Official Title: A feasibility study of a novel mHealth clinical decision support application to enable community health workers to manage hypertension with remote physician supervision

NCT number: NCT05479097

Document description: Study protocol

Document date: 10/2/2023

University of Wisconsin-Madison
MR IRB Application

Study # : 2022-0794

Principal Investigator:
Sean Duffy

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> A feasibility study of a novel mHealth clinical decision support application to enable community health workers to manage hypertension with remote physician supervision

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Sean Duffy

Type of Research Application

1. Type of Research Application

* Select one of the following: Full review

PI Information

1. Principal Investigator

PI : Sean Duffy

2. Primary Appointment

* Is the PI's primary appointment through the University of Wisconsin – Madison?

(•) **Yes** ( ) No

2.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
(•)	**Assistant Professor (CHS)**	**AS**	**A532050**	**SMPH/FAMILY MED/CLINIC WINGRA**

2.2. Appointment Not Found

[ ] Check if the appointment is not listed above.

Protocol Feasibility

School of Medicine and Public Health **policy 70.10** requires departments to assess and document the feasibility of non exempt human subjects research prior to IRB review.

SMPH departments are required to evaluate and confirm local capacity (e.g., qualified staff, adequate resources and facilities, sufficient patient

population) to warrant pursuit of a research study. Feasibility assessments help identify and address potential factors that can prevent or slow study execution.

Please see **https://ictr.wisc.edu/protocol-feasibility/** for guidance and to download the "Research Feasibility Attestation Form."

1. Research Feasibility Attestation Form

Upload the signed "Research Feasibility Attestation Form."

There are no items to display

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Mary Checovich	mary.checovich@fammed.wisc.edu
Taryn Valley	tmvalley@wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email
Valerie Aguilar	vaguilar@wisc.edu
Juan Aguirre	jjaguirre@wisc.edu
Ian Arthur	iarthur@wisc.edu
Alvaro Bermudez-Canete	bermudezcane@wisc.edu
Guanhua Chen	gchen25@wisc.edu
Pablo Nunez Perez	nunezperez@wisc.edu
Kaitlin Tetreault	tetreault2@wisc.edu
Elizabeth White	eawhite4@wisc.edu

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.

Mary Checovich

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?

(•) **Yes** ( ) No

2.1. Study Team Details

For each study team member below, click the Δ button and check the boxes to indicate that study team member's roles for this study. Note: Some study team members may not have any roles listed below.

Tell us which study team members will: recruit human subjects, obtain informed consent from human subjects, interact with human subjects, or perform cognitive assessments on human subjects.

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Valerie Aguilar			yes
Juan Aguirre			yes
Ian Arthur			yes
Alvaro Bermudez-Canete			
Mary Checovich			
Guanhua Chen			
Sean Duffy	yes	yes	yes
Pablo Nunez Perez			
Kaitlin Tetreault			
Taryn Valley			yes
Elizabeth White			

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

(•) **Yes** ( ) No

1.1. Funding Sources

For **federal funds**, pending sources may be listed if the grant has received a highly meritorious score. For example, an impact score of <30 is an indication of a highly meritorious NIH grant proposal. Receipt of a request for Just In Time (JIT) documentation is another indication of a highly meritorious proposal.

For **non-federal funds**, pending sources may be listed if you have confirmation from the sponsor that funding will be awarded due to merit AND the sponsor has a peer-review process.

For **industry**, do not select industry sponsors who are only providing drug/device OR only limited support for the study.

* Use this chooser to select each funding source administered through UW-Madison that will support this study or project.

Funding Source Details

View

PI Name	Duffy,Sean
Proposal ID	MSN245065
Award ID	MSN245065
Funding Title	mHealth to Enable Task Sharing for Hypertension Care in LMIC
Project ID	*No Value Entered*
Sponsor (Source)	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH
Sponsor Reference Number	1R21TW011891-01
Primary Sponsor	*No Value Entered*
Primary Sponsor Reference Number	*No Value Entered*
Federal	Yes
Status	Active
Start Date	8/10/2021
End Date	4/30/2026

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

○ Yes ◉ **No**

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and managed entities data below before answering the questions on this page.

The following study team members have not completed their OAR for the year:

Valerie Aguilar, Juan Aguirre, Ian Arthur, Alvaro Bermudez-Canete, Pablo Nunez Perez, Taryn Valley, Elizabeth White

*NOTE: Per **campus policy** all study team members must **submit an OAR** every year and keep it up to date.*

No study team members have any managed entities at this time.

1. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

Yes **No**

2. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

Yes **No**

3. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

Yes **No**

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**.

1. VA Status

* Does this study involve the Madison VA (Wm. S. Middleton VA Hospital); e.g., funding from the VA, conducted under VA appointment, use of VA facility, recruitment of veterans or use of their data or samples at the Madison VA?

Yes **No**

Scientific Review: PRMC & CRU

1. Cancer Related

* Is the scientific question of the protocol cancer related?

Yes **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

○ Yes ◉ **No**

4. Use of CRU

If the answer to this question is Yes, you must upload a copy of the CRU application to the Submit activity form.

* Will this study use the Clinical Research Unit (CRU)?

○ Yes ○ No

ClinicalTrials.gov Information

This page is designed to aid in identifying ClinicalTrials.gov registration requirements. Registration may be required by the FDA, NIH, or if you are planning to publish in a journal that follows International Committee of Medical Journal Editors (ICMJE) guidance. Please answer each question carefully.

UW-Madison has a free service available to assist you in registering your record with ClinicalTrials.gov. Contact **CT.gov_Help@clinicaltrials.wisc.edu** for more information.

For information on registration and results reporting requirements see our **KnowledgeBase page** or contact the Office of Research Compliance at **ClinicalTrials.gov_Support@research.wisc.edu**.

1. Study Intervention(s)

Prospective assignment means enrolling study subjects and collecting data on them in the future. It is a study not solely reliant on existing or retrospective data. It is not a requirement to have multiple groups or arms for a study to be considered prospectively assigned.

An **intervention** is any manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Any study that is not observational (where participants may receive a drug, device, medical procedure, or behavioral intervention as part of their standard clinical care) should be considered interventional. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

A **health-related biomedical or behavioral outcome** is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical status, behavioral status, or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

* Are subjects prospectively assigned by the protocol to any intervention(s) that are being evaluated for any health-related biomedical or behavioral outcomes?

