Colorectal Cancer Screening Assessment Study in American Samoa

NCT04500171- American Samoa Community Cancer Coalition and the UH Cancer Center

Background / Statement of Need

Brief Summary.

Colorectal Cancer is the third most prevalent cancer in American Samoa for both men and women. Fortunately, screening modalities such as FOBT, flexible sigmoidoscopy, and colonoscopy are available on island. However, only 7% of eligible adults have reported receiving screening versus 62.9% in the U.S. (ASDOH, 2013[1]). Low and/or no participation in preventive health services is associated with knowledge deficits on health promotion behaviors. However, there were no studies to identify contributing knowledge risk factors and colorectal cancer screening within the indigenous Samoan population. In 2018 the Indigenous Samoan Partnership to Initiate Research Excellence (INSPIRE) conducted a pilot study to determine colorectal cancer (CRC) health literacy levels within the adult population 45 years or older in both English and Samoan using the Short-Test of Functional Health Literacy (S-TOFHLA). Results indicate 81% of the Samoan speaking (N=293) and 44% of the English speaking (N=418) participants demonstrated "inadequate" health literacy. Accordingly, these groups are most likely to have difficulty reading, understanding, and interpreting health materials, directions for their health care and most likely to fail to follow prescribed diets or treatment regimens. Therefore, modifications must be made to CRC screening materials in order to enable the appropriate actions and understanding with these persons.

Purpose and Primary Outcomes.

This study, led by the American Samoa Community Cancer Coalition's INdigenous Samoan Partnership to Initiatie Research Excellence (INSPIRE) and the UH Cancer Center's project team including Dr. Cassel, will utilize a community-based and culturally relevant process to assess the uptake of fecal occult blood testing (FOBT) using tailored colorectal cancer patient education materials for those with inadequate health literacy. Our primary outcomes include: 1) process to develop "suitable" and "comprehensible" health promotion materials for populations in English and Samoan with various health literacy levels, 2) commitment to use the FOBT Colocare home kit, and 3) use of a FOBT Colocare home kit.

Study Overview

Readability, Suitability, and Comprehensibility.

Health literacy is defined by the Institute of Medicine as the "degree to which indivduals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." The s-TOFHLA has been used to determine individual health literacy in the indigenous population in American Samoa by the 2018 INSPIRE pilot study. However, creating an effective health message that meets varying standards of health literacy levels is the next challenge in which this pilot project addresses.

Creating appropriate messaging to initiate a behavior change involves more than readability. The SMOG and Flesch-Kincaid tools determine grade level reading by the number of polysyllabic words in a paragraph or set number of sentences. This is a limitation as it does not take into account factors that comprise a print message including numeric presentation, illustrations, motivators and reader interaction. Realizing this, Doak et al., determined an improved method to assess the efficacy of patient education material (PEM) was the Suitability Assessment of Materials (SAM), and it evaluated 6 categories: content, literacy demand, graphics, layout/typography, learning stimulation and motivation, and cultural appropriateness. Helitzer et al. (2009), added terms to assess reading, calculating and solving problems creating

the Suitability and Comprehensibility Assessment of Materials (SAM + CAM). The SAM + CAM is comprised of 22 evaluation items within the 6 original categories. The instrument has been validated using 69 PEMs on cervical cancer care. Thus, all PEM developed for this project will be evaluated using the SAM + CAM.

Evidence-Based Model

The proposed pilot study is a randomized controlled trial utilizing the evidence based program "Against Colorectal Cancer in Our Neighborhoods" (ACCION) for the Latino population in Texas as a guide. The health belief model and social cognitive theory were used as foundational principles to develop an intervention that builds awareness to initiate a CRC screening behavior modification.

The program was administered in two separate counties (El Paso - intervention & Cameron - control) and used convenience smplaing methods. Recruits in the intervention group were randomized into three areas: presentation only, video, only, or presentation plus video. The control group was given the usual CRC screening protocol and no intervention components. Inclusion criteria were those age 50-75, being uninsured, lived in Texas, and being due for CRC screening.

