



Los Angeles
Urban League

Empowering communities.
Changing lives.



Charles Drew University of Medicine and Science

CONSENT TO PARTICIPATE IN RESEARCH

The Healthy Community Neighborhood Initiative: A Block Pilot Study within the 70 Block Project

The Healthy Community Neighborhood Initiative Pilot

[Community investigator names]

[Academic investigator names]

You are being asked to participate in a research study conducted by [insert community and academic investigators names] and the Clinical and Translational Science Institute (CTSI), which is being reviewed for funding by the National Institutes of Health (NIH). You have been asked to participate in this study because you are 18 years or older and reside in the Park Mesa Heights community.

Your participation in this study is entirely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Disclosure Statement

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. If you choose to participate in this study, you will be given the option to send your health results to your primary care physician. You are not under any obligation to participate in any research project offered by your physician.

• **PURPOSE OF THE STUDY**

The purpose of this research study is to learn more about the health needs of residents of Park Mesa Heights and to develop programs to improve residents' health outcomes and access to health care. The study includes an interview and a clinical exam. You are being asked to be in this study because you are an adult resident of Park Mesa Heights (the 70-block area of study).

You will be in this study about 2 years. If we receive further funding for our research, we may ask you if you are willing to continue your participation beyond the initial 2 years.

- **PROCEDURES**

We are conducting a household survey among adult residents of Park Mesa Heights. If you volunteer to participate in this study, we would ask you to do the following things: A survey consisting of an interview, a household health screening, and the collection of laboratory data, all of which will take a total no more than 2 hours. Approximately one year after the initial survey, we will contact you to conduct a follow-up survey.

The following tests and procedures will be done at some or all of the study visits.

- 60- to 90-minute interview (including questions about your health status, quality of life, experience of health care, health habits, and medical conditions)
- Physical exam (including measurement of health indicators such as height, weight, and blood pressure)
- Blood will be collected via a fingertip prick test. Less than a teaspoon of blood will be collected. If you permit, we will also collect blood through a blood draw, which will require less than a tablespoon of blood. Blood collection will be performed by a trained nurse or phlebotomist. The blood spot test will include tests for diabetes, anemia, inflammation, and stress. The blood draw tests will also allow us to obtain cholesterol levels, kidney function, and additional measures of chronic disease control and inflammation. Combined, the physical exam and blood collection will require approximately 30 minutes. If you permit us, we will store your blood for additional blood tests that allow us to test for other chronic conditions and your genetic risk of common chronic conditions.
- For study visits conducted in the home, there will be one interviewer and one person doing the clinical examination. On some chosen visits, a supervising nurse or doctor may also accompany the interviewer and examiner for quality control purposes. You may also choose to have the laboratory assistant who draws blood come on the same day, but you can also set up the blood draw for another day or time.

- **POTENTIAL RISKS AND DISCOMFORTS**

There is a very small risk that you will experience some psychological discomfort while discussing personal information during the interview or during the collection of clinical data such as height and weight measurements. We believe these risks are minimal, but our staff has been trained to address any psychological discomforts you may experience. Should you experience any such discomfort during the household survey and would like to stop the interview or clinical data collection at any point, please let us know and we will discontinue immediately.

Procedure risks

Drawing blood from your finger may cause pain, very mild bruising and, rarely, lightheadedness and/or infection.

- **ANTICIPATED BENEFITS TO SUBJECTS**

This is not a treatment study. You and other participants may not receive any direct benefit, though participating in the study may result in future benefit to the community as a whole. You may gain increased knowledge about health issues that are important to you or your family members and may gain valuable information about the health needs

of the community in which you live. Some participants may benefit from referrals to needed services.

• **ANTICIPATED BENEFITS TO SOCIETY**

The results of this research study may lead to improved health in the future for people in communities like ours as the information we collect will be used to help develop programs for better community health. We plan to use the information obtained from this project to work collaboratively with community members to reduce rates of chronic conditions, promote healthy behaviors, and improve health outcomes in Park Mesa Heights and similar communities.

• **ALTERNATIVES TO PARTICIPATION**

This is not a treatment study. Your alternative is to not participate in this study.