○ Yes ◉ **No**

2. ClinicalTrials.gov Determinants

* Check the box(es) that apply to this study:

NIH funded, when registration is a required condition of the grant (consult your award letter or with your NIH Program Officer if unsure)

3. FDA or NIH Requirement

* Based on your responses, registration with ClinicalTrials.gov may be required by the FDA or NIH. Will UW-Madison (study team or service line support staff) register the study with ClinicalTrials.gov?

◉ **Yes** ○ No

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

Yes No

1.1. Describe Activities at Non-UW Locations

* Describe what activities will be occurring outside the UW/UW Health or Madison VA and at which locations.

> Recruitment of subjects and all study activities will occur in the rural communities of the municipality of San Lucas Tolimán at mobile clinics run by our Guatemalan partner, the San Lucas Mission (SLM).

2. Requesting UW Serve as IRB

Please note that you must consult with RELIANT before you submit a request for the UW to serve as the reviewing IRB for external sites or individuals. A consultation may be requested here.

* Are you requesting that UW Madison serve as the reviewing IRB for any external sites or individuals?

Yes No

2.1. External Entity Type

Sites with an IRB or FWA typically include universities and larger hospitals or health systems. A database of current FWAs and IRB registrations can be found here: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html

Individuals not affiliated with an entity with an IRB or FWA typically include people working with community organizations, schools, or non-profits.

* Indicate for which of the following you are requesting that UW Madison serve as the reviewing IRB.

Individuals not affiliated with an entity with an IRB or Federalwide Assurance (FWA)

3. Study Team Responsibilities

See: Study Team Responsibilities When UW Madison is Serving as the Reviewing IRB

* Do you confirm the study team has reviewed and will meet the responsibilities described in Study Team Responsibilities When UW Madison is Serving as the Reviewing IRB?

(•) **Yes** ( ) No

Reviewing IRB: Individuals

Use this page to list individuals for whom you are requesting UW Madison serve as the reviewing IRB. Individuals listed on this page should only be those unaffiliated with an entity with an IRB or Federalwide Assurance (FWA). Please contact the Reliance Team Reliance and Navigation Team (RELIANT) (irbreliance@wisc.edu) with any questions about who should be listed on this page.

1. External Individuals

Using the add button below, list each individual for whom UW Madison will serve as IRB of record.

Full Name	Organizational Affiliation	Identify Recruit Subjects	Interact With Subjects	Obtain Informed Consent	Other	Human Subjects Training	Good Clinical Practice Training	Training Docu

Olga Ajcalon	San Lucas Mission	yes	yes	yes	Training and supervision of community health workers	11/24/2024	2022-0794_Ajcalon_
Audelina Alvarez	San Lucas Mission	yes	yes	yes		6/16/2026	Audelina Alvar
Miriam Marisol Alvarez	San Lucas Mission	yes	yes	yes		11/10/2024	Miriam Alvarez
Carmen Castro Calabay	San Lucas Mission	yes	yes	yes		7/26/2025	Carmen Castro 2.pdf(0.01)
Cesia Castro Chuta	San Lucas Mission	yes	yes	yes	Training and supervision of community health workers	11/24/2024	2022-0794_CastroCh
Alejandro Chavez	independent contractor	no	no	no	Mobile application design, community health worker training, technical support and troubleshooting	6/13/2024	Acuerdo de In Alejandro.pdf(
Alejandro Chavez	independent contractor	no	no	no	Mobile application design, community health worker training, technical support and troubleshooting	6/13/2024	Alejandro Chav 2021.pdf(0.01
Guisela Coche Castro	San Lucas Mission	yes	yes	yes		11/11/2024	Guisela Coche
Maria Elena Coraxon	San Lucas Mission	yes	yes	yes		7/26/2025	Maria Elena Co
Martha Coz	San Lucas Mission	yes	yes	yes		7/26/2025	Martha Coz IIA
Amparo Rita Culan Pérez	San Lucas Mission	yes	yes	yes		7/26/2025	Amparo Rita C
Alma Veronica Florian	San Lucas Mission	yes	yes	yes		11/10/2024	Alma Veronica
Silvia Esperanza Garcia	San Lucas Mission	yes	yes	yes		11/10/2024	Silvia Garcia II
Samuel Gonzales	San Lucas Mission	yes	yes	yes		7/26/2025	Samuel Gonzal
Magaly Guarcas Batzibal	San Lucas Mission	yes	yes	yes		6/16/2026	Magaly Guarca

Dora Maribel Hernandez Perez	San Lucas Mission	yes	yes	yes	11/10/2024	Dora Hernande
Clavelina Leon	San Lucas Mission	yes	yes	yes	6/16/2026	Clavelina Leon
Yoselin Emelina Letona Lopez	San Lucas Mission	yes	yes	yes	5/27/2025	Yoselin Letona
Ana Teresa Lopez Martin	San Lucas Mission	yes	yes	yes	7/26/2025	Ana Lopez Mar
Jose Vicente Macario	San Lucas Mission	yes	yes	yes	11/24/2024	2022-0794_Macario_
Romelia Macario Cosigua	San Lucas Mission	yes	yes	yes	7/26/2025	Romelia Macar
Renato Martin Perez	San Lucas Mission	yes	yes	yes	7/26/2025	Renato Martin
Blanca Meijia Xamba	San Lucas Mission	yes	yes	yes	6/16/2026	Blanca Meijia X
Clara Culan Perez	San Lucas Mission	yes	yes	yes	11/10/2024	Clara Perez IIA
Sonia Perez	San Lucas Mission	yes	yes	yes	11/24/2024	Sonia Perez IIA
Roxana Pilo Lopez	San Lucas Mission	yes	yes	yes	6/16/2026	Roxana Pilo Lo
Ingrid Recinos	San Lucas Mission	yes	yes	yes	3/2/2026	Ingrid Maribel
Abelino Sabuc	San Lucas Mission	yes	yes	yes	7/26/2025	Abelino Sabuc
Ana Patricia Sabuc Mejia	San Lucas Mission	yes	yes	yes	11/10/2024	Ana Patricia M
Dominga Salazar	San Lucas Mission	yes	yes	yes	11/24/2024	2022-0794_Salazar_
Saira Noemi Sequec Macario	San Lucas Mission	yes	yes	yes	7/26/2025	Saira Macario
Yolanda Alian Sicay Cutuj	San Lucas Mission	yes	yes	yes	6/16/2026	Yolanda Alian S 2.pdf(0.01)
Manuela						