Results of the study show after a six month follow-up 80.5% (n=467) of the intervention group followed screening recommendations versus 17% (n=317) of the control group. It is also notable there were no discernible differences in screening rates between the intervention methods.

Material Development and Project Resources.

Table 1 provides a brief summary of the Patient Education Materials (PEM) and the assessment tools that will be used to determine efficacy. The project staff will use existing original materials developed by the ColoCARE manufacturer and the Centers for Disease Control and Prevention. A brief instructional video will be created to accompany modified materials for the experiment group.

Table 1. Brief Summary of Patient Education Material Development

Control Group PEM	**English Original Assessment Tools**	**Samoan Original Assessment Tools**
Colocare Instruction Sheet	SAM + CAM SMOG	SAM + CAM Cloze Procedure
CDC Colorectal cancer screening for life brochure	SAM + CAM SMOG	SAM + CAM Cloze Procedure
Experiment Group PEM	**English Modified Asessment Tools**	**Samoan Modified Assessment Tools**
Colocare Instruction Sheet	SAM + CAM – Superior rating SMOG – 5th Grade Level	SAM + CAM – Superior rating Cloze Procedure
CDC Colorectal Cancer Screening for Life Brochure	SAM + CAM – Superior rating SMOG – 5th Grade Level	SAM + CAM – Superior rating Cloze Procedure
Colocare Instruction Video	Modified SAM + CAM -Superior rating	Modified SAM + CAM -Superior rating

ColoCARE Disposable Fecal Occult Blood Test

The ColoCARE FOBT is cost effective and a simple way to detect presymptomatic bleeding caused by gastrointestinal diseases. Based upon the design of a traditional guiac slide test, the test pad is placed in the toilet after a bowel movement. The pad is treated with chomogen and if blood is detected will turn a blue and/or green color. There is no requirement for lab staff or the handling of stool. Each kit contains three pads, one large test square and two smaller control squares to verify the system is working properly. Participants who are reported as symptomatic will be referred to the Lyndon Baines Johnson Tropical Medical Center (LBJTMC) for immediate follow up by clinical staff.

Translation

The translation of materials will be done in the following process: forward translation, synthesis, back translation, expert committee review and pretesting (Beaton et al., 2000). The Samoan vocabulary can be described as limited compared to English. The same Samoan word, or phrase, may be used to translate from English even if the PEM is revised to lower grade readability. Consideration of the translations between the control and experiment groups will be discussed within the project staff and consulted with the expert committee.

Assessment Tools: SAM + CAM, Samoan-s-TOFHLA, s-TOFHLA, and HINTS

All original and modified PEMs in both languages will be administered by project staff and pre-testing group. Each of the 22 items within the 6 identified categories are given a score of 0 – 2 based upon certain criteria. Total scores are calculated into percentages and 100% to 70% is superior, “69% to 40%” is “adequate”, while 39% - 0% is “not suitable”.The data gathered on the original materials will be used to develop the modified versions of the PEM. The goal of the modified version is to achieve a rating of “superior”. If the current PEM results in a “superior” rating efforts will be made to increase the modified versions to a higher percentage.

The s-TOFHLA and Samoan-s-TOFHLA are timed reading comprehension tests that uses a modified Cloze procedure to measure understanding of the material. Participants read sentences with missing words and circle the letter (either a, b, c, or d) in front of the word they feel would fit the best. Individual results scored on a scale of 0 to 36. Participants are categorized as having “adequate” if the score is 23–36, “marginal” if it is 17–22, and “inadequate” health literacy if the score is 0–16 (Morris et al., 2006). The s-TOFHLA is a reliable and valid instrument. The Samoan-s-TOFHLA has been used in the INSPIRE study, however is currently being piloted tested in another study for validation.

