Title of Research Study: Community Intervention to Reduce Cardiovascular Disease in Chicago (CIRCL-Chicago)

Principal Investigator: Abel Kho, Justin Dean Smith, Paris Davis

Supported By: This research is supported by a Disparities Elimination through Coordinated Interventions to Prevent and Control Heart and Lung Disease Risk (DECIPHeR) award of the National Heart, Lung, And Blood Institute (NHLBI) of the National Institutes of Health (NIH) under Award Number UH3-HL154297.

Collaborating Institutions: The Community Organization Collaborators are Total Resource Community Development Organization (TRCDO)/ Pastors4PCOR. The Clinical Partners are ACCESS Community Health Network and Advocate Aurora Health. The Educational Organization Collaborators are Northwestern University, The University of Utah, and Vanderbilt University. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to identify more effective means for treating hypertension in your community.
- You will be asked to fill out some basic information about yourself and your health on our secure study website. We will also measure your blood pressure and collect other health information from your medical records. Once you have completed this information and have agreed to grant access to your medical records, we will use the data you provide to us to study ways to improve the way we reach and care for people with high blood pressure.
- We expect that you will be in this research study for one year with four virtual surveys and two in-person study visits.
- The primary potential risk of participation is increased time and attention spent on blood pressure can result in worry and stress. There is also a risk of a security breach that could lead to loss of privacy and confidentiality of your data.
- The main benefit of being in this study may include better control of blood pressure and knowledge about how to better manage blood pressure.

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.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have high blood pressure or hypertension and identifying more effective means for treating hypertension in your community.

How many people will be in this study?

We expect about 5670 people will be enrolled in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You do not have to answer any question you do not want to answer.

What happens if I say, "Yes, I want to be in this research?"

We invite you to take part in a research study, called Community Intervention to Reduce Cardiovascular Disease in Chicago (CIRCL-Chicago) at Northwestern University, which seeks to identify a more effective means of treating hypertension and reducing cardiovascular disease on the South Side of Chicago community. Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our study team members. You are welcome to talk to your family and friends about it and take your time to make your decision. If you decide you would like to participate, you must sign this form to show that you want to take part. Some of the essential information you will need to decide whether to participate in the research study has been outlined below.

If you agree to participate, you will be asked to fill out some basic information about yourself and your health on our secure study website. We will also measure your blood pressure and collect other health information from your medical records. We will ask you to sign a HIPAA Authorization form, to allow us access to these medical records. Once you have completed this information and have agreed to grant access to your medical records, we will use the data you provide to us to study ways to improve the way we reach and care for people with high blood pressure.

If you agree to take part in this study, your involvement will last approximately one year. You will be asked to come to a clinic or community setting two times to measure your blood pressure. Each study visit will take approximately 15-30 minutes.

You will be asked to complete four surveys over the course of the study: at the start of the study (baseline) and then 4 months, 8 months, and 12 months later. These surveys will be completed online or on a smartphone app. Each survey will take approximately 10-15 minutes to complete. The surveys will ask questions about your demographics, blood pressure and health, and your lifestyle and community.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include better control of blood pressure and knowledge about how to better manage blood pressure. However, there is no guarantee that you will benefit from being in this research.

The results of this research may improve the identification and treatment of high blood pressure and hypertension, particularly for African American adults living in the South Side of Chicago community.

Is there any way being in this study could be bad for me?

Participation in the study should not result in any increased physical risk. However, a few basic risks are present:

- Increased time and attention spent on blood pressure can result in worry and stress, especially if you don't have a good way of accessing a clinician to talk with.
- As with any electronic data collection, there is a risk of a security breach that could lead to loss of privacy and confidentiality of your data.

You will receive the results of your blood pressure measurements. You will not receive results from the surveys you answer as part of this research study.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern University, ACCESS Community HealthCare

Network, Advocate Aurora Health, or Total Resource Community Development Organization (TRCDO)/ Pastors4PCOR.

You can leave the research at any time and it will not be held against you.