Simalaj Coraxon	San Lucas Mission	yes	yes	yes		7/26/2025	Manuela Simal
Candelaria Tobar Salugui	San Lucas Mission	yes	yes	yes		7/26/2025	Candelaria Tob
Yuli Elizabeth Toc Chuc	San Lucas Mission	yes	yes	yes		6/16/2026	Yuli Elizabeth T
Mariluvia Tos Buch	San Lucas Mission	yes	yes	yes		7/26/2025	Mariluvia Tos B
Maria Tun	San Lucas Mission	yes	yes	yes		11/10/2024	Maria Tun IIA 2
Rafael Tun	San Lucas Mission	no	yes	no	Local medical director, co-investigator. Supervise community health workers carrying out study activities	7/9/2024	Rafael Tun - C Training 2021.p
Telma Viridiana Gomez	San Lucas Mission	yes	yes	yes		6/16/2026	Telma Viridiana 2.pdf(0.01)
Delfina Xiap Chenol	San Lucas Mission	yes	yes	yes		7/26/2025	Delfina Xiap Ch

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

(•) **Yes** ( ) No

2. Sending Data or Specimens

* Select which of the following will be released outside the UW Madison/Madison VA (Wm. S. Middleton VA Hospital).

	Data
☐	Images
☐	

Specimens

3. Recipients

Select the entities with whom the data, images, or specimens will be shared.

Institution Name	Smart IRB Member	AAHRPP Accredited	Other
There are no items to display			

4. Other External Recipients

For entities or individuals not listed above, list them here.

> Data will be shared with Guatemalan team members affiliated with the San Lucas Mission (health promoters and physicians).

5. Purpose of Sharing Data or Specimens

* Describe the purpose of sending the data, images, or specimens to each recipient site. If data, images, or specimens will be included in registry or repository, state that below.

> These team members will be interacting with subjects, collecting study data, contacting subjects for the follow-up study visit if applicable, and providing or arranging clinical care for subjects as necessary.

6. Information Included

* Describe what information will be included with the data, images, or specimens that will be shared.

> Patient demographic and contact information, past medical history, social history, vital signs, medication list, information on current symptoms, lab test results.

7. Identifiability

* Select the level of identifiability of the data, images or specimens being shared.

☑	**Directly Identifiable**
☐	Coded (i.e., indirectly identifiable)
☐	Anonymous (i.e., de-identified)

8. Transmitting Data or Specimens

* Describe how the data, images, or specimens will be transmitted (e.g. Box) and how confidentiality will be protected (e.g., who maintains the key code).

> Guatemalan study team members will access subject data through the secure, HIPAA-compliant CommCare platform. The CommCare application itself is encrypted and password- protected and will only be accessed on password-protected Android devices and Windows computers, which will be kept in a locked cabinet or room when not in use.

9. Return of Data or Specimens

* Address whether the data, images or specimens will be returned to UW Madison and if not, why not (e.g., samples will be exhausted).

> Data will be shared with study personnel at UW Madison through the CommCare platform, but will also be retained with San Lucas Mission staff for purposes of ongoing patient care.

10. Informing Subjects

* Are subjects being informed of the plans to share data, images, or specimens?

◉ **Yes** ○ No

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)
International Research

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* Is the research designed to include any of the following populations? Select “Not Applicable” if the research will not include any of the populations below. NOTE: If enrolling pregnant women, children, or prisoners, and you can identify them as such, check the box.

Illiterate or Low-literacy participants
Non-English Speaking subjects or subjects whose primary language is not English
Poor/uninsured, elderly/aged, or educationally disadvantaged

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> This is a single group study assessing the feasibility of hypertension management by community health workers (CHWs) equipped with a mobile clinical decision support (CDS) application and working with remote physician supervision.

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> An estimated 1.13 billion people worldwide are currently living with hypertension, the leading preventable cause of death and disability.[1,2] Two thirds of these patients live in low- and middle-income countries (LMIC).[1,2] Treatment of hypertension has been found to be cost-effective in reducing morbidity and mortality across a broad range of settings.[3] Despite this, less than 10% of patients with hypertension in LMIC have good control of their blood pressure.[2] Health systems in LMIC, which are often focused on providing episodic care for acute illnesses and suffer from inadequate and poorly distributed health care infrastructure and workforce, are ill-equipped to address the rise in chronic non-communicable diseases (NCDs) such as hypertension.[4–6] Governments and NGOs are increasingly turning to community health workers (CHWs) - lay people trained to carry out a variety of tasks and who often are from or have a close connection to the communities they serve - to help fill care gaps for hypertension and other NCDs in LMIC.[7–10] In most cases, CHWs have played supportive (e.g. providing patient education) rather than direct care roles. While such programs have led to improved chronic disease outcomes, they still rely on clinic-based physicians, mid-level providers or nurses to directly provide medical management, and therefore do not address the essential problem of inadequate primary care infrastructure and workforce, particularly in rural areas. Overcoming this problem is key to reducing the growing burden of untreated hypertension in LMIC.
>
> To solve this problem, we are developing an innovative mobile application to assist CHWs in the treatment of hypertension in adults with remote physician supervision. This application is built on the widely-used CommCare[11] platform and will provide clinical decision support (CDS) to CHWs based on protocols from the WHO[12,13] and the International Society of Hypertension[14] for antihypertensive medication initiation and titration, lifestyle counseling, and identification of patients requiring a higher level of care. We will develop and test this approach in a rural area of Guatemala with poor primary care infrastructure and where our team has worked extensively in the past and has an ongoing collaboration with a local NGO, the San Lucas Mission, and affiliated CHWs. Through this collaboration, we have developed and implemented a CHW-led rural diabetes program enabled by a CDS mobile application and have demonstrated that CHWs can safely and effectively manage diabetes using the application.[15,16] We hypothesize that we will be able to adapt the model to hypertension management and are evaluating the feasibility of this approach with this pilot study.
>
> [1] World Health Organization. Hypertension Fact Sheet 2019. https://www.who.int/news-room/fact-sheets/detail/hypertension (accessed November 13, 2019).
> [2] Mills KT, Bundy JD, Kelly TN, Reed JE, Kearney PM, Reynolds K, et al. Global

