

Study Title: Family Model of Diabetes Self-Management Education in Faith Based
Organizations
PI (researcher): Pearl McElfish, PhD

**FAMILY MODEL OF DIABETES SELF-MANAGEMENT EDUCATION IN FATH-
BASED ORGANIZATIONS**

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MELELE KO RAORŌK KŌN EKKATAK EO NAETAN “FAMILY MODEL OF DIABETES SELF-MANAGEMENT EDUCATION (DSME) IN FAITH BASED ORGANIZATIONS”:

KEY INFORMATION FOR FAMILY MODEL OF DIABETES SELF-MANAGEMENT EDUCATION (DSME) IN FAITH BASED ORGANIZATIONS:

Kōmij kajjitōk bwe kwōn kelet elañe kwōj kōnaan ak jab kōnaan bōk konaam ilo ekkatak in nān jibañ armij ro ewōr aer nañinmej in tōñal koba baamle ko aer nān katak kōn nañinmej in tōñal im wāwein ko nān kōjparok. Kilaaj ko an ekkatak in renaj kōmman ilo imōn jar ko ak jikin ko jet an mwōn jar ko.

Pepa in ej kwalok melele ko raurōk nān jibañ iok kōmman kelet eo am im kalikar kwōj ke bōk konaam. Emōj droor melele ko remelijlok ālikin pepa in. Lelok kajjitōk ko am nān team eo ej bōk eddoin ekkatak in. Elañe ewōr am kajjitōk tok ālik, melele ko nān tōbar rijerbal ro an ekkatak in rej bed āliktata in pepa kein.

We are asking you to choose whether or not to volunteer for a research study about helping persons with diabetes and their family members learn how to manage diabetes. Classes for this study will be done in a church or other faith-based setting.

This page gives you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

EKKATAK IN EJ KŌN TA IM EWI AITOKAN?

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Ilo ad kōmmane ekkatak in, jej kōjatdikdik ke jenej maroñ loe elañe Rimajōl ro ewōr aer nañinmej in tōñal remaroñ kōkmanman lok ejmour ko aer im jokkin mour ko aer elañe er im baamle ko aer renej ekkatak ibben dron kōn bōbrae nañinmej in tōñal ko aer. Jej bar kōnan jelā elañe katakin kōn nañinmej in tōñal ilo mwōn jar ko emman lok jen jikin ko jet. Nān kajjioñ men in, jenej etale elañe nañinmej in tōñal ko aer rej emman lok. Ewōr 408 rutto in Majōl ro (18 iiō im rutto lok) im ewōr aer nañinmej in tōñal im 1-2 uwaan baamle ko aer renej maroñ mōttan ekkatak in. Ilo am bōk konaam ilo ekkatak in eo aitokan enej tarrin 10 allōñ nān juōn iiō koba 10 awa in ekkatak kōn nañinmej in tōñal ilo 8-12-wiik aitokan im konej bar bōk konaam ilo jillu nān emen ien ko nān ebbōk melele ko am. Ñe konej kobatok ilo ekkatak in, renej kajjitōk ibbam nān bed ilo kilaaj in kejbarok nañinmej in tōñal ko im ien ebbōk melele ko ijo renej ebbōk melele ikkijen ejmour jen kwe.

By doing this study, we hope to see whether Marshallese patients with diabetes can improve their health and quality of life if they and their families learn together about managing their diabetes. We also want to learn if teaching about diabetes in a church setting is better than teaching in other places. To test this, we will measure if their diabetes improves. Up to 408 Marshallese adults (ages 18 years and older) with diabetes and one to two of their family members may be part of this study. Your participation in this research will last about 10 months to one year with 10 hours of diabetes education over an 8-12 week period and you will participate in three to four

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data collection events. If you join the study, you will be asked to attend diabetes management classes and data collection events where we collect health information from you.

ETKE INEJ MAROÑ KELET BWE IN BŌK KONAŌ ILO EKKATAK IN? WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

Emōj kajjitōk ibbam ñan koba tok ilo ekkatak in kōnke ewōr am nañinmej in tōñal ak kōnke juon eo uwaan baamle eo am ewōr an nañinmej in tōñal ej kūr tok eok ñan koba tok ibbeir. Einwōt juōn eo ej bed ilo ekkatak in, konej bed ilo kilaaj in tōñal kein ko rej kōmman jen juon eo ewōr an kapeel ikkijen katakin kōn nañinmej in tōñal. Ilo ien kilaaj kein kwonej ekkatak kōn kejbarok ad mōñā, makūtkūt, etale tōñal eo am, im kapeel ko jet im rej jibañ armej bōbrae nañinmej in tōñal. Am bed ilo ekkatak in emaroñ jibañ bwe kwōn ejmour lok, im emaroñ jibañ armij ro ewōr aer nañinmij in tōñal iliju im jeklaj. *Ñan melele ko remelijlok ikijien emman ko an ekkatak in, kwonaj riiti pepa in Full Consent eo elikin pepa in.*

You are being invited to join in this study because you either have diabetes or because a family member with diabetes has invited you to join with them. As a person in the study, you will attend diabetes education classes led by a trained diabetes teacher. During these classes you will learn about healthy eating, being active, tracking blood sugar, and other skills that help people to manage diabetes. Being in the study may help your health improve and may help other persons with diabetes in the future. *For a complete description of benefits, refer to the Full Consent.*

ETKE INEJ KELET BWE IN JAB BŌK KONAŌ ILO EKKATAK IN? WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Emaroñ wōr ien eo im juōn armij emaroñ jelā kōn melele ko ikijen ejmour eo am, bōtaap jenaj kōjparok bwe en jab walok wāwein in. Ilo am bōk kilaaj ko, armij ro jet remaroñ jelā melele ko kōn kwe make elañe kwonaj kenono kaki.