• **PAYMENT FOR PARTICIPATION**

You will be paid for your time and effort for being in this study. You will receive a \$25 gift card for completing the survey and another \$25 gift card for participation in the combined physical examination and laboratory assessment of the study, even if you choose not to participate in any component of the examination and laboratory assessment. If you choose to continue the study, you will also receive a \$25 gift card for a 1-year follow-up survey and \$25 gift card for a combined follow-up examination/laboratory assessment. You will receive your gift cards at the time of the corresponding study visit (PLEASE SEE PAYMENT CHART BELOW). If you do not complete the study, you will be paid only for completed study visits.

PAYMENT CHART		
Date Received:	Participant Tasks:	Gift Card Amount:
After Completion of Survey	Survey	\$25 Gift Card
After Completion of Assessments	Combined Physical Examination/Laboratory Assessments	\$25 Gift Card
1-year	Follow-up Survey	\$25 Gift Card
1-year	Combined Follow-up Examination/Laboratory Assessments	\$25 Gift Card
TOTAL PAYMENT FOR PARTICIPATION IN THE ENTIRE STUDY:		\$100

- **POSSIBLE COMMERCIAL PRODUCTS**

All tissue (also known as blood) and/or fluid samples are important to this research study. Your sample will be owned by the Charles Drew University and UCLA or by a third party designated by the University (such as another university or a private company). If a commercial product is developed from this research project, Charles Drew University and UCLA, or their designee will own the commercial product. There are no plans to provide financial compensation to you should this occur.

- **FINANCIAL OBLIGATION**

There are no charges for the study visits. You and your insurance company will not be billed for anything required by the research.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

Being in this research study carries minimal risk of injury or other possible problems. You participate in this research at your own risk. Charles Drew University of Medicine and Science, UCLA, LAUL, and HAAF have not set aside funds for compensation or payment of research related injuries. However, you are not waiving any legal claims, rights or remedies because of your participation in this research study.

- **PRIVACY AND CONFIDENTIALITY**

Members of the research team and, if appropriate, your physicians and nurses will know that you are a research participant. Authorized representatives of a funding agency, such as the National Institutes of Health, may need to review records of individual participants. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others. (No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- If necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- If required by law (i.e., child abuse, elder abuse).
 - **Examples of child abuse:** repeated injuries (i.e., bruises, welts, burns), neglected appearance (i.e., not having proper clothing, left alone or wandering at all hours, not eating enough food), and disruptive behavior (i.e., very aggressive, negative behavior)
 - **Examples of elder abuse:** bruises, pressure marks, broken bones, abrasions, burns, unexplained withdrawal from normal activities, sudden changes in financial situations, bedsores, unattended medical needs, poor hygiene, unusual weight loss, and threats.

Any information collected about you during the study will only be available to members of the research team and will be stored in locked filing cabinets when not in use. Your

responses will be assigned to a study ID number so that no one outside the study can ever link your responses to you, and after 8 years, any personally identifying information will be destroyed completely, and the data will be stored only in combined format for future use.

When the results of the research are publicly published or discussed in conferences, no information will be included that would reveal your identity.

TISSUE/FLUID SAMPLES

Sample remaining at the end of the study.

On the checklist below, you will be asked to indicate if you would permit part of this sample to be shared with other researchers. If you agree to have your sample shared with other researchers and later decided to withdraw, we may not be able to retrieve any or your entire sample from other researchers. The researcher is not required to store your sample(s) for long periods of time.

Please check the appropriate box below and initial:

- _____ I agree to have my tissue/fluid sample shared with other researchers.
Initials
- _____ I do not want my tissue/fluid sample shared with other researchers.
Initials

Information about your sample.

On the checklist below you are asked to let us know if you would like to receive information about the results of this study. Please indicate by checking and initialing the category below what type of information you want to receive. You can check more than one category. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators." You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

- _____ General Information about what the study found.
Initials
- _____ Specific information about what the study found about me.
Initials
- _____ I do not want any information about my sample.
Initials
- _____ I want information to be sent to my physician.
Initials

Genetic information in your sample: Possible limits to individual confidentiality.

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research that we will not always be able to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggesting different parentage is obtained during research. We do not plan to report such findings to participants unless required by law.

Each tissue and fluid sample contains genetic information about your parents and ancestors such as the information contained in DNA, RNA, or protein. It may be helpful to study members of your family. Your relatives will not be contacted without your permission.

