COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH

Study Title: An adolescent-mediated intervention to improve diabetes prevention and management in Pacific Islander families

Principal Investigator (the person who is responsible for this research):
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Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to test a family-based intervention designed to improve diabetes-related outcomes. You will be participating as a pair with an adolescent who lives with you.
- There will be two study groups and you (as a pair) will be randomly assigned to one of them. In both cases, the adolescent you are participating with will be the one to receive the intervention - they will either receive leadership and life skills training or a diabetes education program. During the study we will ask you to continue with your usual diabetes care and to complete research assessments.
- We will assess your eligibility for the study today, then if you (and the adolescent you are participating with) are eligible and choose to participate we will ask you both to complete three research assessments over the course of 12 months. These research assessments will happen approximately every 6 months and will take place in your home.
- Research assessments will include questionnaires and physical measurements (blood glucose, blood pressure, height, weight, and waist circumference). You may also be asked to participate in an interview with one of our research team members or a focus group discussion in the months following the completion of the program.
- There are some risks from participating in this study; however, the risks of participating in this study are considered to be small. There are no physical risks associated with participating in this study. However, some of the questions in the questionnaires may make you feel uncomfortable and there is a possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If there are questions in our questionnaires that you feel uncomfortable asking, you have every right to refuse to answer.
- The study may have benefits for you. There are a number of potential benefits to participating in this study. If the intervention is successful, those who are randomized to the intervention group may experience direct health benefits: lower HbA1c, weight loss, and reduced blood pressure. Beyond the benefits to individual participants, we hope that this research study may tell us how best to deliver diabetes care programs and improve diabetes outcomes for all American Samoans.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you

make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to join a research study because you are an adult who has been diagnosed with diabetes. You are also the parent/grandparent of an adolescent between the ages of 14-17 years old, who has expressed interest in participating in this research study. We will enroll 160 pairs into the study (a parent/grandparent with diabetes + an adolescent), meaning that a total of 320 people will participate.

Who is paying for the study?
This study is supported by a grant from the US National Institutes of Health, National Institute for Diabetes, Digestive, and Kidney Diseases (NIH R01DK128277; awarded to Dr. Hawley).

What is the study about?

The goal of the study is to understand whether adolescents - if given sufficient education and practical skills - can support their family members in improving the control of their diabetes and their diabetes management.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

If you decide to participate, you will begin the study today and will remain enrolled and in contact with us for 12 months. During that time, you will complete three research assessments. These research assessments will take place approximately every 6 months. We may also ask you to complete an open-ended interview about your experience of the study and/or to participate in a group discussion with others who complete the research study.

If you decide to participate in the study, we will ask you to complete a few activities today:

1. We will measure your weight and height, your blood sugar levels (HbA1c; using a fingerstick blood sample), blood pressure and waist circumference
2. We will ask you to complete a questionnaire to determine your eligibility

These activities will take approximately 25 minutes to complete.

If you remain eligible for the study after completing these activities, and the adolescent who you are planning to participate with also meets eligibility criteria, you will be enrolled in the study.

Upon enrollment, you will be asked to participate in the first (baseline) assessment. This assessment can take place today, or can be scheduled for another convenient time. During this assessment you will be asked to complete a series of questionnaire measures. These questionnaires will collect information about you and your household. We will ask questions about your health, diet, and physical activity practices and about your diabetes - specifically, what you understand about your condition, how you currently manage your diabetes, how it impacts your life, and who supports you in coping with your diabetes. We will ask questions about your household, including how many people share your home, about your income and access to food, and about the relationships among family members, particularly your

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relationship with the adolescent who you enrolled with. If you schedule the baseline assessment for a later time, we will also re-measure your height, weight, blood pressure, and waist circumference. These activities are expected to take approximately 60 minutes to complete.