The Health Information National Trends Survey (HINTS) instrument was developed by the National Cancer Institute to monitor differential dynamics of communication in various cultural contexts to enhance communication strategies and messages effecting health behaviors. The instrument is capable of collecting data on over 23 cancer and health related topics. Our administration of HINTS will include items relevant towards improving the cancer prevention practices and health care utilization of the indigenous Samoan population. The topics and items addressed by our use of HINTS will include: 1) Cancer Communications; 2) Cancer Perceptions and Knowledge; 3) Health Communications; 4) Internet Use; 5) Patient Provider Communications; 6) Risk Perceptions; 7) Social Networks; 8) Tobacco Use; 9) Health Services; 10) Health Status.

Simple Measure of Gobbledygook (SMOG)

The SMOG is a readability assessment tool that uses a formula to calulate grade levels by the number of sentences, total number of words in the sentences, and the number of polysyllabic words. The SMOG has been identified as reliable by the Centers for Medicare and Medicaid Services and considered a more appropriate metric for health materials. The Joint Commission has recommended PEM is written at no higher then a 5th grade level for facilities

seeking accreditation. However, the SMOG is not reliable to determine grade level of PEM translated into non-English languages. Thus, SMOG will be used to determine the grade readability and number of polysyllabic words within the original English PEM. The goal will be to modify the PEM for the experiment group to meet the Joint Commission's recommendation. The modified PEM will be translated for use in the experiment group.

Contextual Measure

There is no known literature to determine the readability of the Samoan language. However, previous studies identify the cloze procedure, used in the s-TOFHLA, as a method to determine contextual meaning. The use of a passage with missing text relies on the reader's "redundancy utilization" or the knowledge of vocabulary, linguistic conventions, and general knowledge. This allows for the reader to predict the context of the passage and is consistent with the natural reading process. For this reason, all translated materials will be pretested using a cloze procedure. Briefly, passages from the PEM will be provided to an individual who meets the eligibility criteria. The PEM will have deleted words replaced by a blank line from the passage in regular intervals. Under each blank line, the test taker will select one out of four options that will complete the passage. The total score will reveal to the project staff if the translation is contextually understood.

Sampling and Recruitment

Program Sites.

Project development, study recruitment and other related activities will take place at the American Samoa Community Cancer Coalition's office in the village of Nu'uuli. Centrally located, it is currently operating two separate studies utilizing RDS. The use of a central point for the study and incentive payment makes it easier for participants to find.

Recruitment of Participants.

To recruit a final sample of 312 participants (English n=156, Samoan n=156), the project staff will initially recruit 24 participants as RDS seeds (12 men and 12 women; 12 English and 12 Samoan). Seeds will be required to meet eligibility requirements and known to have substantial social networks within the community. These seeds will then each recruit a maximum of 3 additional community members. This recruitment pattern will continue to create 3 consecutive recruitment waves (Wave 1, n=24; Wave 2, n=72; Wave 3, n=216). This model will rely on the social networks of the paritipant to recruit and has been successful in the INSPIRE study that recruited 718 participants in 51 days.

Participant Recruitment and Eligibility.

Participants will be eligible if they: 1) are a resident of AS; 2) over age 50; 3) have not been diagnosed or treated for colon cancer; 4) are not high risk for CRC by having family history or diagnosed with irritable bowel syndrome; 5) can read and speak English and Samoan; 5) can provide written informed consent; 6) have a home address and working phone; and 7) are willing to provide information on their health behaviors. Exclusion criteria include persons who indicate they speak or read and write Samoan or English less than well.

Intervention Participation

Participants will be divided into English and Samoan subgroups based upon their RDS recruitment and language preference. Next, participants will take the Samoan-s-TOFHLA or the s-TOFHLA, and the Heatlth Information National Trends Survey (HINTS). Then, participants will be randomized into the control or experiment group (figure 1). Participants in the control group

will receive a ColoCARE FOBT, ColoCARE Instruction Sheet, and the Centers for Disease Control and Prevention's "Colorectal Cancer Screening Saves Lives" brochure in English and Samoan. Participants selected in the experiment group will receive a ColoCARE FOBT, modified ColoCARE Instruction Sheet, ColoCARE instructional video, and a modified CDC "Colorectal Cancer Screening Saves Lives" brochure in English and Samoan. The results will be reported to study staff by phone or in-person at the study center for data entry.