Ejjelok kallimur ke ekkatak in enaj jibañ eok. *Ñan melele ko remelijlok ikijien emman ko an ekkatak in, kwonaj riiti tarlepen pepa in Mālim eo ālikin pepa in.*

There is the chance that someone could find out about your private health information, but we will take special care to reduce this risk. By taking part in the educational sessions other people in the session may learn information about you if you talk about yourself.

There is no guarantee that the study will help you. *For a complete description of risks, refer to the full Consent.*

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IJ KE AIKUJ BŌK KONAŌ ILO EKKATAK IN? DO I HAVE TO TAKE PART IN THE STUDY?

Jaab. Ejjelok bwōd nē kwonaj ba jaab. Elañe kwonaj errā in bōk konaam ilo ekkatak in, ej aikuj kōnke kwe make kwōj kōnaan bōk konaam. Eban jako jabdrewōt maroñ ko am ak jibañ ko ekkā am būki elañe kwonaj kelet in jab bōk konaam. No. It is okay to say no. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

University of Arkansas for Medical Sciences Informed Consent Form

- **Jej kajitōk ibbam bwe kwōn bed ilo ekkatak in. kwojjab aikuḡ bed elaḡe kwojjab kōnan.**
We are asking you to be in a research study. You do not have to join the study.
- **Kwōḡ maroḡ wōt bōk jibaḡ ikkijen taktō jen UAMS meḡe kwojjab bed ilo ekkatak in.**
You can still get your medical care from UAMS even if you are not in the study.

Jouḡ im bōk ien elap joḡan wōt eo kwoḡ aikuḡi ḡan riiti pepa in im kelet ta eo emman ḡan kwe. Please take as much time as you need to read this form and decide what is right for you.

Etke rej kajjitōk ibba bwe in bed ilo ekkatak in?

Why am I being asked to be in this research study?

- **Jej kōnan katak elap lok kōn katakin kōjebarok naḡinmej in tōḡal.** We want to learn more about teaching diabetes self-management.
- **Ekkatak in enej jibaḡ kōḡ jelā elaplok melele ko elaḡe rimajōl ro ewōr aer naḡinmej in tōḡal im remaroḡ kōkmanmanlok ejmour ko aer im wāweḡin jikkunmour ko aer elaḡe er im baamle ko aer renej ekkatak wāweḡin kōjebarok naḡinmej in tōḡal ko aer ilo mwōn jar ko.** This study will help us learn more about whether Marshallese patients with diabetes can improve their health and quality of life if they and their family learn about managing their diabetes in a church setting.
- **Kōmij kajjitōk ibben armeḡ einwōt kwe eo im ewōr an naḡinmej in tōḡal ak emōḡ kūr tok eok jen juon ian baamle eo am ewōr an naḡinmej in tōḡal ḡan jibaḡ kōm. Ewōr 408 rutto in Majōl ro (18 iiō im rutto lok) im ewōr aer naḡinmej in tōḡal im juon ian baamle ko aer bwe ren bar mōttan ekkatak in.** We are asking people like you who have diabetes or have been invited by a family member with diabetes to help us. Up to 408 Marshallese adults (ages 18 years and older) with diabetes and one of their family members may be part of this study.

Elañe ewōr jabdrewōt men eo ijjab melele kake?

What if I don't understand something?

- Emaroñ wōr melele ko kwojjab melele kaki ilo pepa in. Elañe kwōj kōnaan, ro rej jermal ilo ekkatak in remaroñ riiti im etale pepa in ibbam. This form may have words you don't understand. If you'd like, research staff will read it with you.
- Kwomaroñ kōmman am kajitōk jabdrewōt ien – mokta, ien eo, ak ālikin ekkatak in. You are free to ask questions at any time – before, during, or after you are in the study.
- Jouj im kajitōk joñan wōt eo kwoj kōnan mokta jen am kelet elañe kwoj kōnan bed ilo ekkatak in. Please ask as many questions as you like before you decide whether you want to be in this study.

Ta enej walok elañe inaj ba aet, ij kōnan bed ilo ekkatak in?

What will happen if I say yes, I want to be in this study?

Jenaaj lale mokta elañe kwoj ekkar ñan bed ilo ekkatak in. Jenaj kajitōk ibbam elañe kwe...We first will see if you qualify to be in the study. We will ask if you...

- juōn ri Majōl, identify as Marshallese.
- 18 am iiō ak rutto lok, are 18 years or older.
- ewōr nañinmij in tōñal type 2 ibbam ak juon eo uwaan baamle eo am ewōr an nañinmej in tōñal type 2 (HbA1c eo ej einwōt ak laplok jen 6.5), have type 2 diabetes (HbA1c equal or greater than 6.5) or are a family member of a person with type 2 diabetes.
- emōj am bōk kilaaj in DSME ilowaan iiō ko lalem rej mootlok, have received DSME in the past five years.
- ewōr juōn armij uwaan baamle eo am im emōj an errā in bōk konaan ilo ekkatak in ibbam, have at least one family member who will agree to take part in the study with you.
- Kwōj lōmnak in emmakit jen jikin ko rej kōmmame ekkatak eo ie ilowaan 12 allōn ko, Plan to move out of the area in the next 12 months
- Ewōr am nañinmej ko renej bōbraik eok jen am bed ilo kilaaj ko einwōt nañinmej ko ejjelok unokaer ak rejjab maroñ kōmadmōdi, jab maroñ jutak make ian ak ejjab maroñ etetal, nañinmej in kōmālij, jab lolok ijen ak jaroñroñ, ak ejjab jejjet wāwein aer mōñā, have an illness that would prevent you from fully participating in the classes such as terminal illness, non-ambulatory, severe mental illness, severely impaired vision or hearing, or eating disorder

