RESEARCH PARTICIPANT INFORMED CONSENT

I. Investigators

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II. Title

The **H**awaii **P**atient **R**eward **A**nd **I**ncentive **P**rogram to **S**upport **E**mpowerment (HI-PRAISE) Project.
Sponsor: Centers for Medicare and Medicaid Services (CMS).
CMS-1B1-11-011 CFDA 93.536

III. Informed Consent

You are being asked to participate in a research study HI-PRAISE. This is a consent form. It is to provide you with information about this study. Your health care team (study staff) will talk with you about this information. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your regular doctor, friends and family before you make your decision. If there are any words or sections in this consent form that you do not understand, please ask the study staff to explain them. If you agree to take part in this study, you will be asked to sign this consent form.

It is important that you understand that taking part in this study is of your own free will. You may decide not to participate, or you may decide to stop being in the study at any time, and it will not affect your regular medical care now, or in the future.

IV. Why is this Study Being Done

This study is being conducted to study the impact of patient rewards and incentives in improving diabetes management. You are being asked to take part in this study because you have either Type 1 or Type 2 diabetes and your medical insurance provider is MedQuest or Medicaid. Approximately 1000 adults with diabetes will participate in this study. The purpose of this study is to compare the effects (good and bad) of rewards and incentives, and diabetes education in assisting persons with diabetes in self management. We want to see if giving rewards for healthy behaviors will help people manage their diabetes better, reduce the complications of diabetes, and cost associated with these

complications. This research is being done because we do not know if patient rewards and incentives improve the health of persons with diabetes.

V. Study Procedures

We will enroll all persons with diabetes on Medicaid at the community health centers (CHCs) up to Dec 31, 2014. Rewards and Incentives will be given out yearly for the duration of the study to all persons with diabetes who attain the American Diabetes Association (ADA) guidelines.

If you take part in this study, you will have the following tests and procedures:

1. The following usual blood tests for persons with diabetes will be done by your physician – Hemoglobin A1C and fasting lipid profile. We are asking you to give 15 cc of blood (about 1 tablespoon).
2. You will be encouraged to receive the recommended immunizations of pneumococcal vaccination and annual influenza vaccination.
3. Health coaches, care coordinators, or someone on your health care team will assist with making appointments for eye examination.
4. Heath coaches, care coordinators, or someone on your health care team will assist with obtaining treatment for smoking cessation and/or behavioral health counseling if needed.
5. Satisfaction surveys will be conducted randomly at the health centers.
6. Your medical chart will be reviewed for recent hospitalizations and emergency room visits, brief medical history, and medication compliance.
7. You may be requested to participate in an optional focus group discussion.

Participation in the study will be for a total of 2 - 3 years. The researcher may decide to take you off this study if funding is stopped; your condition worsens such as progression of end-stage renal disease, amputation, cardiac surgery or multiple hospitalizations. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff and your regular doctor first. There are no serious health consequences of sudden withdrawal from the study. The results of your blood tests will be shared with you and your doctor to help with the care of your diabetes.

VI. Risks

While on the study, you are at risk for certain side effects:

1. Taking blood may cause some brief soreness, bleeding, and bruising where the needle enters the body, and in a few cases swelling at the site where the needle enters the body. Rarely, fainting and infection can occur. Risk of infection is slight since only sterile one-time equipment will be used.
2. You might also have anxiety as a result of the questions you will be asked and the information that will be shared with you related to the serious nature of diabetes and related health conditions.
3. Your condition may not improve or may worsen while participating in this study.

VII. Benefits

By participating in this study, you will be providing information to the study doctors that will show the effects of the *HI-PRAISE: Hawaii Patient Reward And Incentive Program to Support Empowerment* project on impacting change in lifestyle and management in persons with diabetes. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit other participants with diabetes to make lifestyle changes to improve their health in the future.

VIII. Costs

All clinic and professional fees, diagnostic and laboratory tests which will be performed as part of this study are provided at no cost to you. Your regular medical insurance will be billed for the blood testing as these are usual tests for the care of persons with diabetes.

IX. Compensation

You will be provided incentives (gift cards, gift items, or vouchers) ranging from $\leq$ \$10 to $\leq$ \$50 for obtaining the recommended ADA guidelines of care. Maximum earned incentives could total $\leq$ \$320 per year.

X. Alternatives

Instead of being in this study, you may request the standard medical treatment for your diabetes. You do not have to participate in this study to receive treatment for your condition. Please talk to your regular doctor about all your treatment options.

XI. Confidentiality

All research information about you will be held confidential to the extent allowed by state and federal law. Your personal information will not be given to anyone without your written permission. A code, which will be known only to study personnel, will be used instead of your name on medical records in this study. Research records which may be identifiable to you will be kept in a secure locked file when not being used.

If you switch primary care physicians to another community health center, and wish to continue to participate in the HI-PRAISE study, your research record will be shared with the new community health center. Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Agencies with research oversight, who may review your records include: the University of Hawaii Human Studies Program, Hawaii Department of Human Services, Centers for Medicare and Medicaid Services, study evaluators Research Triangle Institute and National Academy of State Health Policy. The results of this program will be used to improve the quality of preventative health services funded by CMS. Confidentiality does not prevent you from releasing information about yourself and your participation in the study. You will be asked to sign an authorization form should there be a need to release personal health information.

XII. Voluntary Participation

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other medical care at this site.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

XIII. Injury Related to the Study

If you are injured as a result of being in this study, you will be provided what immediate treatment is available for your injuries. You will then be told where you may get other treatment. The cost for this treatment will be charged to your insurance company or to you. Your insurance company may not pay for these costs. If your insurance will not pay for these costs, they will be your responsibility. The University of Hawaii has no program to pay you or compensate you in any way for your injuries.

XIV. Questions

You are free to ask questions that you may have about your treatment and your rights as a research participant at any time. If you have questions about this study, or a research-related injury you should contact the investigator Dr. Rebecca Ozaki at (808) 956-4126. You may also contact Dr. Ritabelle Fernandes at (808) 523-8461. If you have questions about your rights as a research subject, contact the Human Studies Program at (808) 956-5007 or uhirb@hawaii.edu.

XV. Statement of Consent

I have read the above information, or it has been read to me. I have had the opportunity to discuss this research study with study staff, and I have had my questions answered by them in language I understand. I take part in this study of my own free will, and I understand that I may withdraw from participation at any time and this will not affect my medical care. My consent to participate in this study does not take away any of my legal rights in the event of negligence or carelessness of anyone working on this project. A copy of this consent form has been given to me. I agree to take part in this study.

_____

Subject's Name (print) **Signature** **Date**

Medical Interpreter for Non-English speaking participants:
I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____ **Date** _____

Signature: _____ **Role in the study:** _____