Participants will be given a two week time period to complete the ColoCARE kit, report findings to program staff and recruit 3 additional participants. Participants will receive $10 during the initial intake screening and completion of the required assessments, $30 upon report of the ColoCARE results to study staff, and and additional $15 for each recruit who participates. The total possible incentive for each participant is $85. This tiered compensation plan is designed to address the increased burden on participants and reduce drop-out by incentivizing continued participation in the study.

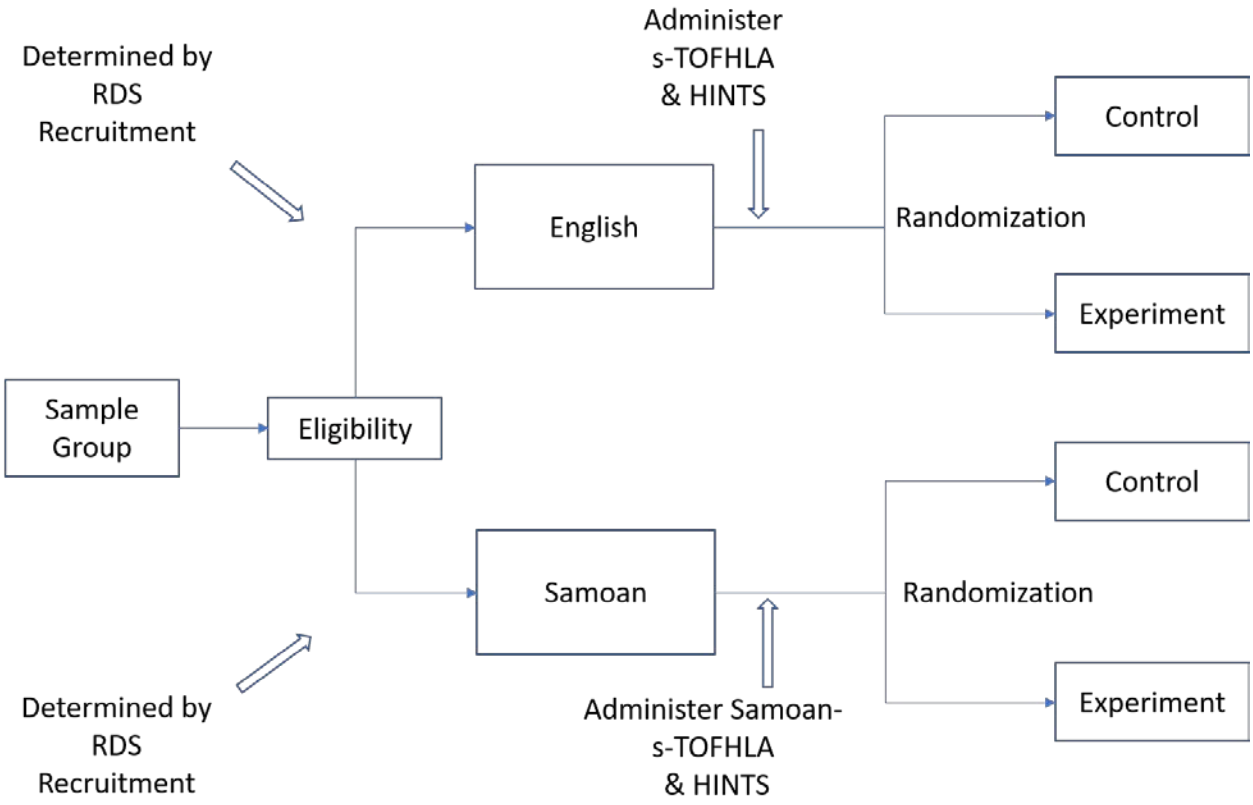

Figure 1. Project Flowchart

UNIVERSITY OF HAWAI'I
CANCER CENTER

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Colorectal Cancer Screening Assessment Study