Elañe kwoj ekkar ñan bōk konaam, kōm naj kōmmami wāwein kein:

If you qualify, we will do these things:

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- Kadeloñ etam ilo kilaaj in nañinmij in tōñal ko. Kilaaj ko ikijien nañinmej in tōñal renaaj 10 awa aitokier ilowaan 8-12 wiik. Im kajojo iien kilaaj kein enaj 60 ñan 90 minit aitokier. Kilaaj ko renaj kōmman ilo mwōn jar ko ak bar juōn jikin an mwōn jar ko. Ro rej bōk konaer im uwaan baamle ko aer renej bed ilo kilaaj kein ilo juon doulul in armej ibben ro jet mōttan ekkatak in im ro uwaan baamle ko aer. Ñe kwōj kōnaan tōbar eok ilo text message ak jeje waj ilo cellphone eo am, jenej jeje waj ilo kajojo wiik ñan kakemejmej eok kōn ien eo, awa eo, im ia eo kilaaj eo enej kōmman. Jeje waj ak text message ekoba juon link eo enej boklok eok ñan calender eo ej kallikar kilaaj ko an mwōn jar eo am. Jenej maroñ bar jeje waj ñan kakemejmej eok kōn raan in data collection ak ebbōk melele ko. Ñan ad maroñ nej jeje wōj ñan cellphone ne am, jenej lelok nōmba in cellphone eo am ñan Twilio. Ejjelok bar jabdrewōt melele jenej lelok ñan Twilio. Ilo kilaaj kein, kwonaj ekkatak kōn wāwein kōjebarok am mōñā, makūtkūt im exercise, etale joñan tōñal, im wāwein ko jet remaroñ jibañ ikijien nañinmej in tōñal. Jenaj bar kajjitōk ibben armij ro nukum kwar kūr er bwe ren bar bōk konaer ilo kilaaj ko ikijien nañinmij in tōñal. Armij ro nukum remaroñ bed ilo kilaaj ko, jekdron ñe raar jab lelok etaer ñan ekkatak in. Enroll you in diabetes education classes. Classes will cover 10 hours of diabetes education over an 8-12 week period and each class will last between 60 and 90 minutes. Classes for this study will be done in a church or other faith-based setting. Participants and family members will attend classes in a group setting with other participants and their family members. If you agree to be contacted via text message, we will text you each week during classes to remind you of the date, time, and location of your class. Class reminder texts may include a link leading to a class calendar for your church. We may also text you to remind you of upcoming data collection events. In order to contact you via text message, we will share your phone number with the third-party service Twilio. No other information will be shared with Twilio. During these classes you will learn about healthy eating, being active, tracking blood sugar, and other skills that help people to manage diabetes. The family members you invite will be asked to join the study and participate in diabetes education classes. Family members can attend the classes, even if they are not in the study.
- Jenaaj kajjitōk kōn melele ko am einwōt etam, atōreej in jikin jokwe, talepon nōmba, raan in lotak, kōrā/emmaan, mare, kabijuknen, jikuul, jerbal, injuren, taktō, im jikin ko kwōj itok jeni. Jenaj kajjitōk kōn melele ko ikijien ejmour, einwōt joñan aitok, eddo, bōro, kakōlkōl in tōñal, aibōlat, jibañ jen baamle eo am, exercise ak makūtkūt, kain uno ko kwōj būki, mōñā, dren, im melele ko ikijien am kiki. Ask about demographic information such as your name, address, phone number, date of birth, sex, marital status, number of persons in your home, education, employment, insurance status, ability to access health care, and race/ethnicity. Ask about information related to your health such as height, weight, pregnancy status, tests for diabetes, blood pressure, support from your family, managing your weight, exercise, what medications you take, what you eat and drink, and your sleep.
- Rijerbal ro rej kajin majōl renaj riiti kajjitōk ko im kanne pepa in ibbam, ñe kwōj kōnaan. Kwōjjab aikuj uwaak jabdewōt kajjitōk elañe kwojjab kōnaan. Bilingual staff members will read the questions out loud and fill out the form with you, if you like. You don't have to answer any questions you don't want to answer.

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Kajojo mwōn jar ko renaj maroñ bed ilo juon ian doulul ko ruo. Mwōn jar ko ilo doulul eo juōn renaj mōkaj im jino kilaaj ko aer ālikin wōt aer ebbōk melele ko aer. Mwōn jar ko ilo doulul eo kein karuo renej bōk ejja kilaaj ko wōt bōtaab renaj jino ālikin doulul eo juōn.

Jenaj ebbōk melele (data collection) jen kwe im ro nukum raar errā in bōk konaer ilo ien kein: mokta jen an jino kilaaj kein, ālikin an jemlok kilaaj eo eliktata, im 3 allōñ ālikin kilaaj kein. Melele ko jenaj aini ilo ien data collection ko renaj einwōt kein: joñan aitokam, eddoūm, im blood pressure ak aibōlat. Kwe im ro nukum rej bed ilo ekkatak in naj bar lale joñan tōñal ko aer. Kakōlkōl kein renaj aiku j bwe jen wākār jabon adiin peim im bōk jidrik bōtōktōk. Ilo ruo lak nān jilu ian ien data collection kein, kwe im eo uwaan baamle eo am naaj bareinwōt kanne survey ko rej kajjitōk kōn nañinmij in tōñal im wāwein kōjbaroke. Ilo kajojo ien data collection kein 3 ak 4, renaj bōk tarrin 2-4 awa aitokier.

Each church will be assigned to one of two groups. Churches in one group will begin classes immediately after the first data collection event. Churches in the second group will have the same classes but they will start later than the classes for the first group.

