any additional questions or concerns.

Principal Investigator's Name: Elham Hatef, MD, MPH
IRB# 00354803

Sincerely,

Elham Hatef, MD, MPH
IRB Number

Recruitment Opt-out card



Approved July 11, 2023

Protocol Title: Piloting a clinical decision support tool to identify and refer patients with social needs to community-based organizations (IRB00354803)
Principle Investigator: Elham Hatef, MD, MPH
Document: PT Recruitment Opt-out
Date: April 20, 2023

OPT OUT CARD TO BE INCLUDED IN RECRUITMENT LETTER
IT WILL BE PLACED ON POSTCARD STOCK AND SELF-ADDRESSED AND
STAMPED FOR EASY RETURN TO STUDY TEAM
THE POSTCARD WILL LIST THE PATIENT STUDY ID (NOT THEIR NAME)

Now is not a good time but I am interested in learning more. **Please call me after:** _____ **(date)**

OR

Please do not call me to further describe the study at this time because:

I am too busy.

Sounds like too much trouble.

I am too sick/tired.

Other reason: _____

Identifying and referring patients with social needs to community-based organizations (IRB00354803)
(PARTICIPANT ID#)

Epic Smart Phrase Template document



Epic Smart Phrase Template document

Dear [Participant's name],

I am writing to you about a research program that may be of interest to you. This program wants to *identify people who might have needs such as food problems, housing issues, and lack of transportation services to attend medical appointments and help them get connected to community-based social services organizations to help with their needs.*

A computer search of information in the Johns Hopkins medical records found you might be eligible for this study. Specifically, we are looking to identify adults (18+ years old) 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.

Participation: Participation in this project is voluntary. If you decide not to be part of this project, it will not change the medical care you receive. If you are interested in participating in this project, please contact our project manager, Sofia Hail, by phone or text at 443-927-3004 or by email at shail1@jh.edu to receive additional information about the project.

Project Process: If you agree to join this project a member of your provider team may contact you to assess your social needs and may refer you to a community-based social services organization to address those needs. About 3 months after your doctor's visit, you will have a 30-minute phone interview.

Confidentiality and Data Protection: Your personal information and data collected during the project will be kept strictly confidential, adhering to all applicable laws and regulations. Any data shared will be used only for research purposes and reported without any personal identifying information.

Impact: By participating in this project, you have the opportunity to contribute to the advancement of medical research and help shape future interventions designed to support individuals facing social challenges in our community.

Benefits: There is no cost to participating in this project and any social services provided in this study will be covered. **You will also receive a \$20 gift card for complete participation in this project.**

We value your consideration and potential participation in our project. Should you have any questions or require further information, please do not hesitate to reach out to us.

Thank you for your time and support.

Sincerely,

Elham Hatef, MD, MPH (Project Lead Investigator)