OFFICIAL TITLE: Colorectal Cancer Screening Assessment Study (*Use this title for internet search on http://www.ClinicalTrials.gov*)

NCI PROTOCOL VERSION DATE:

PROTOCOL NO.: Cassel-2020-1

SPONSOR: University of Hawaii Cancer Center

ClinicalTrials.gov IDENTIFIER:

INVESTIGATOR:
Victor Tofaeono, MD.
American Samoa Community Cancer Coalition
PO Box 1716
Pago Pago, AS 96799

STUDY-RELATED PHONE NUMBER(S):
Victor Tofaeono, MD.
(684) 699-0110

University of Hawai'i Cancer Center Clinical Trials Office
808-586-2979

The University of Hawai'i Cancer Center and the American Samoa Community Cancer Coalition (ASCCC), are conducting a research study to explore the effectiveness of tailored colorectal cancer messaging to promoting healthy behaviors in Samoans. You have been preselected by the project staff or selected by a peer who believes that you meet the study criteria.

PROCEDURES:

Assessments:

If you participate in this study, you will be first asked to take a brief survey about your knowledge of colorectal cancer. Next, you will watch a five-minute educational video on colorectal cancer and take another brief survey about the video. Then you will take the short-Test of Functional Health Literacy in Adults (s-TOFHLA). This assessment contains passages with missing words. You must select the answer that best completes the passage. Your participation is strictly voluntary, and you can stop taking the survey at any time.

Patient Education Materials (PEM):

Upon your completion of the assessments, you will receive patient educational materials in the form of a brochure and instructional sheet on colorectal cancer and the ColoCARE Fecal Occult Blood Test (FOBT) home test kit.

Colorectal Cancer (CRC) Screening:

You will be provided a ColoCARE FOBT home test kit. The research study staff will show you how to complete the test and how to use the reply card to report your results. If a test has a positive result for possible blood in your stool, you will be referred to the Lyndon B. Johnson Tropical Medical Center (LBJ TMC) for further testing.

Recruitment:

You will be provided three coupons to recruit potential participants for the study. The participants must also meet the eligibility criteria and provide consent.

Time Commitment:

Your participation in this study will take approximately **one hour to complete the assessments**, and **two weeks for Colorectal Cancer Screening**. Only the **consenting participant** will be permitted to take the assessment.

BENEFITS AND RISKS:

Assessments:
We want to protect your privacy and ensure your comfort. A possible risk of the study may be that answering certain survey questions may be uncomfortable. Please let the researcher know at any time fi you do not feel comfortable taking the survey, talking about the survey or giving information for difficult questions, or if you would like to stop at any point.

Colorectal Cancer Screening:
The ColoCARE test holds the potential benefit to find colorectal cancer at early stages when cure rates are higher. As a result, there is a decrease in the percentage of colorectal cancer deaths using this early detection method. However, no test is perfect. Like any test or procedure, ColoCARE screening comes with risks. The following risks may occur using the ColoCARE screening kit:

1. The risk of a positive test that **is** colon cancer.
2. The risk that the test will be negative, **but** colorectal cancer is present, also known as a **false negative**.
3. The risk of a positive test **but** is not colorectal cancer, also known as a **false positive**.

These risks are estimated to be low and, in some cases, have created anxiety. However, in the event of a positive screening results, it may become necessary for further testing such as a colonoscopy, or flexible sigmoidoscopy, to make sure a positive test either represents colorectal cancer or does not. If you have a positive result for blood in your stool, the project staff will take the necessary steps to ensure you are referred to a primary care physician at the LBJ Tropical Medical Center. If you already have a primary care physician, it is highly recommended that **you contact them immediately**.

Privacy and Confidentiality:
All project data will be secured in a locked filing cabinet in a locked office or encrypted on a password protected computer. Only my supervisor or research mentor will have access to the information. Other agencies that have legal permission have the right to review research records. The institutional review board has the right to review records for this project. Your name will not be used in reporting the results of our project. Results will be used in a way that protects your privacy and confidentiality to the extent allowed by law.