Before classes begin, after classes end, and 3 months after the classes, we will collect information from you and your participating family members. These data collection events will include measuring your height, weight, and blood pressure. You and any participating family members will also have some tests done to track blood sugar over time. This test will require a finger prick to get a small drop of blood. At two to three of the data collection events, you and any participating family members will also fill out surveys that ask questions about diabetes care and management. Each of the 3-4 data collection events will last about 2-4 hours.

Ewi aitokan ekkatak in?

How long will this study take?

Elañe kwonaj errā nān bed ilo ekkatak in, konaj bok tarrin 10 awa in kilaaj in tōñal, 8-12 wiik aitokan im bōk konaam ilo 3-4 ien ebbōk melele ko ak data collection. Aolepen ekkatak in, koba kilaaj in tōñal ko im ien data collection ko, emaroñ bōk joñan in 10 allōñ nān juon iiō aitokan.

If you agree to join this study you will participate in 10 hours of diabetes education over an 8-12 week period and you will participate in three to four data collection events. The entire study including, the diabetes education classes and data collection will be over a period of about 10 months to one year time period.

Ak ne inaj ba jaab, ijjab kōnaan bed ilo ekkatak in?

What if I say no, I do not want to be in this study?

- Ejjelok jorāān enaj walok. Nothing bad will happen.

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- [Kwonej maroñ wõt bōk jibañ ikkijen taktō ilo UAMS.](#) You can still get medical care at UAMS.

Ewōr ta elañe inaaj ba aet, im ukōt aō lōmnak tok ālik?

What happens if I say yes, but change my mind later?

- Komaroñ bōjrak jen ekkatak in jabdewōt ien. You can stop being in the study at any time.
- Ejjelok jorāān enaj walok. Nothing bad will happen.
- Kwōj maroñ wōt taktō ilo UAMS. You can still get medical care at UAMS.
- Elañe kwōj lōmnak in bōjrak jen ekkatak in, call e Dr. Pearl McElfish ilo 479-713-8680
If you decide to stop being in the study, call Dr. Pearl McElfish at 479-713-8680.

Ewōr ke onāān aō bed ilo ekkatak in?

Will it cost me anything to be in the study?

Ejjelok onāān am bed ilo ekkatak in.

The study will not cost you anything.

Enaaj ke wōr aō kōllā kōn aō bōk konaō ilo ekkatak in?

Will I be paid for being in the study?

Aet. Kōm naj lewaj \$20 – \$100 gift card ñan kamolol eok kōn ien ko am. Ilo jilu ñan emen ien ebbōk melele kein jenaj joñe aitokam, eddoum, aibōlat, im bōk jidik bōtōktōk ñan lale joñan tōñal eo am iumwin 3 allōñ ko. Ruo lak ñan jilu iaan iien data collection kein enaj bareinwōt wōr juon survey, ñan iien kein kōm naaj lewaj ñan eok \$30 gift card nan pre-intervention im \$100 ilo gift card ilo ien ebbok melele kein 2 alikin kilaaj im mokta jen an jinoe kilaaj ko nan ro rej bed ilo kilaaj ko emokaj aer jinoe im ro rej bed ilo kilaaj ko erumwij aer jinoe. Kwoban bōk onāām jen am bed ilo kilaaj ko. Elañe kwonaaj bed ilo aolepen jilu ñan emen ien ebbōk melele kein (data collection), kwonaj bōk joñan in \$150 ñan \$180 ilo gift card. Konej maroñ in wōt ebbōk gift card ilo am nej bed ilo ien data collection ak ebbōk melele ko. Armej ro renej bed ilo 6 iaan ien ekkatak ak kilaaj ko 8 naaj bar lelok ñan er \$100 gift card. Ñe kwonaaj ped ilo jilu ñan emān ien data collection ak ebbōk melele ko im 6 ian kilaaj ko, kwonaaj maroñ bōk joñan in \$250 ñan \$280 ilo gift card. Ñan am bōk kōllā kein, jenej kajjitōk ibbam bwe kwōn kadede lok pepa in gift card eo koba lok survey eo ñan kallikar etam im signature eo am. Melele kein renej kakuni ilo juon jikin eo etiljek ilo UAMS im rijerbal ro wōt ilo ekkatak in nej maroñ deloñe. Et eo etam jenij tilmake lok ñan Tango Rewards Genius eo, ro rej loloodjake kaat in jibañ ko. Ejjelok bar melele ko ikkijem ilo pepa in ijellokin wōt etam ak jabdrewōt uwaak in melele ko am ilo ekkatak ko jar jerbal ibbam kaki jenej lelok ñan Tango Rewards Genius eo.

Yes. We will give you a \$20-\$100 in gift cards to thank you for your time. At three to four data collection events we will collect your height, weight, blood pressure, and prick your finger to collect HbA1c. For those shorter data collection events, we will give you \$20 in gift cards. Two

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to three of the data collection events will also include a survey, for those data collection events we will give you \$30 in gift card for pre-intervention and \$100 gift card for data collection events immediate post and pre intervention #2 for those who are in the intervention arm and waitlist arm respectively. You will not be paid to attend the educational classes. If you attend all three to four information collection events, you will receive \$150 to \$180 in gift cards. You will only receive gift cards for the times you attend the events. Persons who attend at least 6 of the 8 educational sessions will receive an additional \$100 gift card. If you attend all three to four data collection events and at least 6 of the classes, you will receive a total of \$250 to \$280 in gift cards. To receive payment, we ask that you complete a Gift Card Receipt Form following the survey which records your name and signature. This information will be kept on a secure UAMS server and only the program staff will have access to the information. Your name will be shared with Tango Rewards Genius, the gift card vendor. No other information from the gift card form will be shared with Tango Rewards Genius.

