IRB APPROVED
Oct 01, 2022

Consent Form

TITLE: Alzheimer's Disease and Related Dementias (ADRD) prevalence in American Samoa

PROTOCOL NO.: Tofaeono-2022-01
WCG IRB Protocol #20222217
ePROST 20220756

SPONSOR: Department of Health and Human Services (HHS/NIH/NCI/NHLBI/NIAID)

CO-INVESTIGATORS:

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University of Miami Miller School of Medicine
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Boca Raton, FL 33433
United States

STUDY-RELATED PHONE NUMBER(S): (684)699-0110 (24 hours) or
(561)869-6808

The American Samoa Community Cancer Coalition (ASCCC), is conducting the ***Puipui Malu Manatu*** research study to explore the prevalence of Alzheimer's Disease and Related Dementias (ADRD) in American Samoa. We are hoping to identify resilience and vulnerability factors that are contributing to ADRD in American Samoa. Should you choose to participate

you will be asked to provide medical records, family history information, and a biological sample. You will also participate in tests to determine your memory and thinking skills and receive a neurological examination. Your participation is strictly voluntary, and you can stop at any time during the study.

PROCEDURES:

1. **Psychometric testing:**

   First, you will be asked to complete forms asking for your demographics (e.g., gender, income, education, etc.), personal, and family medical history. This may take 30 to 40 minutes and consists of questions regarding habits and behaviors such as smoking, alcohol intake, physical activities, and your past medical history. We will ask about the state of health of many of your close relatives (mother, father, brother, sister, and children). We will ask you about their past medical history including whether or not they had ADRD. You may also be asked to provide medical records. Next, the study staff will ask set of questions that will assess your memory and thinking skills, also called **psychometric testing**. Lastly, you will be given a neurological examination by clinical research staff.

2. **Blood test:**

   You will be provided a referral form to LBJ Tropical Medical Center (TMC). **Take the referral form to the Laboratory**. Provide the form to the laboratory staff and they will draw approximately 3 tablespoons of your blood.. Your blood will be packaged and shipped to the **University of Miami's Miller School of Medicine** where we will analyze your blood to determine any small genetic differences, known as **genotyping**. We will then conduct **phenotyping** to see if these small differences have made larger changes noticeable in an individual. Finally, your blood will be shipped to the **National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)** at the Indiana University **to be stored indefinitely**. Your blood will be used to examine some of your genetic material (DNA) by qualified investigators to conduct invaluable research in ADRD.

3. **Unique Subject Identifier**

   All your information from the psychometric testing, neurological examination, and blood tests will be deidentified (all identifying information has been removed) and a unique subject identifier will be used. The deidentified data will be kept on a secure computer at the American Samoa Community Cancer Coalition, the University of Miami's Miller School of Medicine, and the National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site (NIAGADS) at the University of Pennsylvania and will only be

accessed by authorized investigators. De-identified (all identifying information has been removed) clinical, biological sample and genetic data may be provided to qualified researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies. Results of analyses performed using the biological samples collected as part of this study may be submitted, along with de-identified clinical data, to a government health research database that will assist other researchers investigating various diseases, including AD and dementia. This government health research database will have access limited to approved researchers. Your data may be withdrawn at any time, upon your request. However, data that has already been distributed for approved research will not be retrieved.

Time Commitment:
Your participation in this study will take approximately **3 hours to complete the assessments**, and **one hour to complete the blood draw**. Only the **consenting participant** will be permitted to take the assessment and complete the blood draw.

You may be invited to participate in this study on a yearly basis, during which you may be asked to complete the psychometric testing, neurological examination, and/or blood test. This may be done to detect any change in your cognitive status. **You will be required to sign a new consent form if you are invited to participate again.**

BENEFITS AND RISKS:

There is no direct benefit to you in this study, however it is out hope that the information gained from the study will help increase accurate and early diagnosis, expand access to care, and improve health outcomes in American Samoa.

Psychometric testing:
There are minimal risks associated with psychometric testing including possible embarrassment regarding performance and/or stress from the test questions. This may occur in some cases because the testing exposes the seriousness of impairment, or the process may be interpreted as an increased risk for impairment. Some individuals may experience fatigue or test performance anxiety. Therefore, testing will be performed by trained staff in a private, culturally sensitive fashion to minimize this. Periodic breaks will be available during cognitive testing and you will receive full supportive care from our study staff while participating in the study. Study physicians remain on-call 24 hours per day to respond to any questions regarding subject's health concerns while participating in this protocol.

Blood tests:
There is a minor risk of bruising and/or infection from the blood draw, but this is minor and adequate precautions including medical personnel and access to the emergency room will be available.

Genotyping:
There are potential dangers in the genotyping including the release of DNA information. Genetic testing can generate information about a subject's personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to social discrimination. To greatly reduce the possibility of psychological or social risks, all blood and other tissue used for genetic studies are coded and no personal identification will link the subject with the samples.

Confidentiality:
The potential legal and social risks to the patients relate to the questions of confidentiality of information. It is possible that the information obtained which relates to the patients' medical or psychiatric condition might adversely affect the patients' legal or social position if such information were not kept strictly confidential. All project data will be secured in a locked filing cabinet in a locked office or encrypted on a password protected computer. Only the Program Director and the Principal Investigators 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 decline to participate or stop participation, there will be no penalty or loss of benefits to which you are otherwise entitled**. 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 results will not be provided to you by the project staff. Although these are your individual results, they are being collected for **research purposes**. 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 1089.