Disparities of Hypertension Prevalence and Control: A Systematic Analysis of Population-Based Studies From 90 Countries. Circulation 2016;134:441–50.
[3] Zhang D, Wang G, Joo H. A Systematic Review of Economic Evidence on Community Hypertension Interventions. Am J Prev Med 2017;53:S121–30.
[4] Hunter DJ, Reddy KS. Noncommunicable diseases. N Engl J Med 2013;369:1336–43.
[5] World Health Organization. Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020. WHO; 2013.
[6] Checkley W, Ghannem H, Irazola V, Kimaiyo S, Levitt NS, Miranda JJ, et al. Management of NCD in low- and middle-income countries. Glob Heart 2014;9:431–43.
[7] Vedanthan R, Bernabe-Ortiz A, Herasme OI, Joshi R, Lopez-Jaramillo P, Thrift AG, et al. Innovative Approaches to Hypertension Control in Low- and Middle-Income Countries. Cardiol Clin 2017;35:99–115.
[8] Kim K, Choi JS, Choi E, Nieman CL, Joo JH, Lin FR, et al. Effects of Community-Based Health Worker Interventions to Improve Chronic Disease Management and Care Among Vulnerable Populations: A Systematic Review. Am J Public Health 2016;106:e3–28.
[9] Mishra SR, Neupane D, Preen D, Kallestrup P, Perry HB. Mitigation of non-communicable diseases in developing countries with community health workers. Global Health 2015;11:43.
[10] Khetan AK, Purushothaman R, Chami T, Hejjaji V, Madan Mohan SK, Josephson RA, et al. The Effectiveness of Community Health Workers for CVD Prevention in LMIC. Glob Heart 2017;12:233–43.e6.
[11] Svoronos T, Mjungu P, Dhadialla R, Luk R, Zue C, Jackson J, et al. CommCare: Automated quality improvement to strengthen community-based health. Weston: D-Tree International 2010.
[12] World Health Organization. WHO | HEARTS Technical Package 2019. https://www.who.int/cardiovascular_diseases/hearts/en/ (accessed November 14, 2019).
[13] World Health Organization. Guideline for the pharmacological treatment of hypertension in adults. Geneva: World Health Organization; 2021.
[14] Unger T, Borghi C, Charchar F, Khan NA, Poulter NR, Prabhakaran D, et al. 2020 International Society of Hypertension Global Hypertension Practice Guidelines. Hypertension 2020;75:1334–57.
[15] Duffy S, Svenson J, Chavez A, Kelly M, Wise P. Empowering Community Health Workers With Mobile Technology to Treat Diabetes. Ann Fam Med 2019;17:176.
[16] Duffy S, Norton D, Kelly M, Chavez A, Tun R, de Guzmán Ramírez MN, et al. Using Community Health Workers and a Smartphone Application to Improve Diabetes Control in Rural Guatemala. Global Health: Science and Practice 2020. https://doi.org/10.9745/GHSP-D-20-00076.

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

CHWs will meet with patients at enrollment visit and monthly thereafter. All study data will be collected using the CommCare application running on Android smartphones or tablets.

At enrollment, information on basic demographic information, past medical history, and current medications will be collected. CHWs will measure blood pressure, height and weight. Patients will also be administered the Hypertension Self-Care Activity Level Effects (H-Scale) questionnaire and the Patient Assessment of Chronic Illness Care (PACIC) survey on their satisfaction with their current hypertension treatment. They will be assessed for side effects of current medications and signs and symptoms of possible complications of hypertension, including ischemic heart disease, cerebrovascular disease, heart failure, and kidney disease. Blood will be drawn by venipuncture or capillary sample to assess lipid profile, serum creatinine, sodium, chloride, potassium, ALT and blood glucose.

Based on information entered by the CHWs into the CommCare application designed for this study, the application will provide recommendations (and underlying rationale for these recommendations) for prescription of antihypertensives (amlodipine and/or losartan OR enalapril) and medications to reduce cardiovascular risk (aspirin and atorvastatin) if indicated, lifestyle modification, and referral to the supervising physician (Dr. Tun) if indicated for potential complications of hypertension.

CHWs will then provide these interventions assisted by recommendations from the application. These procedures (aside from the enrollment panel of lab tests and questionnaires described above) will repeat at monthly visits.

CHWs will be able to contact Dr. Tun, Dr. Letona, or PI/PD Dr. Sean Duffy during the visit as needed for advice on patient management. After each visit, clinical data will be uploaded to CommCare's secure server and reviewed within one week of the visit by Dr. Duffy, Dr. Letona, and/or Dr. Tun, who will verify the current treatment plan and contact the coordinators of the CHW program if any changes to treatment are necessary, including the addition of other medications outside of the treatment algorithms per their clinical judgement. In the case that changes are necessary, CHWs will contact patients via phone or visit them at home to communicate and carry out changes.

CHWs will provide continuous feedback on the application, as well as program workflows and logistics. Based on this feedback, as well as monthly analysis of patient data, we will revise application algorithms, workflows, and user interface. This pragmatic design will allow for iterative application and program improvements, leading to a refined product that we can then scale up and evaluate in a larger controlled trial during the R33 phase of this NIH funded project.

At the 6 month visit, the blood tests and questionnaires listed above will be repeated and subjects will undergo semi-structured interviews to gain additional insight into their experience with the program.

4. Incidental or Adventitious Findings

* Will any study procedures produce incidental or adventitious findings (e.g., imaging scans, laboratory blood tests, depression screening questionnaires, etc.)?

(•) **Yes** ( ) No

5. Instruments Involved

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys, questionnaires, or statistical analysis software.

* Are there instruments of any kind, including software, tests run on samples, and algorithms, used in the study?

(•) **Yes** ( ) No

5.1. Health-Related Purpose

* Are any instruments used for health-related purposes including diagnosis or treatment?