Ekkatak in enaj ke jibañ ña ilo jabdewōt wāwein?

Will being in this study help me in any way?

Ekkatak in emaroñ ak emaroñ jab jibañ eok, bōtaab emaroñ jibañ armij kōjbarok nañinmij in tōñal Type 2 ilju im jōklaj.

Being in the study may or may not help you but may help people manage their Type 2 Diabetes in the future.

Ta kauwōtata ko remaroñ walok jen aō bed ilo ekkatak in?

What are the risks of being in this study?

Kauwotata ko rej:

The risks are:

- Kauwotata ko ekkā aer walok jen raan ñan raan. The risks for this study are no more than what happens in everyday life.
- Komaroñ abōnōnō ilo aer wākāre addin bweūm. You may experience discomfort from the finger prick.
- Ro jet remaroñ jelā ke kwoj bed ilo ekkatak in im jelā melele ko am im kwojjab kōnan bwe ro jet ren jelā. Kōm nej kajjioñ joñan wōt am maroñ kōjebarok melele ko am, einwōt an kōmeleleik elap lok ijiko tok imaan ilo pepa in. Someone could find out that you were in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.
- Ilo am naj bed ilo kilaaj ko, armij ro jet ilo kilaaj eo remaroñ roñ melele ko am elañe konaaj kenono kōn kwe make. By taking part in the educational sessions other people in the session may learn information about you if you talk about yourself.

Elañe inaj nañinmej ak jorāān ilo aō bed ilo ekkatak in?

What if I get sick or hurt while I'm in this study?

- Elañe kwonaaj jorāān ilo ien eo kwoj bed ilo ekkatak in, jenaj jibañ eok kabbok jibañ eo kwoj aikuji. Ekoba first aid, jikin taktō ko rediñ, im jikin takto ko jet. If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and/or follow-up care.

Ta wāwein ko jet ijjelokin bed ilo ekkatak in?

What are the alternatives to being in this study?

Kwomaron jab bed ilo ekkatak in.

Ejjelok bar jet wāwein ko jet ñan bed ilo ekkatak in, einwōt an jab kōmman kōmadmōd ak wāwein ko jet remaron jibañ eok.

You do not have to be in this study.

There are no alternatives to being in this study, as it does not involve treatment or other procedures that may help you.

Remaron ke jolok ña jen ekkatak in elañe ij kōnan wōnmaanlok wōt?

Can I be taken out of the study even if I want to continue?

Aet, taktō eo (ak eo ej bōk eddoin ekkatak in) remaron kabōjrak am bōk konaam ilo ekkatak in elañe:

Yes, the study doctor (or head researcher) can take you out of the study if:

- Kwojjab loori kōmelele ko an ekkatak in. You do not follow study instructions.
- Ejjab ekkar im emman ñan kwe bwe kwōn wōnmaanlok wōt. It is not in your best interest to continue.
- Ekkatak in enaj bōjrak kōn jabdrewōt wūn. The study is stopped for any reason.

Melele ta ko renaj būki jen ña ilo ekkatak in?

What information will be collected about me in the study?

Ilo ekkatak in, jenaj aikuji melele ko kōn kwe, einwōt:

During the study, we will need to learn private things about you, including

- Melele ko am einwōt etam, atōreej, talpoon nōmba, im melele ko jet rej kallikar wōn kwe. General contact and background information about you, such name, address, telephone number, and other demographic information

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- Melele ko ikijien ejmour, einwōt joñan aitok, eddo, bōroro, kakōlkōl in tōñal, aibōlat, jibañ jen baamle eo am, makūtkūt ak exercise, wuno ta ko kwōj būki, im mōñā ko kwoj kañi koba dren ko nimōm. Medical information about you, such as height, weight, pregnancy status, tests for diabetes, blood pressure, support from your family, managing your weight, exercise, what medications you take, and what you eat and drink
- Ñe kwoj rinañinmej ilo jikin taktō eo an UAMS, jenej kajjitōk mālim eo am ñan ad maroñ bōk melele ko am kōn tōñal jen jikin taktō eo am ilo nej tarrin 12 allōñ ālikin kilaaj ko, ilo nej 18 allōñ ālikin kilaaj ko, im ilo 24 allōñ ālikin kilaaj ko. If you are a patient of UAMS, we will request permission to get information about your diabetes care from your healthcare provider 12 months after classes, at 18 months after the end of the classes, and at 24 months after the end of the classes.

Wōn enaj loi melele kein? Ewi wāwein am nej kōjbaroki jen ro jet?

Who will see this information? How will you keep it private?

- Team eo loloodjake ekkatak in enej jelā etam im naaj loi melele ko am. The local study team will know your name and have access to your information.
- Enej et eo etam wōt jenej tilmake lok ñan Tango Rewards Genius eo, ro rej lolodjake kaat in jibañ ko. Only your name will be shared with Tango Rewards Genius, the gift card vendor.
- Jenaj loloodjake im kōjbarok bwe ro rejjab bed ilo ekkatak in ren jab loi melele ko am. We will do our best to make sure no one outside the study knows you are part of the study.
- Jeban likit etam ilo melele ko am jenej buki jen kwe ilo ien ekkatak in. We will take your name off of information that we collect from you during the study.
- Ñe jenaj kwalok tōbrak ko an ekkatak in ilo pepa ko an university ko, jeban likit etam ak jabdrewōt melele ko renaj kallikar wōn kwe. When we share the results of the study in academic publications, we will not include your name or anything else that identifies you.
- Ewōr armij ro rej loloodjake bwe en jimwe an ettōr ekkatak in. Armij rein remaroñ loi melele ko am. Armij rein rej There are people who make sure the study is run the right way. These people may see information from the study about you. They are
 - ✓ Rijerbal ro an ekkatak in, The research staff
 - ✓ OHRP (Office for Human Research Protections), juon federal agency, OHRP (Office for Human Research Protections), a federal agency
 - ✓ UAMS Institutional Review Board, UAMS Institutional Review Board
 - ✓ Obij ko rellaplok im rej etali jermal kein, Other institutional oversight offices

Kakien ko an State aikuj bwe jen ba ñan ijoko rej eddoik elañe jejlā, State law requires we tell the authorities if we learn

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- ✓ **Kōn kakure ko nān ajiri ak rutto ro**, about possible child or adult abuse
- ✓ **Elañe komaroñ kakure eok make ak ro jet**, that you might hurt yourself or someone else

Melele ko aō renaj bed ia im ewi toon aer naj dābiji?