Compensation: You will not receive any monetary incentive for participation in the study. However, all costs associated with the collection of your blood sample, storage, shipping, neurological examination, and analysis will be paid for by the study.
Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Any blood, urine, tissue, or other biological specimens obtained for the purposes of this study become the exclusive property of the University of Miami.

The University of Miami may retain, preserve, or dispose of these specimens and may use these specimens for research which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project.

Compensation for Injury: Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed for this care. Funds to compensate for pain, expenses, lost wages and other damages

caused by injury are not routinely available. This policy does not prevent you from trying to obtain compensation through the legal system.

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

Where can I get more information?

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

Contact your study doctor Robin Faumuina-Vasai or Principal Investigator, Va'atausili Tofaeono, 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.

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:

WCG IRB
Telephone: 1-855-818-2289
E-mail: researchquestions@wcgirb.com

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. What is the purpose of this form?

The American Samoa Community Cancer Coalition (ASCCC) is an organization that does research to learn about the causes of disease, and how to prevent and treat them. 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 ASCCC 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 ASCCC 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 ASCCC will collect your health information and use your information in their research study.

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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:

- Va'atausili Tofaeono, MBA, BS, James Galvin, MD, MPH, and his/her sub-investigators and research staff for the purposes of conducting this research study at research locations which have been approved by the WCG IRB.
- Your primary care provider

- Hospitals and providers that treat you
- Laboratories that perform testing for the study
- University of Miami, Miller School of Medicine
- National Institute on Aging Genetics of Alzheimer's Disease Data Storage Site
- National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)

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 ASCCC 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 ASCCC may also permit the following groups to review your original records so that they can monitor their research study:

- the University of Miami, Miller School of Medicine's Comprehensive Center for Brain Health
- the University of Hawai'i Cancer Center Biostatistical Center
- the University of California San Francisco;
- the National Alzheimer Coordinating 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;
- 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 WCG IRB, a group of people who review the research study to protect your rights;
- representatives of groups that audit studies to make sure the study is done as approved.

5. How will information about me be kept private?

The ASCCC will keep all patient information private to the extent possible. Only researchers working with ASCCC will have access to your information. ASCCC 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, Tofaeono-2022-01, Alzheimer's Disease and Related Dementias (ADRD) prevalence in American Samoa.

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:

Va'atausili Tofaeono
American Samoa Community Cancer Coalition
PO Box 1716
Pago Pago, AS 96799

James Galvin
Comprehensive Center for Brain Health
University of Miami Miller School of Medicine
7700 W. Camino Real Suite 200
Boca Raton, FL 33433

STUDY-RELATED PHONE NUMBER(S): (684)699-0110 or (561)869-6808

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 ASCCC. You do not have the right to review and/or copy records kept by the ASCCC or other researchers associated with the research study.

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

You may contact the principal investigator at the following address:

American Samoa Community Cancer Coalition
PO Box 1716
Pago Pago, AS 96799
Telephone: 1-684-699-0110

Comprehensive Center for Brain Health
University of Miami Miller School of Medicine
7700 W. Camino Real Suite 200
Boca Raton, FL 33433
Telephone: 1-561-869-6808

Future contact

I agree to be contacted by the ASCCC 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**

ADDENDUM: UNIVERSITY OF MIAMI RESEARCH AUTHORIZATION

HIPAA Authorization Form

You signed a Consent Form to join the research study described above. This form includes more information about that study, including your rights to the information obtained, created and collected about you and your involvement in the study.

What is the purpose of this part of the form?
State and federal privacy laws protect the use and disclosure of your Protected Health Information "PHI". Under these laws, your health care providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the ASCCC and the University of Miami, the Principal Investigators and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. These people and institutions are called "Providers" in this form.

What Protected Health Information will be used or shared?
You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

- Your past medical history,
- Medical information from your primary care physician,
- All other medical information relating to your participation in the study listed at the top of this document,
- Genetic (DNA) analysis or genomic sequencing if these procedures are part of this research.

Who may receive my Protected Health Information?
The Providers may use and share your health information with:

- The Principal Investigator and his/her research staff
- Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the American Samoa and Florida Departments of Health
- Groups that collaborate and sponsor research (Cooperative Groups)
- Institutional Review Boards (groups of people who oversee research)
- Other persons who watch over the safety, effectiveness, and conduct of research
- The Sponsor of the research, its agents, monitors, and contractors
- Other participating researchers; and
- Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of your health but are not involved in this research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, any study-related information may be placed in your permanent hospital, clinic, or physician's office records.

Why will my Protected Health Information be used and disclosed?

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor and its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in this informed Consent Document and for other activities related to the research, such as assessing the safety or effectiveness of the drug, device or treatment being studied, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
- The University of Miami's clinical trial organizations will use your information to review and support clinical trials at the University and health system.
- Other University of Miami offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance may use your information to ensure the research is performed correctly.
- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who are authorized by law may use your information to review or oversee this research or to see if a new drug, device or other health care product should be approved for marketing.

What other information should I know?

1. Once your information has been disclosed to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your right to other medical treatment will not be affected.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at 1400 NW 10th AVE, Suite 1200A, Miami FL 33136.
4. If you revoke this Authorization, you will not be able to continue taking part in the research. Also, even if you revoke this authorization, the institutions and people listed above will continue to use and disclose the personal information they have already collected if the information is needed to protect the reliability of the research.
5. While the research is in progress, you will not be allowed to see your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.

6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. You will be given a copy of this authorization after you sign it.

_____ _____

Signature of participant or participant's legal representative (LAR) *Date*

_____

Printed name of participant