(•) **Yes** ( ) No

5.2. Specific Medical Mobile Application

* Does this study involve a medical mobile application focused on specific health related conditions and not just general wellness activities?

(•) **Yes** ( ) No

5.3. Instrument Assessment

Please contact the FDA Regulated Research Oversight Program if you are unsure whether your project involves assessing the safety and/or efficacy of an instrument.

* Do any aims of the study involve assessing the safety and/or effectiveness of those instruments?

( ) Yes (•) **No**

5.4. Data Submitted to FDA

* Will data from the proposed activity be submitted in an application to the FDA?

( ) Yes (•) **No**

Reporting Results

Studies with potential for discovery of incidental or adventitious findings require special consent form language. Review the guidelines on consent form language in **HRP-503 Consent Form Template**.

1. Originating Procedure

* Identify the procedure that could create the findings. (e.g., imaging scan, laboratory blood test, depression screening questionnaire, etc.)

> Laboratory tests may identify conditions previously unknown to subjects, such as kidney disease, liver disease, or diabetes.

2. Results Released

* Will findings be released to subjects?

(•) **Yes** ( ) No

2.1. Type of Results

* Describe which findings will be released to subjects, and why. Explain what the subject (or their doctor, if applicable) could do with this information.

> All abnormal laboratory findings will be released to the patient as they could be clinically important and may require alteration of current treatment plans. The supervising physicians for this study will use laboratory results to guide treatment related to the aims of the study (hypertension and cardiovascular risk reduction) as well as to provide appropriate management and/or referral to other physician(s) for management of abnormalities not related to the specific aims.

2.2. Entity Assessing Release

The IRB would not expect (and in some cases will not allow) the dissemination of information to subjects generated from tests or procedures that are considered experimental.

* Indicate who will assess whether the information should be reported to subjects and the qualifications of those making such assessments. If it is based on a score, address whether the samples are run in a CLIA-certified laboratory.

> The supervising physicians (Dr. Tun, Dr. Letona, and Dr. Duffy) for this study will guide reporting of incidental findings. Dr. Tun is a general practitioner and Dr. Duffy is a family physician and both are skilled in the evaluation of common laboratory tests (such as those used in this study) and management of abnormalities in these tests.

2.3. Reporting Timeframe

* Provide the timeframe for reporting findings to subjects, and if applicable, their physicians.

> Within 1 month.

2.4. Reporting Process

* Describe the process for reporting results to subjects, including who will disclose results and whether any additional resources are in place. If results will be place in the subjects' medical records, please indicate this.

> One of the supervising physicians will review patient data, including laboratory tests, on a monthly basis. Incidental findings/abnormal results will be discussed with the community health workers, who will then relay this information to subjects and any recommendations/instructions for treatment or other follow-up. Subjects will be able to access treatment or further work-up for abnormalities as needed at Hospital Obras Sociales Monseñor Gregorio Schaffer in San Lucas Tolimán, Guatemala (where Dr. Tun is the attending physician). Abnormal results will be noted in the patient's medical record.

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

(•) **Yes** ( ) No

1.1. CRDS Usage

CRDS assists UW investigators with developing data queries and delivering data from the UW Health Enterprise Data Warehouse (EDW) to be used in feasibility assessments, recruitment of participants, pilot studies, and retrospective analyses.

* Will you use the Clinical Research Data Service (CRDS) to identify subjects via these records?

( ) Yes (•) **No**

1.2. Record Identification Details

* Describe how eligible subjects will be identified using medical records, including 1) which records will be accessed and 2) who will identify eligible subjects.

> Patients with hypertension who may be eligible to participate in the study will be identified by community health workers (CHWs) and other study personnel (including PI Dr. Duffy and research assistant Taryn Valley) from lists of such patients maintained by the community health worker program, as well as from records stored in the secure CommCare database of patients identified as having hypertension through the concurrent study of hypertension diagnosis by CHWs, which is also funded by this grant.

Risks and Benefits

1. Direct Benefits Intended

For this type of research there are generally no direct benefits to subjects. The response to this question, "There are no direct benefits to subjects", would be acceptable.

* Are any of the research activities intended to directly benefit subjects?

Yes No

1.1. Direct Benefit Details

* Describe how subjects will benefit from the research activity.

> Controlling hypertension reduces the risk of stroke, coronary artery disease, congestive heart failure, end-stage renal disease, peripheral vascular disease, as well as overall mortality. Providing statins, +/- aspirin, for hypertensive patients who are at high risk of heart attack and stroke or have a history of these complications greatly reduces the risk of these potentially fatal or life-altering events.

2. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> If we can show that CHWs can effectively manage hypertension with remote physician supervision, this would have important implications for global hypertension control. Currently, less than 10% of patients with hypertension in low- and middle-income countries (LMIC) have blood pressure at goal. If this is shown to be an effective strategy, task sharing with CHWs and other frontline health workers could help to improve treatment of hypertension in LMIC, which often lack sufficient numbers of more highly trained health workers, such as physicians and nurse practitioners, to address this important global health problem.

3. Direct Physical Intervention

A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Does this study involve direct physical intervention with subjects?

Yes No

3.1. Physical Risks and Discomforts

* Describe the most common or frequent physical risks and discomforts expected related to study participation (e.g. pain, bruising, redness/itching).

> Bruising is a common outcome from drawing blood (venipuncture). Blood pressure measurement does cause mild arm discomfort.

3.2. Unusual Physical Interventions

* Does the protocol involve physical interventions that will NOT be conducted in clinical settings (e.g., blood draws in a medical clinic) or designated research areas (e.g., exercise testing in an approved lab) where they would normally occur?

(•) **Yes** ( ) No

3.2.1. Outside Physical Interventions

* Describe the physical interventions performed outside a clinical setting or designated research area.

> Measurement of blood pressure and other vital signs; blood draws.

3.2.2. Interventions Location

* Describe where the interventions will occur.

> These interventions will primarily occur in clinical settings (clinical sites in rural communities run by the network of community health workers with which we are collaborating), but may occur during home visits.

3.2.3. Emergency Plan

* Describe the plan for handling emergencies, including who will provide medical oversight, if applicable.