Where and how long will my information be kept?

- **Jenaj droor jet nōmba ko renaj bōk jikin etam im droor melele ko am ilo juon jikin kakkon eo etiljōk**. We will code your information and keep the key to the code in a locked file on a secure UAMS server.
- **Rijerbal ro wōt rekkar ilo ekkatak in remaroññ jelā nōmba ta ko rej kallikar melele ko am**. Only designated research study staff will be able to link your information to you.
- **Ilo nej dedelok in ekkatak in, melele ko am naj jako im nōmba ko nān melele ko am renej juloki**. At the conclusion of the study, the data will be permanently de-identified and the key code will be destroyed.
- **Melele ko am renaj jako ālikin jiljilimjuon iio ko ālikin an jemlok ekkatak in elañe kwonaj kwalok am jab kōnaan bwe jen kōjerbal melele ko am nān ekkatak ko jet ilju im jeklaj**. Your de-identified information will be destroyed seven years after the end of the research if you don't agree to let us keep your information for future research.

Elañe inaaj bōjrak jen ekkatak in, ta enaj walok nān melele ko aō im emōj kar būki ilo ekkatak in?

If I stop being in the study, what will happen to any information collected from me in the study?

- **Jenaaj kōmakit melele ko am jen ekkatak in elañe kwonaj ba jen jab kōjerbali. Jejjab maroñ kōmakit melele ko am jen ekkatak in ālikin an mōj ad jeje pepa ikijien ekkatak in**. We will remove your data from the study if you tell us you want it removed. We will not be able to take your information out of the study after it has been published.

Melele ko aō ak teej ko aō jen ekkatak in renaj ke kōjerbali nān jabdrewōt wāwein ko jet, koba nān ekkatak ko ilju im jōklaj?

Will my information or samples from the study be used for anything else, including future research?

- **Aet. Elañe kwonej errā ijin ilal, jenej kōjerbal melele ko am nān ekkatak ko ilju im jōklaj ikijien nañinmij in tōnal im nañinmij ko jet aelrok wōt**. Yes. If you agree below, we will use the information in future research related to diabetes and other metabolic disease.

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- Melele ko kōn kwe renaj kōmakiti im juon code ak nōmba ilo juon key ñan code eo ñan kōjenokloki. Melele ko renej kakuni ilo juon file eo ej lock im etiljok ilo UAMS ekkar ñan kakien ko an UAMS. Melele ko ilo computer ewōr aer password im ejjab aolep rijerbal ro an ekkatak in remaron deloñi. Elañe kwonaj ukōt am lōmnak kōn kōjerbal melele kein am ñan ekkatak ko ilju im joklaj, kūr lok Dr. Pearl McElfish ilo 479-713-8690 ak ilo pamcelfish@uams.edu. Personal identifiers will be removed and a special code or number with a key to the code will be kept separately. Information will be stored in a locked file on a secure UAMS server consistent with UAMS policies. Electronic data will be in a password protected database with access restricted to research staff. If you change your mind about use of your information in future studies, contact Dr. Pearl McElfish at 479-713-8690.
- Jeban aji melele ko am ñan armij ro jet ijelokin rijerbal ro ilo ekkatak in. Your information will not be shared with persons other than the current research staff.
- Elañe kwonaj errā bwe jen kōjerbal melele ko am ñan ekkatak ko ilju im jeklaj, innem melele ko am renaj bed wōt iumwin kōjparok ko an UAMS. If you agree to let us keep your information for future research, we will keep it indefinitely.
- Elañe kwojjab errā bwe jen dābij melele ko am ñan ekkatak ko ilju im jeklaj, innem jenaj julok aolep melele ko am jiljimijuon iiō ālikin an jemlok ekkatak in. If you don't agree to let us keep your information for future research, your information will be destroyed seven years after the end of the research.

Kom nej ke ba ñan ña kōn tōbrakin ekkatak in?

Will you tell me the results of the study?

- Aet. Jenaaj kennanik eok im kajojo armij ro rej bed ilo ekkatak in kōn jabdrewōt melele ko reaurōk renaj walok jen ekkatak in. Yes. We will tell you and every person in the study about anything important that we discover from the study.

Kom nej ke kōnnanōk iiō kōn jabdewōt wāwein ko remaron jelet ejmour eo aō?

Will you tell me anything you learn that may impact my health?

- Aet. Jenaaj kōnnanōk eok elañe enaaj walok jabdewōt melele ko raurōk ikijien ejmour eo am. Yes. If we learn something about you that might be important for your health, we will tell you.

Ta enaaj walok elañe ewōr melele ko rōkāāl ikijien ekkatak in?

What if new information comes up about the study?

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- [Jōknaan bwe kwon jelā kōn jabdewōt melele ko im remaroñ jāniji am lōmnak kōn am bed ilo ekkatak in.](#) We want you to know about anything that may change your mind about being in the study.
- [Team eo ej loloodjake ekkatak in enaaj kōnnanik eok ilo an.](#) The study team will let you know by:
 - ✓ [call eok](#), calling you
 - ✓ [jilkinwaj juon leta](#), sending you a letter
 - ✓ [kōnnanik eok ilo juon ian ien bar rool waj ko](#), telling you at a follow up visit

Ak ñe ewōr aō kajjitōk?

