

**Development of a Research Infrastructure for Understanding and Addressing Multiple Myeloma
Disparities**

**[NCT Not Yet Assigned]
December 2, 2019**

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**University of California at Davis
Consent to Participate in Research**

Title of study: Development of a research infrastructure for understanding and addressing multiple myeloma disparities.

Principal Investigator: Drs. Luis Carvajal-Carmona, PhD; University of California Davis Comprehensive Cancer Center & Rosemary Cress, *DrPH*; Cancer Registry of Greater California.

Experimental Subject's Bill of Rights

Someone will explain this research study to you, including:

- **The nature and purpose of the research study.**
- **The procedures to be followed.**
- **Any common or important discomforts and risks.**
- **Any benefits you might expect.**
- **Whether or not you take part is up to you.**
- **You can choose without force, fraud, deceit, duress, coercion, or undue influence.**
- **You can choose not to take part.**
- **You can agree to take part now and later change your mind.**
- **Whatever you decide it will not be held against you.**
- **You can ask all the questions you want before you decide.**
- **If you agree to take part, you will be given a copy of this document.**

Introduction and Purpose

You are being invited to join the research study because you were previously diagnosed with multiple myeloma within the past five years, were at least 21 years old at the time of diagnosis, are of African American, Latino, Asian American, Native Hawaiian/Pacific Islander or Non-Hispanic White, and live within one of the 48 California counties. This study is being done to learn more about the potential causes of multiple myeloma.

If you agree to participate in this research, you will be asked to complete a questionnaire survey and provide a 2ml saliva sample for this research. This form will refer to the samples we obtain from you as “specimens.”

Here are some issues to think about before you decide whether to join this research:

We will use the specimen(s) and data we collect for the following research purpose(s):

While this study does not involve banking the data and/or specimens we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data or specimens to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. We will use a code on the bio-specimen and information, and we will keep a link between the code and your identity in a different location, in a password protected document and only those who are conducting the study will have access to the study records. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data or specimens in additional research.

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You will not receive the results of any of the tests performed on your specimens. Data summarizing the study results will be available as aggregate study findings are published.

You will also not receive any commercial value or income that may result from the use of your specimens and data. You will only receive a one-time compensation for participating in the study, totaling \$50. \$20 for completion of the survey and \$30 for completion of the saliva kit.

Participation in research is completely voluntary. You can choose to participate now and change your mind in the future. Whatever you decide, there will be no penalty to you or loss of benefits to which you are otherwise entitled. If you decide to have your specimens and information removed from the research, contact the research team and ask to have your biospecimens and information removed from the study. No new research will be conducted with your specimens and information after you contact the research team.

You will not receive any direct benefit if you take part in this study. We hope this research will bring more knowledge about the potential causes of multiple myeloma

The physical risks of this research are minimal but you may feel a bit of discomfort for a short period of time while saliva is being collected.

Genetic and Genomic Research

Researchers will use your specimens for genetic or genomic testing.

Genetic testing involves examining DNA in the cells of the bio-specimen. DNA is the chemical database that carries instructions for your body's functions. Genetic testing can reveal changes (mutations) in your genes. Mutations can cause illness or disease. Genetic testing can also provide important information for diagnosing, treating and preventing illness.

Genomic sequencing is different from genetic testing. Genomic sequencing involves a process for analyzing a sample of DNA. Everyone has a unique genome that is made up of the DNA in all of a person's genes. Genomic sequencing is a complex testing can help identify genetic mutations that may relate to diseases and may help scientists determine how the body may react to a drug developed to treat a disease.

Allowing your specimens to be used for genetic testing and genomic sequencing involves some risk. For example, you might receive unwanted information of a personal and sensitive nature -such as paternity information- if the results of the research are returned to you. You might also learn that you are at risk for developing a disease. Information learned from this type of testing may also extend to your relatives. There is a risk that this sensitive information about you and your family might be accessed by individuals who do not have a right to access it; however, we will take the steps described below to prevent inappropriate access from happening.

If the research reveals that you are at increased risk for developing a disease, you should know that there are several laws that prohibit the use of your genetic information to decide whether you qualify for employment or health insurance. However, these laws do not extend to other types of insurance.

Confidentiality

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will record a code on the bio-

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specimen and information, and we will keep a link between the code and your identity in a different location, in a password protected document and only those who are conducting the study will have access to the study records.

People from UC Davis who oversee and monitor research to see if it is done properly may look at the information we collect about you. Regulatory agencies who oversee research may also access your data during audits or other monitoring activities.

This research has received a Certificate of Confidentiality (COC) from the Federal government. The COC will help protect the privacy of the research records. The COC allows the researchers to refuse to disclose identifying information about your participation in this research if the federal, state or local government seeks the information for any legal, legislative or other activity.

The COC will not protect the information if you decide to voluntarily release it. For example, if you or a member of your family sign a consent for an insurer or other individual to access the information, the COC will not prevent the researcher from providing the information to the insurer or individual.

A COC also does not prevent a researcher from disclosing information about you to prevent serious harm to yourself or others, such as reporting to the authorities incidents of child abuse, elder abuse or spousal abuse.

Compensation

You will receive \$20.00 for completing the survey questionnaire and another \$30.00 for submitting a biospecimen.

Questions

If you have any questions about this research, please feel free to contact the investigator at (916) 734-4563 or hs-iniciativa@ucdavis.edu.

If you have any questions about your rights or treatment as a research participant in this study, please contact the University of California Davis, Institutional Review Board at 916-703-9158 or HS-IRBEducation@ucdavis.edu.

If you agree to take part in the research please sign the consent form below and place inside the return envelope.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

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