> Emergencies resulting from these interventions are not anticipated. Guatemalan co-investigator Dr. Tun, study team physician Dr. Letona, and PI Dr. Duffy will be available to consult with community health workers (CHWs) remotely as needed and transport to the hospital in San Lucas Tolimán can be arranged so that Dr. Tun or Dr. Letona can evaluate a patient in person as needed. All CHWs are trained in basic emergency care.

4. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

> Since personal and medical information will be collected from subjects, there is a risk of potential breach of privacy/confidentiality.
>
> If conducting activities in participants' homes, there's a risk associated in situations of suspected abuse which involve mandatory reporting requirements and informing subjects of this reporting requirement.

5. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Study interventions will be performed in a private room or, at a minimum, out of earshot of other people in order to ensure privacy and confidentiality. Data will be collected on encrypted, password protected smartphones or tablets using the CommCare application, which is also password protected and encrypted. Study data will be stored on CommCare's secure server, which is HIPAA compliant, secure University of Wisconsin servers, and secure computers in Guatemala. Any hard copies of data containing PHI will be stored in locking filing cabinets in controlled-access facilities.

Subject Population

1. Total Subjects

You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

* Provide the number of subjects that will be enrolled at sites for which UW Madison is serving as the reviewing IRB.

> 30

2. Inclusion Criteria

* Describe the main inclusion criteria.

> Adults age 18 or greater with diagnosis of hypertension AND blood pressure (BP) >=140/90 OR currently taking
> antihypertensive medication.

3. Exclusion Criteria

* Describe the main exclusion criteria.

> - Pregnancy
> - Severe comorbid condition(s) with life expectancy less than 1 year

4. Targeted Populations

Populations could be racial/ethnic, sex, or gender (this also applies to gender identity, or lack thereof).

* Will this study target or exclude specific populations?

Yes **No**

Special Populations Justification

1. Justification

If more than one special population is enrolled, separate justifications should be provided for each unique population.

* What is the justification for the inclusion of these subjects?

> Study recruitment and activities will occur in the municipality of San Lucas Tolimán, Guatemala. A large majority of the population in this area belongs to the Kaqchikel Maya ethnic group and speaks both Spanish and the Kaqchikel language. Average income in these communities is less than $1000/year.

2. Safeguards

Include the measures that will be taken to minimize any potential coercion or undue influence in recruitment and ongoing participation in the study.

* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

> Potential subjects will be assured that their participation will have no bearing on services that they currently receive or may receive in the future from our local partner, the San Lucas Mission. All consent materials will be translated into Spanish and informed consent will be obtained by CHWs who are bilingual in Spanish and Kaqchikel (which is not generally used as a written language).

Recruitment Methods

1. Recruitment Plan

This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

* Describe the recruitment plan for this study.

> Subjects will be recruited by community health workers (CHWs) from patients identified as having hypertension during the hypertension screening and diagnosis study as well as from among patients previously known to have hypertension by the CHWs.

2. Recruitment Material Upload

Upload recruitment materials such as recruitment emails, letters, phone scripts, brochures, or advertisements.

There are no items to display

3. Approved Recruitment Database Usage

* Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?

○ Yes ◉ **No**

Subject Screening

1. Preliminary Eligibility Screen

* Will subjects undergo a preliminary screen to determine basic eligibility?

◉ **Yes** ○ No

1.1. Screening Materials

* Upload a copy of the screening questionnaire.

Screening Questionnaire - Feasibility study.docx

1.2. Data Retention

If you are retaining screen data, the previously uploaded questionnaire/script should address this and include authorization language for maintaining PHI if HIPAA applies.

* Will you be retaining screen data from subjects who do not enroll in the study?

○ Yes ◉ **No**

2. Planned Study Procedures Before Obtaining Consent

Examples include fasting, discontinuing medications, etc.

* Will there be any procedures performed before informed consent is obtained from subjects (apart from screening)?

◉ **Yes** ○ No

2.1. Procedure(s) Details

* Describe the applicable study procedures that will be conducted before informed consent is obtained from subjects.

> Potential subjects will be instructed to come to study screening/enrollment fasting in case they do quality as baseline labs will be drawn, including fasting lipid panel and fasting glucose. For patients who have been diagnosed with hypertension, but are not currently taking medication, a blood pressure will be checked to see if they qualify (BP >=140/90). For women who are capable of conceiving (premenopausal, no history of tubal ligation or hysterectomy) and who are not sure if they are currently pregnant, a urine pregnancy test will be required prior to enrollment.

Remuneration and Costs

1. Payment

* Will subjects be compensated to participate in the study?

○ Yes ◉ **No**

2. Costs

* Will subjects incur any costs as a result of study participation (pharmacy preparation fees, payment for a device, billing of study procedures to subjects insurance)?

○ Yes ◉ **No**

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> Study interventions will be performed in a private room or, at a minimum, out of earshot of other people in order to ensure privacy and confidentiality.

2. Level of Identifiability

* Select how subjects are identified in the data. Check all that apply.

Directly: Direct Identifiers stored on data (e.g., name, initials, phone number, SSN, or medical record number, stored on data)
Coded or Indirect Identifiers: data includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data but stored separately)

No Identifiers (De-identified, Anonymous, or Anonymized): stored data is stripped of all identifiers

2.1. Necessity of Data

* Explain the necessity of collecting or maintaining data linked to subjects' identities.

> Maintaining data linked to subject's identities is necessary for continuity of medical care for patients enrolled in the study and technical support of the mobile health application that will be used by the community health workers.

2.2. Retaining Data

* How long will data linked to subjects' identities be retained?

> Data containing subject identifiers will be retained on secure CommCare servers and/or in Silo during the period of this grant (through September 2026) to allow for recruitment for other studies funded by the grant. Data containing PHI may also be maintained long-term by the San Lucas Mission for patient care purposes.

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or

specimens will be stored.