Voluntary Participation:
Your participation in this project is completely voluntary. You may stop participating at any time. If you stop participation, there will be no penalty or loss to you. Your choice to participate or not participate will not affect your employment or rights to any services.

Termination:
At any point in time the investigators may terminate your participation in the study without your knowing or consent under certain circumstances including:

- The sample size has been met
- Your data file is incomplete
- It is found that you have not met the eligibility criteria, **after** obtaining consent

Any information you have provided will be removed from the study data set and will not be analyzed or published in any report or manuscript.

Options and Alternatives:
Participation in the study is voluntary and you can leave at any time. The only alternative is to not take part in this research study.

Results:

Assessments:
For this study, your individual assessment results are being collected for **research purposes** and **not to make a clinical diagnosis**. Additionally, results will not contain any identifiable indicators. Therefore, your individual results will not be provided to you by the project staff. However, general study results will be disseminated to study participants first at a debriefing meeting. The debriefing meeting date and location will be determined by the investigators. Afterwards, public release of study data will be done through various communication mediums including conferences, publications, newspapers, and social media.

Colorectal Cancer Screening:
For this study, you will be provided the results of your ColoCARE kit once completed as outlined in the instruction sheet. You will be required to report those results via the Reply Card. Although, these are your individual results they are being collected for **research purposes** and **not to make a clinical diagnosis**. However, if you have a positive result during the study, then you will stop taking the study and be referred to your primary care physician or the Emergency Room at LBJ TMC by the project staff. Any project data collected will be deidentified and grouped with other study participants by various demographics (e.g. education, age, gender, etc.) to be disseminated to study participants first at a debriefing meeting. The debriefing meeting date and location will be determined by the investigators. Afterwards, public release of study data will be done through various communication mediums including conferences, publications, newspapers, and social media.

Additionally, you will be contacted by the investigators of any significant findings that are developed during the course of the research that may have an impact on your willingness to continue participating in the study via telephone call.

What are the costs of taking part in this study?

You may have transportation costs as part of your participation in this study. Additionally, you will be responsible for any medical expenses resulting from participation in this study including but not limited to diagnostic, treatment, palliative care, and/or logistical expenses (e.g. airfare, gas, food, lodging, etc.) provided at LBJ TMC or outside of American Samoa.

Sample size: The total number of participants needed for this study is 312.

Compensation: You will receive $10 in cash for when completing steps 1 & 2, $30 for step 3, and possibly $15 per individual recruit who successfully completes the project (maximum 3 recruits).

Questions: If you have any questions about this project, please call or email Mr. Va'a Tofaeono at (684) 699-0110 or vtofaeono@cancercoalition.as.

Where can I get more information?

You can talk to your doctor about any questions or concerns you have about this study.

Contact your study doctor or Principal Investigator Victor Tofaeono, MD., at (684) 699-0110 for any of the following reasons:

- If you have any questions about this study or your part in it; or
- If you feel you have had a research-related injury or bad reaction to the study drug.

Contact the University of Hawai'i Cancer Center Clinical Trials Office at 808-586-2979 for any of the following reasons:

- If you have any questions about this study or your part in it; or
- If you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

You may also contact the University of Hawai'i Cancer Center Compliance Office at:

University of Hawai‘i Cancer Center Compliance Office
701 Ilalo St., Floor 6
Honolulu, HI 96813
Telephone: 1-808-564-5914

For questions about your rights while in this study, you may call the Western Institutional Review Board at 1-800-562-4789. You may also contact the Principal Investigator, Victor Tofaeono, MD., at (684) 699-0110, or the University of Hawai‘i Cancer Center Clinical Trials Office at 808-586-2979.
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AUTHORIZATION TO USE AND DISCLOSE (RELEASE) IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. What is the purpose of this form?

University of Hawaii Cancer Center is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your personal health information for research. This information may include data that identifies you.

The purposes of releasing your personal health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a University of Hawaii Cancer Center research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease;
- specific information about treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number, medical record number, initials, and date of birth.