Within the limits imposed by technology and the law, every effort will be made to protect the privacy of your genetic information.

Consent to Obtain DNA for Research

I agree to allow the Healthy Community Neighborhood Initiative to obtain additional DNA at this exam for research purposes. This will allow researchers to read my genetic code in detail and to see if my genetic code is related to diseases I now have or may develop in the future. We do not plan to report such findings to participants unless required by law.

- _____ Yes, obtain my DNA for genetic purposes.
- _____ No, do not obtain my DNA.

• PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. You do not have to be in this study. You may decide at any time, for any reason, not to be in this study. If you do join the study, you may quit at any time. Whichever decision you make, there will be no penalties or change in your care.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent because:

- The study staff thinks it necessary for your health or safety;
- You have not followed study instructions;
- The sponsor has stopped the study; or
- Administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, for your safety you may be contacted again for some of the end of study procedures.

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to any future services you may receive.

If you are a CDU or UCLA student, you may choose not to participate or to stop your participation at any time. This will not affect your grades or class standing at CDU or UCLA. You will not be offered or receive any special consideration if you participate in this research.

If you are a CDU, UCLA, LAUL, or HAAF employee, your participation in this research is in no way part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment. You will not be offered or received any special consideration if you participate in research.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience side effects such as psychological distress from any of the study procedures or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, [investigator name], will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to (rather than because you have decided on your own to withdraw), you will be paid for any participation in the interview and health screening up to that point.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad) that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed on page 1. If you have any questions about the research, please feel free to contact [investigator name] at [phone number].

- **RIGHTS OF RESEARCH PARTICIPANTS**

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, you may contact the Charles Drew University of Medicine and Science, Office for the Protection of Human Subjects, at **323-563-5902** or the UCLA Office for Protection of Human Subjects at **310-825-7122**.

SIGNATURE OF RESEARCH PARTICIPANT

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I understand that I am not giving up any of my legal rights by signing this consent form. I understand that I will receive a copy of this consent form, which will show all signatures and dates. In addition, a copy of the Subject's Bill of Rights will be provided to me, if applicable.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Participant

Signature of Participant

Date

Time

PERMISSION TO RELEASE RESULTS TO YOUR PERSONAL DOCTOR

Please indicate by checking and initialing the category below whether you want the results of your exam and laboratory tests to be sent to your personal physician. The information for your physician will be collected in the survey:

- _____ I want to have the results sent to my doctor.
- _____ I do not want to have the results sent to my doctor.

CONSENT TO FUTURE CONTACT BY RESEARCHERS

Please indicate by checking and initialing the category below whether you want the results of your in-home laboratory tests to be sent to your home:

- _____ I want to have the laboratory results sent to my home.
- _____ I do not want the laboratory results sent to my home.
- _____ I want to have the laboratory results sent to an alternate address.

Please indicate by checking and initialing the category below whether you want the L.A. Urban League and its representatives to contact you about community health resources and social services that may be useful to you, based on your responses to the household interview:

- _____ I want the research team to contact me with information about community resources.
- _____ I do not want the research team to contact me with information about community resources.

Please indicate by checking and initialing the category below whether you give permission for the research team to contact you for a follow-up survey and health assessment 12 months after our initial visit to your home:

- _____ I want the research team to contact me for a follow-up survey.
- _____ I do not want the research team to contact me for a follow-up survey.

Please indicate by checking and initialing the category below whether you give permission for the research team to contact you for future studies (after the initial 2-year study period) if additional research funding is secured:

- _____ I want the research team to contact me for future studies.
- _____ I do not want the research team to contact me for future studies.

Please indicate by checking and initialing the category below whether you give permission for your de-identified information to be kept at UCLA and/or Charles Drew University for additional analysis after the initial 2-year study period:

- _____ I consent to having my de-identified information stored for use in future studies.
- _____ I do not consent to having my de-identified information stored for use in future studies.

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the participant or his/her legally authorized representative and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Printed Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date

Time

**SIGNATURE OF WITNESS
(if an oral translator is used or if required by the CDU IRB)**

My signature as witness certified that the participant or his/her legally authorized representative signed this consent form in my presence as his/her voluntary.

Name of Witness

Signature of Witness

Date

Time

Investigator Signature: _____
Date: _____ **Time:** _____