Johns Hopkins University

Project Contact information:
Phone: 443-927-3004

Graphic Summary

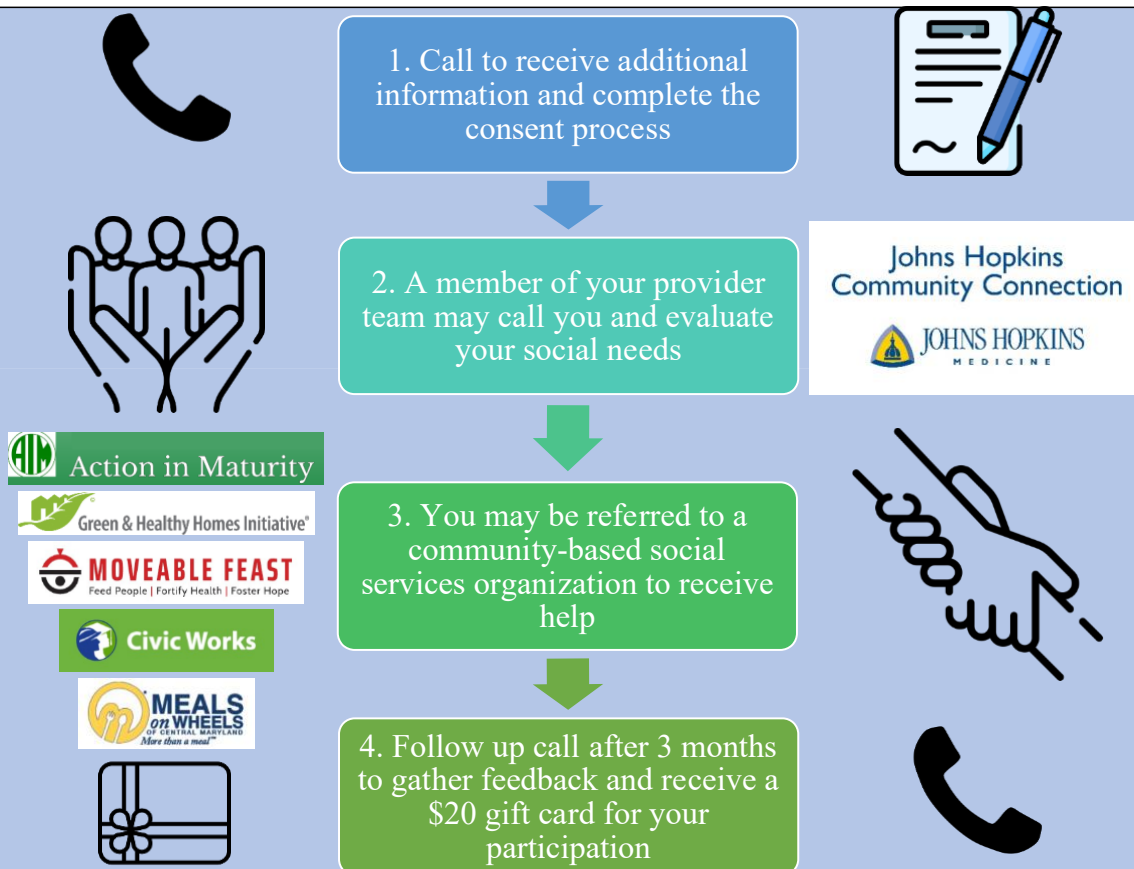


**Participants needed for a research program
about social needs such as food problems,
housing issues, and lack of transportation
services to attend medical appointments**

Who can join? If you are:

- Adult (18+ years old)
- Living in a neighborhood in Baltimore City with some challenges such as a lack of healthy food or public transportation.

You may qualify to join this research. If you are interested, you can call or text 443-927-3004 or send an email to shail1@jh.edu. The steps involved are depicted below:



No extra visits are required in this research!

Staff Messaging Template

Dear Dr [PCP name],

I am reaching out in connection with an ongoing research study on social needs screening and intervention. You may recall receiving an email about it from Dr. [Provider Champion name].

I'd like to inform you that your patient [name], has been identified as eligible to participate in the study. Their scheduled appointment is set for [Date] at [Time] in [Department]. We kindly request you notify the patient about this opportunity and add the Smart Phrase ".NIMHDRCTPATLETTER" to their visit summary if they express interest in participating. We will then take care of all study-related activities.

If possible please inform us about the patient's desire to NOT be contacted by the study team.

Thank you very much for your time and consideration.

Research Program Manager

Telephone Screening Script for Aim 2



Approved April 30, 2024

Date: April 30, 2024
Principal Investigator: Elham Hatef
Application No.: IRB00354803

Telephone Screening Script

Protocol Title: Piloting a clinical decision support tool to identify and refer patients with social needs to community-based organizations

Hello, my name is ____ *will add the name of the Research Program Manager* ____ from the Department of Health Policy and Management at Johns Hopkins.

- I am contacting you because you called (or emailed) and left a message in response to one of our ads.; or
- We are following up on the email/letter we previously sent you about our research.

Our research program is related to screening and referral for patients with social needs such as food problems, housing issues, and lack of transportation services to attend medical appointments. A computer search of information in the Johns Hopkins medical records found you might be eligible for this study. Specifically, we are looking to identify adults (18+ years old) 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.

We are working on a Johns Hopkins-approved research program about identifying patients with social needs and helping them to get connected to community-based social services organizations to address their needs.

Involvement in this program does not require any extra visits with your doctors. The involvement requires attending a regularly scheduled appointment with your primary care physician, a 30-minute telephone assessment of your potential social needs (such as food insecurity, lack of housing, and lack of transportation services to attend medical appointments), and a referral to a community-based organization (such as a food bank or housing services) to address your need. It also requires attending another follow-up call of about 30 min 3 months later. You will receive a \$20 gift card for complete participation in our program.