What if I have questions?

- [Kūr lok armij eo ej bōk eddo in ekkatak in Dr. Pearl McElfish ilo 479-713-8680 ak ilo \[pamcelfish@uams.edu\]\(mailto:pamcelfish@uams.edu\), elañe](#) Please call the head researcher of the study Dr. Pearl McElfish at 479-713-8680 if you
 - ✓ [ewōr am kajjitōk ikijien ekkatak in](#), have any questions about this study
 - ✓ [ewōr am kajjitok ikijien maroñ ko am](#), have questions about your rights
 - ✓ [eñjake ke ewōr jorāān emōj an walok ilo am bed ilo ekkatak in](#), feel you have been injured in any way by being in this study
- [Komaroñ in tōbar rijerbal ro an UAMS ro rej loloodjake ekkatak in ñe kwoj jab maroñ tōbar rijerbal ro ak kwoj kōnaan tōbar juon eo ejjab jerbal ilo ekkatak in. Kūr tok UAMS review board eo ilo 501-686-5667 ilo awa in jerbal ko.](#) You can also call the office at UAMS that supervises research if you can't reach the study team or want to speak to someone not directly involved with this study. To do so call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

University of Arkansas for Medical Sciences HIPAA Authorization Form

- **Health Insurance Portability and Accountability Act of 1996 ej kakien eo an United States im ej kōmman kakien ko ikijien kōjbarok melele in taktō ko an armij. Health Insurance Portability and Accountability Act of 1996 is the United States legislation that provides data privacy and security provisions for safeguarding medical information.**
- **Naan eo “kwe” ej jerbal nān melele kein ruo: armij eo ej bōk konaan ilo ekkatak in koba armij eo ej letok mālim in bed ilo ekkatak in. Pepa in koba pepa in mālim eo (consent form) rej aikuj koba ibben dron ilo aer lewaj melele kein. The word “you” means both the person who takes part in the research study. This form and the program consent form need to be kept together.**

Jej kajitok bwe kwon bōk konaam ilo ekkatak in im emōj kōmeleleiki ilo pepa in consent form ak mālim eo. Nān kōmmane ekkatak in, jenaj aikuj bōk melele ko rej kallikar wōn kwe. Jemaronā naaj kajjitōk kōn melele kein:

- raan in lōtak
- kōrā/emmaan
- emōj ke mare
- jete armij ilo kabijuknen eo am
- jikuul
- jerbal
- injuren
- Nañinmej ko jet remaron walok jen nañinmej in tōñal
- taktō
- kwoj jen ia/lal eo am
- aitokam
- eddoim
- bororo
- kakōlkōl ko nān nañinmij in tōñal
- kakōlkōl ko nān nañinmij in kūruij
- blood pressure ak aibōlat
- jibañ jen baamle eo
- kōjbarok am eddo
- exercise ak makūtkūt
- kain mōñā im dren ko nimōm
- wā in COVID19 ko am

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- uno ko kwōj būki

Melele kein renaj kōjerbali ñan kōlablok melele ko ad ikkijien kōmman kilaaj kōn nañinmij in tōñal im wāwein kōjbarok. Jenaaj bōk wōt melele ko jej aikuji ñan ekkatak in. Melele ko renaaj walok ilo am bōk konaam ilo ekkatak in rej einwōt:

- joñan juka ak tōñal eo ilo ānbwinnūm
- joñan aer in bōtōktōk ilo ānbwinnūm

Bwe kwon bed ilo ekkatak in, kwoj aikuji letok mālim bwe jen bōk melele ko am, kōbooji, im je pepa ko ñan kwalok tōbrak in ekkatak in.

Kōm naaj, ak kōm maroñ kwalok melele kōn ejmour eo am ibben armij ro ilo University of Arkansas for Medical Sciences (UAMS) ro im rej jibañ kōn ekkatak in, einwōt rijerbal ro an ekkatak in, UAMS Institutional Review Board eo, im obij eo ej bōk eddoin kakien ko an ekkatak ko ilo UAMS.

Kom maroñ kwalok melele ko ikijien ejmour eo am ibben armij ro itulikin UAMS im rej loloorjake bwe en jimwe ad kōmmāni ekkatak kein, einwōt obij eo an Office for Human Research Protections im obij ko rej bar loloorjake ak koba lok ibbeir ilo aer jerbali kakien kein an ekkatak in. Jej kōtmene bwe ro rej bōk konaer ilo kōmmāni ekkatak ko remelele aurōkin kōjbarok melele ko am. Bōtaab, jet armij ro itulikin in UAMS remaroñ lilok melele ko am ñan bar jet. Elañe renaaj, kakien eo UAMS ej aikuji loore remaroñ jab jelet er im remaroñ jab kōjbarok melele ko am.

Pepa in mālim in ñan bōk, kōjerbali, im lelok melele ko am enaaj jemlok kitien ilo ien eo ejemlok ekkatak in. Ilo jemlok in pepa in, komaron kelet bwe jen bar kōjerbali melele ko am ñan ekkatak ko iliju im jeklaj.

Elañe kwonaaj jaini pepa in, kwoj letok mālim bwe jen kōmman, aini im aji melele ko emōj kallikari ijin. Kwōjjab aikuji jaini pepa in. Bōtaap, elañe kwoj kelet in jab jaini pepa in, innem kwōjjab maroñ bed ilo ekkatak in. Kwōj aikuji jaini pepa im mālim in elañe kwōj kōnaan bed ilo ekkatak in.