A service known as CommCare will be used to collect data. Whenever data is transmitted between one of the servers CommCare uses and the Android application, it is sent using HTTPS. Here are the standards incorporated:

● Encrypted server-client connections using HTTPS
● All access to the cloud infrastructure is protected behind a firewall and require unique VPN access permissions
● Data is transferred through channels monitored by intrusion monitoring systems
● Encrypted at-rest database and encrypted database backups every night
● Security management meets ISO 27001, PCI-DSS, SOC1, SOC2, SOC3, and HIPAA standards

The CommCare application used to collect data and provide clinical decision support will run on encrypted Android smartphones or tablets. The CommCare mobile application itself is password protected and data collected by the application is encrypted (AES 256-Bit Symmetric Encryption, fully HIPAA compliant). These are only connected to the internet when data is being uploaded via a WIFI connection. As soon as data from the CommCare application is uploaded to the secure servers (described above), it is erased from the device. When not being used for study purposes, these devices will be stored in a locked cabinet in the CHW headquarters.

Study team members interacting with subjects and assisting with their follow-up (Guatemalan study team members, Dr. Duffy, Taryn Valley) and assisting with technical support (Alejandro Chavez) will have access to data with subject identifiers through the CommCare platform. If data containing PHI needs to be downloaded from CommCare to UW servers for these purposes, such data will be transferred securely using the Globus platform to the secure and HIPAA compliant Silo server provided by the UW Social Science Computing Cooperative (SSCC). All other study members will have access only to coded or deidentified data.

Data used for analysis of study outcomes will be deidentified prior to being downloaded from the secure server described above. Any data containing PHI that is downloaded from the secure CommCare database for study purposes or to facilitate appropriate referral of patients determined to need more urgent medical care (e.g. due to significantly uncontrolled hypertension) will be stored on password protected encrypted laptop computers that are stored in locked locations when not in use. Any hard copies of study data containing PHI will be stored in locked filing cabinets at CHW headquarters in Quixaya and/or San Lucas Mission Hospital.

Deidentified data used for outcome analysis will be retained on UW servers for at least 7 years following study completion. Data containing subject identifiers will be retained on secure CommCare servers and/or in Silo during the period of this grant (through September 2026) to allow for recruitment for other studies funded by the grant. Data containing PHI may also be maintained long-term by the San Lucas Mission for patient care purposes.

Study team has discussed the use of CommCare with the SMPH HIPAA Privacy Officer and has obtained an advanced plan for the service that includes full HIPAA compliance and a BAA. CommCare does not sell data to advertisers or other third parties, or transmit such data without express user consent.

4. Certificate of Confidentiality

If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a

Certificate of Confidentiality as part of the terms of the award, answer "Yes".

* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research?

○ Yes ◉ **No**

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

○ Yes ◉ **No**

Consent: General

1. Obtaining Consent/Assent

* Will you obtain consent or assent from some or all participants?

◉ **Yes** ○ No

1.1. Signed Consent/Assent

* Will you obtain signed consent or assent from all participants?

◉ **Yes** ○ No

1.2. Altering Required Elements

* Are you proposing to alter required elements of consent or assent (e.g. required information will not be disclosed, or the research involves deception)?

○ Yes ◉ **No**

1.3. No Consent/Assent

* Are there some participants from whom you will not obtain consent or assent?

○ Yes ◉ **No**

Consent Overview

1. Consent Process

* Describe the consent process, including when and where it will occur and how the consent process will be conducted (e.g., face to face, phone or video discussion) and how consent information will be provided to participants (e.g., in person, mailed/emailed).

> Consent will be obtained in a private location at the study site and out of earshot from other patients. Study procedures, potential risks and benefits will be explained to the patient by the community health worker (CHW) in Spanish and/or Kaqchikel depending on the patient's preferred language. A copy of the study information and consent form in Spanish (as patients are generally only literate in Spanish even if they primarily speak Kaqchikel) will be provided to the patient. If the CHW obtaining consent is unsure about the patient's ability to provide informed consent, the physician involved in the study will assess the patient and make this determination.

2. Disadvantaged Participants Involved

* Will the study enroll participants who are non-English speaking, illiterate/low-literacy, or have visual/hearing impairments?

◉ **Yes** ○ No

2.1. Plan to Ensure Participant Understanding

* Describe the steps that will be taken to ensure the potential participant's understanding and who will determine that a potential participant understands the information.

> Study procedures, potential risks and benefits will be explained to the

> patient by the CHW in Spanish and/or Kaqchikel depending on the patient's preferred language. A copy of the study information and consent form in Spanish (as patients are generally only literate in Spanish even if they primarily speak Kaqchikel) will be provided to the patient. If the CHW obtaining consent is unsure about the patient's ability to provide informed consent, the physician involved in the study will assess the patient and make this determination.

3. Qualification Affirmation

* Do you confirm that all study personnel responsible for obtaining informed consent have the following qualifications: 1) are familiar with the details of the study; 2) will ensure subjects are provided with sufficient information to make an informed and voluntary decision about study participation; 3) are familiar with UW-Madison policies regarding informed consent?

(•) **Yes** ( ) No

Consent and Authorization Upload

1. Consent/Assent Documentation

• E.g., information sheet, consent form, assent form, translated consent documents.
• Please use IRBs informed consent templates to develop consent processes and documents for non-exempt studies.
• For educational and social-behavioral studies, you can use the Consent Form Wizard. The Wizard does not include HIPAA authorization language.

* Upload all consent authorization, and/or assent documents.

Consent Form - Feasibility study.docx
English version of long ICF
Spanish consent form - Feasibility study.docx
Spanish version of long ICF

Non-English Consent

1. Translation Details

* Identify how the consent form and other participant-facing documents will be translated into the subjects' native language. Study team member

2. Translator Qualifications

* Identify who translated the consent documents and other participant-facing documents and describe their qualifications.

> We are currently using the IRB-approved Spanish translation of the short consent form. The long consent form was translated by study team members Taryn Valley and Sean Duffy (PI). Both are fluent in Spanish and have extensive experience with Guatemalan Spanish in particular. Dr. Duffy has been certified as a Spanish medical interpreter in the past and is currently certified by UW Health to see Spanish-speaking patients without an interpreter.

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

(•) **Yes** ( ) No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

(•) **Yes** ( ) No

1.2. HIPAA Authorization

* Will HIPAA authorization for access to the PHI be obtained for all or some subjects, or for only some uses?

- (●) **Yes, always: HIPAA authorization will be obtained from all subjects with signed documentation.**
- ( ) Yes, sometimes or without signed documentation: HIPAA authorization will not be obtained from some subjects/uses or may be obtained without a signature.
- ( ) No: HIPAA authorization will not be obtained from any subjects.