You may request a blank copy of the University of Hawaii Cancer Center data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my personal health information?

The University of Hawai‘i Cancer Center will collect your health information and share it with the University of Hawaii Cancer Center if you enter this research study. The University of Hawaii Cancer Center will use your information in their cancer research study.

TITLE: Colorectal Cancer Screening Assessment Study

PROTOCOL NO.: Cassel-2020-1

4. Who will be able to use my health information?

By signing this form, you authorize the following parties to use and/or disclose your identifiable health information collected or created for this study:

- Victor Tofaeono, MD and his sub-investigators and research staff for the purposes of conducting this research study at research locations which have been approved by the Western Institutional Review Board.
- Your primary care provider
- Hospitals and providers that treat you
- Laboratories that perform testing for the study
- University of Hawai‘i Cancer Center

Your medical records may contain information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services. By signing this form, you authorize access to this information if it is in the records used by members of the research team.

The University of Hawai‘i Cancer Center will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The University of Hawai‘i Cancer Center may also permit the following groups to review your original records so that they can monitor their research study:

- the University of Hawai‘i Cancer Center Operations Center;
- the University of Hawai‘i Cancer Center Biostatistical Center;
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute that supports the research of University of Hawai‘i Cancer Center;
- public health agencies and other government agencies, such as the U.S. Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (HHS), including non-U.S. agencies as authorized or required by law;
- other people or organizations assisting with University of Hawai‘i Cancer Center research efforts. This may include drug manufacturers, drug companies that may provide partial support for the study, drug distributors, and/or their designees;
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above;
- the Western Institutional Review Board (WIRB), a group of people who review the research study to protect your rights;
- the University of Hawai‘i Human Studies Program (UH IRB), the University’s review board;

- the University of Hawai‘i Cancer Center’s Office of Compliance for the purposes of overseeing the research study and making sure that your ethical rights are being protected;
- IRBs and research groups of the medical institutions that work with the University of Hawai‘i Cancer Center; and
- representatives of groups that audit studies to make sure the study is done as approved.

5. How will information about me be kept private?

University of Hawai‘i Cancer Center will keep all patient information private to the extent possible, even though University of Hawai‘i Cancer Center is not required to follow the federal privacy laws. Only researchers working with University of Hawai‘i Cancer Center will have access to your information. University of Hawai‘i Cancer Center will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected. When this happens, your information may lose its federal privacy protection and your information may be disclosed without your permission.

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered. If you choose not to be in the study or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefit that you are allowed.

7. If I sign this form, will I automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and separate consent. You must sign the study-specific consent form for this trial, Cassel-2020-1, “Colorectal Cancer Screening Assessment Study.”

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing to the Principal Investigator listed on the first page of this form. Beginning on the date you withdraw your permission; no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the Principal Investigator. He will make sure your written request to withdraw your permission is processed correctly.

INVESTIGATOR: Victor Tofaeono, MD.
American Samoa Community Cancer Coalition
PO Box 1716
Pago Pago, AS 96799

STUDY-RELATED PHONE NUMBER(S): Victor Tofaeono, MD.
(684) 699-0110

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10.What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or receive copies of your health records kept by the University of Hawai‘i Cancer Center. You do not have the right to review and/or copy records kept by the University of Hawaii Cancer Center or other researchers associated with the research study.

11.Who can answer questions related to my personal health information?

You may contact the University of Hawai‘i Cancer Center Privacy Officer at:

University of Hawai‘i Cancer Center Privacy Officer
701 Ilalo St., Floor 6
Honolulu, HI 96813
Telephone: 1-808-564-5914

Future contact

I agree to be contacted by the University of Hawaii Cancer Center in the future regarding my participation in this study

_____YES _____NO

(Please **initial** your choice)

Signatures

I have been given a copy of this consent form. I have read it (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the HIPAA authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

	Subject's Name – PRINTED
Date	**Signature of Subject**
	Name of Person Conducting Informed Consent - PRINTED
Date	**Signature of Person Conducting Informed Consent**