Elañe kwōnaj jaini pepa in innem tokālik kallikar ke kwōjjab kōnaan bwe jen bōk ak aji melele ko am, kwōj aikuji je im jilkinlok juōn am leta ñan eo ej bōk eddoin ekkatak in ak Prinicipal Investigator eo:

Pearl McElfish, PhD
University of Arkansas for Medical Sciences Northwest
2708 S 48th Street
Springdale, AR 72762

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pamcelfish@uams.edu

Kwōnaaj aikuj jaini leta in, je etan taitōl eo an ekkatak in ie im ej bed itulōn tata in pepa in ālikin naan kein “Study Title”, im aikuj je im kallikar ke emōj am ukōt am lōmnak im kwōj kabōjrak mālīm eo am ilo pepa in “HIPAA Research Authorization” eo. Kwōnaaj aikuj bojrak jen ekkatak in elañe jejjab maroñ bōk im aji melele ko am. Bōtaab, bwe jen dābij wōt melele im jimwe ko an ekkatak in, jemaroñin naj kōjerbal wōt melele ko am emōj kar būki mokta jen an Principal Investigator eo loe leta in nān kabōjrak am bed ilo ekkatak in.

We are asking you to take part in the research study described in the consent form. To do this program, we need to collect health information that identifies you. We may collect the following information:

- date of birth
- sex
- marital status
- number of persons in your home
- education
- employment
- insurance status
- diabetes-related health conditions
- ability to access health care
- race/ethnicity
- height
- weight
- pregnancy status
- tests for diabetes
- tests for cholesterol
- blood pressure
- support from your family
- managing your weight
- exercise
- COVID-19 vaccination history
- what you eat and drink
- what medications you take

This information will be used for the purpose of learning more about teaching diabetes self-management. We will only collect information that is needed for the research. Participating in this study will provide the following health information:

- blood sugar levels
- blood pressure levels

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For you to be included in this study, we need your permission to collect, create and share this information.

We will, or may, share your health information with people at the University of Arkansas for Medical Sciences (UAMS) who help with the research or things related to the research process, such as the program staff, the UAMS Institutional Review Board and the research compliance office at the University of Arkansas for Medical Sciences.

We may need to share your health information with people outside of UAMS who make sure we do the program properly, such as the Office for Human Research Protections and other institutional oversight offices. We believe that those involved with programs understand the importance of preserving the confidentiality of your health information. However, some of the people outside of UAMS may share your health information with someone else. If they do, the same laws that UAMS must obey may not apply to others to protect your health information.

This authorization to collect, use and share your health information expires at the end of the program unless you agree to allow us to use your de-identified information for future research at the bottom of this form.

If you sign this form, you are giving us permission to create, collect, use and share your health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, you cannot be in the program. You need to sign this form and the consent form if you want to be in the program.

If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to Principal Investigator:

Pearl McElfish, PhD
University of Arkansas for Medical Sciences Northwest
2708 S 48th Street
Springdale, AR 72762
pamcelfish@uams.edu

The letter needs to be signed by you, should list the “Study Title” listed on this form, and should state that you have changed your mind and that you are revoking your “HIPAA Research Authorization”. You will need to leave the program if we cannot collect and share any more health information. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

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Ilo aō jaini pepa in, ij kallikar ke:

By signing the document, I am saying:

- ✓ Ñaij melele ke aō bebe bōk konaō ilo ekkatak in. I understand that joining this study is voluntary.
- ✓ Ñaij errā in bed ilo ekkatak in. I agree to be in the study.
- ✓ Juon armij ear konono ibba kōn melele ko ilo pepa in im uwaaki aōlep kajjitōk ko aō.
- ✓ Someone talked with me about the information in this document and answered all my questions.

Ijelā ke:

I know that:

- ✓ Imaroñ bōjrak jabdewōt ien ilo ekkatak in, im ejjelok jorāān enaaj walok ñan ña. I can stop any and all parts of the study at any time and nothing bad will happen to me.
- ✓ Imaroñ kūr lok obij eo ej bōk eddo in ekkatak ko (UAMS Institutional Review Board) ilo 501-686-5667 elañe ewōr jabdewōt kajjitōk ko ikijien ekkatak in ak ikijien maroñ ko aō. I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ Ijjab julok maroñ ko aō ilo aō jaini pepa in. I do not give up any of my rights by signing this form.
- ✓ Kelet eo ao eban kōmman oktak ilo aō nej etal wōt ñan UAMS in taktō. My decision will not change my medical care at UAMS.

Ñaij errā in bed ilo ekkatak in.

I agree to be part of this study.

☐ YES/AET ☐ NO/JAAB

Ij lelok mālim bwe UAMS en kōjrbal melele ko aō ilo ekkatak ñan ekkatak ko jet UAMS ej kōmmani.

I give permission for UAMS to link information from this study to other studies conducted by UAMS.

☐ YES/AET ☐ NO/JAAB

Ij errā bwe melele ko aō im emoj jolok etta jeni ren wōnmaanlok wōt im kōjrbali ñan ekkatak ko an tōñal iliju im jōklaj.

I agree to my de-identified information being used for future diabetes-related research.

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☐ YES/AET ☐ NO/JAAB

Ij errā bwe ren kenaanik nā ikijien ekkatak ko jet iliju im jōklaj.

I agree to being contacted for future research related to this study.

☐ YES/AET ☐ NO/JAAB

Etam (jouj im kallikare)

Your name (please print)

Jaini etam

Your signature

Raan eo

Date

Armej eo ej loloodjake mālim in (kallikar etam)

Person Obtaining Consent name (please print)

Jain eo an armej eo ej loloodjake mālim in

Person Obtaining Consent signature

Raan eo

Date