After you complete the first (baseline) research assessment, you and the adolescent you are participating with will be randomly assigned to one of two study groups. This assignment will determine the activities that the adolescent member of your pair will complete over the next six months. Adolescents from 80 pairs will receive six months of diabetes education (the study intervention) and the other 80 adolescents will receive six months of leadership and life skills training, which will not be diabetes focused. This is called a 'control' group and we will compare outcomes between those receiving the intervention and the control group to see if the intervention has a positive impact on the health of the pairs who receive it. Random assignment means that you will be put into a group by chance - it is like flipping a coin, neither you or the adolescent you are participating with will be able to choose the group.

Six months after the initial research assessment - after the adolescent in your pair has completed their diabetes education or leadership and life skills training - you will be asked to complete a second research assessment. We will ask you several of the same questionnaires about your health, diet, physical activity practices, and about your diabetes and repeat some questions about your relationship with the adolescent you are participating with. We will also measure your height, weight, blood pressure, blood sugar, and waist circumference. Finally, we will ask some questions about any costs you might have accrued while taking part in the study. These activities will again take around 60 minutes to complete.

Six months later (12 months after your initial enrollment) we will repeat the same assessment for a third and final time. This final assessment will also take around 60 minutes to complete. At this point, at the end of the study, if you were assigned to the control group, we will provide you with all of the information that the intervention group received about managing diabetes.

Medical Record Review

Once your participation in the study is complete, we will access any medical records that are kept about your diabetes care at both the Community Health Centers and LBJ Hospital. We will do this so that we can collect some objective data about your health during the program and your use of diabetes care services. We will collect information about your primary care visits, any emergency care, hospitalizations and inpatient stays, use of preventative services (dental, foot clinic, mental health services), and any medications prescribed.

Focus Groups and Interviews

Shortly after the second research assessment (six months after you enroll in the study), you may also be asked to participate in an interview with one of our research team members and/or a focus group discussion in the months following the completion of the program. These interviews and discussions will be used to learn about the experience of participating in the research study. If you are asked, and agree, to participate in this part of the study, these activities will take an additional 1-2 hours of your time. If you are selected to complete an interview, you will complete the interview with the adolescent you are participating with and researchers will ask the two of you questions together. If you are selected to participate in a focus group discussion, you will join other adults participating in the research study for that discussion. All interviews/discussions will be tape-recorded for later review by the research team. We will attempt to protect your privacy in a number of ways, which we describe in more detail below.

Return of information to participants

At each research assessment we will provide feedback on your height, weight, weight status (based on how healthy your weight is for your height), blood sugar (HbA1c) and blood pressure. At the time of your last research assessment, or after it is completed, you may request a copy of all of the information collected about you, including the information abstracted from your medical records. Investigators will provide that information to you.

At the conclusion of this research study, when assessments have been completed on all 320 research participants, we will collate the outcomes of the study and return information about the key study findings to participants. This will occur in the form of a brief study report with information about where to access more detailed study reporting.

What are the risks and discomforts of participating?

There are some risks associated with participating in this study; however, the risks of participating in this study are considered to be small. During the physical assessments you may experience a small amount of discomfort from the finger stick blood sample used to measure blood sugar, and/or pressure from the arm cuff used to measure blood pressure. Some of the questions in the questionnaires or the interviews/group discussions (if you are invited to participate) may make you feel uncomfortable and there is a possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If there are questions in our questionnaires or interviews that you feel uncomfortable answering, you have every right to refuse to answer.

You will continue with your usual diabetes care during the study. The intervention we are testing (the provision of diabetes education to adolescents) is a behavioral intervention and there are no experimental procedures or drugs involved.

If you are asked, and agree, to participate in an interview during the study, you may experience some discomfort associated with discussing issues such as your health and challenges in managing your diabetes in the presence of a family member. The project staff leading the interview will be extensively trained to make you as comfortable as possible in this situation. However, you should consider your comfort in participating with others before signing this consent form seeing as there is a chance that you may be asked to participate in the paired semi-structured interview.