Your taking part in this phone call is completely voluntary. May I ask you a few questions to help determine if you may qualify for the program?

If person says “No,” will thank the person for his/her time and politely end call.

I will be collecting information about you during this phone call. Before I ask you the screening questions, I would like to tell you about what we will be doing with the information you give us.

Whether you join the program or not, the information collected today may be seen by researchers at Johns Hopkins, any sponsor of the program, and those responsible for oversight of the program. We try to make sure that the information we collect from you is kept private and used only for the research program we are discussing. If you do not agree to continue the phone call, it will not affect your current or future care at Johns Hopkins.

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs

PI: Hatef and Weiner



Date: April 30, 2024
Principal Investigator: Elham Hatef
Application No.: IRB00354803

Your personal information will not be kept if you choose not to enroll in the program or if you do not qualify to be in the program.

I have a few questions for you;

Which race/ethnicity do you identify as?

How old are you?

Have you had an appointment at a Johns Hopkins facility in the past year?

Which neighborhood in Baltimore City or county do you live in?

We have completed the telephone screening portion of our call.

- Do you have any questions?
- Do you think you would like to take part in this research?

If you are interested in participating I would like to provide more information on the program, answer your questions, and review the consent document that you received from our team. You can then sign and date/time the consent document during this call, send a photo of the signed consent document to me, or verbally confirm that you signed the form. You will then need to mail, email or fax the document to our team. Please return the original signed document on the day of your next regular appointment with your primary care physician. Alternatively, I can send you the consent form electronically to sign. This will happen through DocuSign and the consent document will be sent via email. On the day of your next regular appointment with your primary care physician, one member of the clinic team will reach out to you to enroll you in the program.

Please feel free to contact our program team at shail1@jh.edu with any additional questions or concerns.

Telephone Screening Script for Aim 3



Date: April 2, 2023
Principal Investigator: Elham Hatef
Application No.: IRB00354803

Telephone Screening Script

Protocol Title: Piloting a clinical decision support tool to identify and refer patients with social needs to community-based organizations

Hello, my name is ____ *will add the name of the Research Program Manager* ____ from the department of Health Policy and Management at Johns Hopkins.

- I am contacting you because you called (or emailed) and left a message in response to one of our ads.; or
- We are following-up on the email/letter we previously sent you about our research.

Our research study is related to screening and referral for patients with social needs. You are being asked to participate in this study because you have been identified as physician, nurse, social worker, care manager, community program coordinator, patient navigator in a primary care clinic and/or at Hopkins Community Connections, staff at a community-based organization, or other users of this social risk score and clinical decision support tool.

We are working on a Johns Hopkins-approved research study about evaluating the satisfaction with a social risk score and the decision support tool we have developed to identify patients with social needs, assess their social needs, and refer them to community-based organizations, to determine any barriers to utilize this tool, and provide thoughts on how to improve the tool and workflow. Involvement in this study requires attending a virtual focus group which will take about 90 min.

Participation in the study is voluntary and none of your supervisors or co-workers will be informed about whether you have or have not elected not to participate.

Your taking part in this phone call is completely voluntary. May I ask you a few questions to help determine if you may qualify for the study?

If person says “No,” will thank the person for his/her time and politely end call.

I will be collecting information about you during this phone call. Before I ask you the screening questions, I would like to tell you about what we will be doing with the information you give us.

Whether you join the study or not, the information collected today may be seen by researchers at Johns Hopkins, any sponsor of the study, and those responsible for oversight of the study. We try to make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, it will not affect your current or future work at Johns Hopkins.

Your personal information will not be kept if you choose not to enroll in the study or if you do not qualify to be in the study.

Piloting a Clinical Decision Support Tool to Identify and Refer Patients with Social Needs to CBOs

PI: Hatef and Weiner



Date: April 2, 2023
Principal Investigator: Elham Hatef
Application No.: IRB00354803

I have a few questions for you;
Did you have access to our social risk score and decision support tool in the clinic?
How long did you have access to the tools?
How often did you use the risk score and the decision support tool? And in which capacity?

We have completed the telephone screening portion of our call.

- Do you have any questions?
- Do you think you would like to take part in this research?

If you are interested in participating I would like to schedule the focus group for you to attend.
On the day of your focus group you will be asked to agree with an oral consent form.

Please feel free to contact our study team at ehatef1@jhu.edu with any additional questions or concerns.