**INFORMED CONSENT FORM**

**STUDY TITLE: Mechanisms of Ethnic/Racial Differences in Lung Cancer Due to Cigarette Smoking: Study 1 - Observation Study in members of the Oahu community**

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**CO-INVESTIGATORS:** Charles Rosser, M.D, Irina Stepanov, Ph.D

## PURPOSE

The purpose of this study is to obtain health and tobacco use information and blood, urine and cheek cell samples that will allow us to study how tobacco use affects one's risk of developing cancer and other diseases, and how genes and lifestyle may influence metabolism and other body processes. Results from an earlier study have raised some interesting questions about cigarette smoking that we hope to answer in this study.

We are inviting you to participate in the new study. The information and procedures provided in this consent form will apply to all participants.

## PROCEDURES

If you agree to participate, we would like you to complete one study visits that can be scheduled at our clinic. Prior to your visit, we will call you to ask questions about exposure to or symptoms of COVID-19. At your visit, you will first be provided a mask and have your temperature taken. After passing that assessment, you will be interviewed and complete questionnaires that ask about your background, tobacco use history, health history, prescription and over-the-counter medication and nutritional supplement use, diet, use of alcohol, exposure to chemicals and your exposure to tobacco smoke at home and work. Some of these questionnaires will be mailed to you to be completed at home and bought in to the visit. You will have your vital signs (blood pressure, heart rate, height and weight) measured.

You will be asked to provide a first morning urine sample and about 2 tablespoons (30 cc) of blood will be collected. We will provide you with a urine collection kit prior to your visit. We will have you collect cells from your mouth by having you brush your teeth, then swish with a mouthwash which will be collected, followed by using a soft brush to collect cells from your cheek. Your blood, cheek cells and urine will be used for research purposes only. Some of the samples will be sent to the University of Minnesota Cancer Center Biomarker Laboratory for storage and analysis.

Your biological samples will be barcoded to protect your confidentiality. Background information about you that accompanies these samples will only be identified with a study number. None of the information or samples will contain any personally identifying information. There will be no way for the laboratory staff to identify or contact you.

## RISKS/BENEFITS

The risks of participating in this study are small, and include mild pain or bruising at the place where blood is drawn. Rarely, a person may faint or feel faint during the blood draw. The risk of infection is slight since only sterile, one-time use equipment is used. In the highly unlikely event that you are injured during the course of this research, you may be responsible for the cost of any treatment needed. There is no cost for taking part in the study, and your participation is completely voluntary. You are free to stop participating at any time. Although you will not receive any immediate benefit, the knowledge gained from this research may help you and others in the future.



**UMN IRB #:00000335**
**University of Hawaii IRB: CHS#17649** **Version Date: 7/3/2020**

If you are using public transportation to get to your appointment, you may put yourself at increased risk for exposure to the COVID-19 virus. We advise you to wear a mask and practice social distancing when possible while using public transportation.

**STUDY COSTS AND COMPENSATION**

There is no cost for taking part in the study, and your participation is completely voluntary. You are free to stop participating at any time. You will receive $75 in gift cards at each visit to compensate for your time and effort.

**FUTURE RESEARCH STUDIES**

If your results from this study meet our criteria for the next component of this study (Study 2), we may contact you to ask if you would be willing to participate. You will be able to accept or decline that invitation at that time.

Some of the blood and urine will be stored for use in future research studies. Although the exact tests that will be done are not known at this time, researchers may study: 1) how diet, lifestyle, environment, race/ethnicity, age and other factors are related to the development of cancer or other diseases; 2) how differences in genes affects one's ability to process substances that cause diseases; 3) how damage to one's chromosomes is related to risk of cancer and other diseases. Any studies using these stored samples for other purposes will be submitted to the Committee on Human Studies, University of Hawai'i, and the Institutional Review Board at the University of Minnesota for review and approval. All studies will be done in accordance with the guidelines of the Committee on Human Studies and with federal regulations for the protection of human subjects.

**CONFIDENTIALITY**

Multiple safeguards are in place to protect the confidentiality of your research records. Your records and samples will be identified by a study number. Your name and other identifying information will be stored separately in a place restricted to authorized study personnel. You will not be identified in any publications or presentations about this study. These safeguards will minimize any risk from loss of privacy.

Your record for the study may, however, be reviewed by the National Cancer Institute, the study sponsor and by departments at the University of Minnesota with appropriate regulatory oversight as the coordinating site for this study. We will not include any information in publications or presentations that will make it possible to identify you. Any study data transmitted via the Internet will be de-identified and meet all required protections for privacy. To these extents, confidentiality is not absolute. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**RESEARCH RESULTS**
Because this is a research project, we will not be releasing the results of any individual research tests.

**STUDY CONTACT INFORMATION**
For additional questions concerning this study, please contact us at (808)237-3901. If you have any concerns or questions about your rights as a research participant, or complaints about your treatment in this study, contact the Committee on Human Studies, University of Hawai'i, 2425 Campus Road, Sinclair 10, Honolulu, HI 96822. Phone: (808) 956-5007. In addition, to share feedback privately about your research experience with the lead site, including any concerns about the study, call the University of Minnesota's Research Participants Advocate Line: 612-625-1650 or give feedback online at www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455.

*I have read the above information. I have asked questions and have received answers. My signature documents my permission to take part in this research. I will be provided a copy of this signed document.*

*I understand that the samples collected from me may be used for research in the future. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow laboratory staff to readily ascertain my identity.*

*I have been advised that I am free to withdraw (take away) my consent and can refuse to take further part in the study at any time without it making any difference to my care in the future.*

*I give my consent to be part of this study with the understanding that such consent does not take away any of my legal rights nor does it release the investigators or the institution or any employee or agent thereof from liability for negligence.*

| _____ | _____ | _____ |
|---|---|---|
| **Signature of Participant** | **Participant's Name (please print)** | **Date** |
| _____ | _____ | _____ |
| **Signature of Staff Obtaining Consent** | **Staff Name (please print)** | **Date** |



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