1.3. External PHI Access

* Will you access or obtain fully identifiable health information from a health care provider that is not UW or UW Health or the Madison VA, such as Meriter or ACHC, without first obtaining patient permission or authorization?

( ) Yes ( ) No

International Research

1. Countries Involved

* List the country(ies) in which study activities will occur.

> Guatemala

2. Site Details

* List the specific sites (e.g., name of clinic, hospital, school) at which study activities will occur in the countries listed above.

> San Lucas Mission (SLM) Health Care Program, Municipality of San Lucas Tolimán.

3. Ethics Committee or IRB Approval(s)

* Do any of the international sites involved in this study have ethics committee or IRB approval?

Yes **No**

3.1. Regulatory Oversight Details

Explain how regulatory oversight for human subjects research at study sites will be provided.

> While the San Lucas Mission does not have an affiliated formal ethics committee or IRB, this study was reviewed and approved by the San Lucas Medical Committee and San Lucas Medical Director Dr. Rafael Tun. In our past collaborations with the San Lucas Mission, the UW IRB has served as the IRB of record for individuals affiliated with the Mission who are involved in the research.

4. Letters of Support or Approval(s)

Upload any letters of support or approval for this study from relevant officials or collaborators at these sites.

San Lucas Mission Letters of Support.pdf

5. Local Knowledge

Describe the study team's knowledge of the local culture, community, laws, and regulations.

> UWSMPH has a long-standing relationship with SLM. In particular, PI Sean Duffy has collaborated with SLM medical director Dr. Rafael Tun and SLM-affiliated CHWs on several research projects over the past 5 years and has developed a strong working relationship with this team. Dr. Duffy has successfully completed another project with this community and is well-known to the clinic and its director.

6. Location Justification

Describe why the particular location(s) has been selected to conduct the research.

> UWSMPH has a long-standing relationship with SLM. In particular, PI Sean Duffy has collaborated with SLM medical director Dr. Rafael Tun and SLM-affiliated CHWs on several research projects over the past 5 years and has developed a strong working relationship with this team Foreign research is paramount for this proposal because the NIH grant projects developing and/or evaluating mobile health interventions to improve health outcomes in low- and middle-income countries. We propose the development and evaluation of a mobile health clinical decision support application for community health workers to allow them to diagnose hypertension in LMIC and thus the use of a domestic research site would not be appropriate. SLM is a particularly well-suited site for this study because of its well-developed CHW program, which currently uses the CommCare mobile application to facilitate care for diabetes and childhood malnutrition.

7. Potential Risks

Describe whether the cultural, economic, or political conditions of the country or countries would alter the risk for participants compared to the same research conducted within the U.S.

> No alteration of risks.

8. Communication Considerations

The consent form should include the methods for communicating with researchers taking into account means available to subjects at the study location(s).

Describe any special considerations for communicating with subjects during the course of the study (e.g., access to a local researcher/coordinator, access to telephone or other methods of communication, etc.).

> We will communicate with subjects directly and through CHWs in individual villages.

9. Consent Considerations

Describe any special cultural considerations for obtaining informed consent (e.g., community consent, presence of elders, etc.).

> None

Interviews, Focus Groups, Surveys, Questionnaires

1. Tool Details

* Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

View

Tool Description	Spanish translation of the Patient Assessment of Care for Chronic Diseases (PACIC). Highlighted items will be asked. These were selected with input from community health workers based on their relevance to the research setting.
Tool Standardized	Yes
File name	PACIC Spanish
Tool Manner	In-person
Tool Manner Other	At community health worker clinic sites or patient homes in Guatemala
Date Modified	12/11/2022

View

Tool Description	Patient Assessment of Care for Chronic Conditions (PACIC). Highlighted items will be asked. These were selected with input from community health workers based on their relevance to the research setting.
Tool Standardized	Yes
File name	Patient Assessment of Care for Chronic Conditions_revisions Dec 22.pdf
Tool Manner	In-person

Tool Manner Other	At community health worker clinic sites or patient homes in Guatemala
Date Modified	12/11/2022

View

Tool Description	Semi-structured interview guideline for interviews conducted at the end of the study to elicit patient feedback about the hypertension program.
Tool Standardized	No
File name	Semi-structured interview questions.docx
Tool Manner	In-person
Tool Manner Other	At community health worker clinic sites or patient homes in Guatemala
Date Modified	5/31/2022

View

Tool Description	Hypertension—Self-care Activity Level Effects (H-SCALE) - Spanish translation
Tool Standardized	Yes
File name	Final H-SCALE Spanish w DASH-Q_FINAL.doc
Tool Manner	In-person
Tool Manner Other	At community health worker clinic sites or patient homes in Guatemala
Date Modified	5/31/2022

View

Tool Description	Hypertension - Self-care Activity Level Effects (H-SCALE)
Tool Standardized	Yes
File name	H-SCALE English.pdf
Tool Manner	In-person
Tool Manner Other	At community health worker clinic sites or patient homes in Guatemala
Date Modified	5/31/2022

2. Cognitive or Psychological Assessment

* Are any of the uploaded instruments used to assess cognitive or psychological status or function?

○ Yes ◉ **No**

Interviews, Focus Groups, Surveys, Questionnaires Cont.

1. Focus Group

* Will the study involve conducting focus groups?

○ Yes ○ No

2. In-Home Visit

* Does the study involve in-home visits?

○ Yes ○ No

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

2022-0794_Ajcalon_27Jun2022.pdf
2022-0794_CastroChuta_27Jun2022.pdf
2022-0794_Macario_27Jun2022.pdf
2022-0794_Salazar_27Jun2022.pdf
IIA template

1.1. Describe Documents

Describe what additional documents were added in 1.

> Signed IIAs (Independent Investigator Agreement) by San Lucas Mission personnel; translated in Spanish (previously by Carol Pech). Please note: in the December 2022 revision, additional IIAs have been uploaded along with the addition of each external collaborator.

Final Page

1. Assurance

The information presented in this application is accurate;
If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(•) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

1. Select Ready to Submit or Exit on this page to be directed to the application workspace.
2. In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.