If you are asked to participate in a group discussion during the study, you may experience similar discomfort associated with discussing your health and diabetes management and your opinions about the program in the presence of other group members. The focus group leaders will also be extensively trained to make you all comfortable in the group environment, however you should again consider your comfort participating with a group before signing this consent form seeing as there is a chance that you may be asked to participate in a group discussion. In any group discussion there is the potential for loss of confidentiality. The importance of confidentiality will be discussed with the group before any discussion begins, but there will remain a risk that information discussed in the group will be shared with others.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study. This information will be communicated to you either by phone or with an in person visit.

How can the study possibly benefit me?

Participating in this research study may have benefits to you. If the intervention approach we are testing is successful, the adolescent you are participating with may be able to share information and/or offer practical support that may help you to manage your diabetes. Regardless of which group you are assigned to, we will give you feedback every six months about your health, including your weight status, blood sugar, and blood pressure. If at any research assessment you are determined to have high blood pressure or dangerously poor control of your diabetes we will provide referrals to appropriate health care providers. Beyond the benefits to individual participants, we hope that this research study may tell us how best to deliver diabetes care programs and improve diabetes outcomes for all American Samoans.

How can the study possibly benefit other people?

The study might help other people and science by helping us understand more about how to effectively improve diabetes outcomes among Samoan families.

Are there any costs to participation?

You will not have to pay to take part in this study. Study assessments will take place at your home or at another preferred location. Costs you may incur as a family will include providing transportation for the adolescent you are participating with to group education sessions (which will take place every other week for 6 months; 12 sessions total) and transportation for you both to a group discussion if you are asked to participate in that part of the study.

Will I be paid for participation?

You will be paid for taking part in this study. You will receive $20 after completing each study assessment (baseline, 6 months post-randomization, and 12-months post-randomization). You will receive an additional $20 if you are selected to take part in one of the group discussions. You may be responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

Study Assessments

All of your responses to study questionnaires, along with your clinical measures (i.e., HbA1c, blood pressure values, waist circumference, weight, and height), and information extracted from your medical records will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, and the Yale University Human Subjects Committee, or the American Samoan Department of Health Institutional Review Board) will have access to any information that could identify you.

You will be assigned a unique study ID number. Any time you complete a study questionnaire, we collect a physical measurement, and/or if you are asked to complete an interview/group discussion, this ID number will be the only thing used to identify you. The code linking your ID number with your name will be stored separately from any information about you, in a locked file cabinet. When we publish any results from this study, we will do so in a way that does not identify you unless we get your specific permission to do so.

We may share your data from this study with other researchers so that they can check the accuracy of our conclusions but will only do so if we are confident that your confidentiality is protected. We may also share your data with other researchers for use in future research studies. You, or your legally authorized representative, will not be asked to provide additional informed consent if that were to occur. We will do our best to protect your identity. We will only share de-identified data with others. They will not be able to link the ID number assigned to your data to you. We follow strict security safeguards to avoid other people knowing your identity.

Group Discussions

If you are selected to participate in a group discussion we will keep any information you share during that discussion confidential. We ask all group members not to repeat any information shared during the group discussion with others. However, we have no control over what happens outside of the group. Therefore, if you choose to participate, please be aware of what you share in the group and do not share anything you hear from others outside of the group.

Certificate of Confidentiality

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

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.
Except as permitted by law, your health information will not be released in an identifiable form outside of the Yale University research team. Note, however, that your records may be reviewed by those responsible for the proper conduct of research such as the Yale University Human Research Protection Program, Yale University Human Subjects Committee or representatives of the U.S. Department of Health and Human Services or the National Institutes of Health.

Information may be re-disclosed if the recipients are not required by law to protect the privacy of the information. At the conclusions of this study, any identifying information related to your research participation will be destroyed, rendering the data anonymous.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

What will happen with my data if I stop participating?

Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, Dr. Hawley, at **(203) 737-7176**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date