If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used. The study investigators may take you out of the research study without your permission. A possible reason for this is that you do not have a medical diagnosis of high blood pressure or hypertension. If you do not want to participate, you will not lose any benefits to which you are otherwise entitled

How will the researchers protect my information?

Your research records that are reviewed, stored, and analyzed by our research team will be kept in secure, HIPAA-compliant cloud storage by the Eureka Platform. Developed with the National Institute of Health (NIH) funding, Eureka is a digital research platform and a non-profit resource based out of the University of California San Francisco. The platform helps build online medical or health-related research studies by making it easier to answer surveys and contribute data from apps, devices, and other sources.

While Eureka cannot provide an absolute data security guarantee, your information will be transmitted and stored using state-of-the-art security systems similar to those that protect websites used by banks and electronic health record systems.

Eureka will never sell, rent, or lease your data or identifying information or voluntarily share it without your permission. Eureka may share your data, without your name, location data, and other identifiers, with other qualified researchers so your data can be used for research studies. Eureka will not share your identity, location data, contact information, or any other identified data with any research studies without your permission. If you'd like to know more, please review the Privacy Policy here: https://www.ucsf.edu/website-privacy-policy.

The information we collect from you will be used for research. This information will be analyzed and results of these analyses may be presented at scientific conferences and published in scientific journals, as well as shared via community forums and publications. In the event of any presentation or publication resulting from the research, no personally identifiable information will be shared.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

Your identifiers might be removed from the information obtained as part of this research study. This unidentifiable information may be used for future research studies or shared with another investigator for future research studies without additional informed consent from you.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

Assessments, educational and/or clinically relevant research results, including individual research results, will not be disclosed to participants. Most tests done in research studies are only for research and have no clear meaning for healthcare. If the research results have meaning for your health, the researchers will not contact you to let you know what they have found.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping and for potential use in future research projects. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared.

Despite these measures, we cannot guarantee anonymity of your personal data.

The results of this study could be shared in articles and presentations but will not include any information that identifies you unless you give permission for the use of information that identifies you in articles and presentations.

Will I be paid or given anything for taking part in this study?

There could be indirect costs for participating in the study (e.g., parking, transportation costs, and typical costs associated with clinical visits). There could also be data charges for text messages sent from the Eureka research platform.
There is no payment or reimbursement for participating in this study.

HIPAA Authorization -- Permission to Use Personal Health Information For Research

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information including health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

All Information in a medical record

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of the study.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the University of Utah Institutional Review Board Office, the Northwestern University Institutional Review Board Office, and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases: Eureka, a Digital Research Platform through University of California San Francisco (UCSF). The following registry was developed with NIH funding and is designed to facilitate mobile and internet-based medical or health-related research for any interested investigator. The Eureka platform is designed for mobile research broadly defined as any research utilizing mobile applications (apps), sensors, connected devices, and/ or the Internet, or for investigators seeking to leverage technology to enhance the efficiency of human subject-based research. The Eureka platform includes an engaging participant-facing "front-end," a study management portal, a secure "back-end" for data storage and analyses, and a cohort of volunteers interested in contributing to research.
- Others:
    - The following individuals or organizations may also access, receive, or use your personal health information:
        - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
        - Other academic research centers we are working with:

- Vanderbilt University
- Community Organizations who are working with this study:
  - Advocate Aurora Health Care
  - ACCESS Community Health Network
  - Total Resource Community Development Organization (TRCDO)/Pastors4PCOR

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.
Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

This consent expires on August 31, 2028, a year following the end of the grant. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. The written revocation should include your signature and the signature of the person who witnessed you signing the revocation.

To revoke your authorization, write to:
PI Name: Dr. Abel Kho
Institution: Northwestern University
Department: Center for Health Information Partnerships (CHIP)
Address: 625 N. Michigan Avenue, 15th FL, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator Dr. Abel Kho at abel.kho@nm.org and Dr. Justin Dean Smith at JD.Smith@hsc.utah.edu.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu

Signature for Adult 18 or Older Capable of Providing Consent

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. ***I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.***

_____ _____
Signature of participant Date

_____
Printed name of participant

Signature for Witness of Consent Process

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process