Department of Public Health Institutional Review Board
313 N. Figueroa St., Room 127
Los Angeles, CA 90012
Phone: (213) 288-7680 Email: irb@ph.lacounty.gov
http://publichealth.lacounty.gov/irb/

Consent to Participate in a Research Study

KEY INFORMATION FOR {*TITLE OF STUDY*}:

Include most crucial information from the potential participant's perspective; must not exceed one page.

We are asking you to choose whether or not to volunteer for a research study about _____ {*insert general description of study*}. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Briefly *describe the purpose of the study and the procedures to be followed in lay terms. For detailed descriptions, use the Detailed Consent.*

By doing this study, we hope to learn _____. Your participation in this research will last about {*state in hours, days, months, years*}.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

State the most important reason(s) {i.e. potential benefit(s)/rewards} a person may want to volunteer to participate in this study? For a complete description of benefits and/or rewards, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

State the most important reason(s) {risk(s)/disadvantages} why a participant may NOT want to volunteer for this study considering the participant's perspective. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is _____ *{Principal Investigator, PI}* of _____ {*list institution/department and program}.* If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact: {*PI contact information}*.

If you have any questions or concerns about your rights as a participant in this project, please contact the Los Angeles County Department of Public Health Institutional Review Board (IRB) by phone: 213-288-7680; or by email: irb@ph.lacounty.gov.

The following detailed consent template includes sample language for many different types of research. REMOVE TEXT THAT DOES NOT APPLY TO YOUR RESEARCH.

Instructions are italicized in blue font. Remove the instructions, unwanted text, and underlines and reformat the final form to fit the protocol.

Use lay language and terminology throughout the document.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

*State the reasons a participant could be excluded from participating (such as being a smoker, being under 18 years of age, being pregnant, etc.). Include only those events/conditions which would **not** be pre-determined by a review of records. Include those events/conditions of which the potential participant would ordinarily be aware.*

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at _____ *{state the general facility}*. You will need to come ___ times during the study. Each of those visits will take about ___ *{state in minutes or hours}*. The total amount of time you will be asked to volunteer for this study is ___ *{state in hours/days}* over the next ___ *{state in days, months or years}*.

WHAT WILL YOU BE ASKED TO DO?

Tell the participant what to expect.

- *Give a timeline description of the procedures that will be performed.*
- *Answer the following for the participant:*
    - *What is being performed as part of the research?*
    - *For studies that also include involvement of routine program or training participation, differentiate procedures being conducted solely for research.*
    - *Clearly identify any procedures that are experimental.*
- *Provide a description of the randomization procedures, if applicable, and describe the chances of being assigned to any one group. Define randomization in simple language such as "by chance."*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

If there are risks to participation, describe them for each procedure. The participant may more easily understand the risks of procedures in the study if the information is presented in table form, graphic, or visual aid.

- *When applicable, group the risks into those that are expected, ranking them as rare, occasional, or often, and describe them as such.*
- *When applicable, in lay terms, list **all reasonably** expected side effects and those that are life-altering or potentially life-altering, no matter how rare.*
- *Explain risks with ramifications, if applicable. For example, what could happen if the participant experiences tightness in his/her chest during physical exercise being done for the study, or what are the consequences of a breach of confidentiality relative to sensitivity of personal information?*
- *Include significant risk of social, psychological, emotional, or financial harm (e.g., breach in confidentiality in sensitive research).*

The risk section must also contain the following statement, when applicable: In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced _____ *{ insert potential benefit not already presented in the Key Information; please note that payment to subjects is not considered a benefit; payment details should be described in the "reward" section below }* when _____ *{qualify when potential benefit experienced}.* However, if you take part in this study, information learned may help others.

OR

You will not get any personal benefit from taking part in this study.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as _____*(describe whether or not there are any activities the participant could do in order to receive the same level of benefit).* ***OR***

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in this study.

OR

Describe any costs the subject may incur as a result of participating in the study (e.g., transportation, parking, data charges for mobile devices). For example: You may have to pay for the cost of getting to the study site and a parking fee.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. *If you are collecting social security numbers, inform participants of this fact. Tell participants whether they can withhold their social security number and still participate and whether social security number is necessary in order to pay subjects.*

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. *{Insert description of procedure(s) used for protecting confidentiality of data, including paper records, computer records, jump drives, and portable storage devices.}*

You should know that there are some circumstances in which we may have to show your information to other people because {*insert circumstances in which the participant's data could be shown or reported to others}.* For example, the law may require us to share your information with:

- authorities, if you have a reportable disease, if you report information about a child being abused, if you pose a danger to yourself or someone else; and/or
- Officials of the Food and Drug Administration (*if applicable*), the National Institutes of Health (*if applicable*), the National Cancer Institute (*if applicable*), Department of Defense (*if applicable*), and _____ {*indicate the sponsor's name or any group/company that may have access to information}* may look at or copy pertinent portions of records that identify you.

Add the following information if online data-collection applies to study: We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of Los Angeles County DPH IRB.

Certificates of Confidentiality (CoC):

*If the study has an **NIH Certificate of Confidentiality**, add the verbiage below to your consent form:*

> This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
>
> {*Use the following language as applicable*} The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by {*THE AGENCY*} which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.
>
> {*language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*.} The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *{list what will be reported, such as child abuse and neglect, or harm to self or others}.*
>
> {*language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants*.} The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document {*restate what will be disclosed, such as including research data in the medical record*}.

CoCs from other agencies: *Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs). If you obtained a CoC from a non-NIH agency, use the suggested template language from the agency.*

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. *Include the following information if applicable:* This may occur for a number of reasons. You may be removed from the study if:

- you are not able to follow the directions,
- they find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

This section may not apply to social/behavioral/educational studies. If not, delete it.

Include the following information if participating in other studies could put your participant at risk:

You may/may not *{please indicate choice}* take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

This section may not apply to social/behavioral/educational studies that are MINIMAL RISK. If not, DELETE this section.

If you believe you are hurt or if you get sick because of something that is due to the study, you should call _____ {*PI or medical supervisor's name*} at _____ *{provide phone number}* immediately.

*For **greater than minimal risk** research, add information for one (or a combination) of the following as a contact for participants to use in case of illness or injury during his/her participation in the study:*

- *a dedicated pager number;*
- *a dedicated cell phone number;*
- *other reliable 24-hour contact option at your discretion; and/or*
- *in addition to one or more of the above, as deemed necessary, referral to 911 for an emergency.*

_____ {*PI or medical supervisor's name*} will determine what type of treatment, if any, is best for you at that time.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive _____ for taking part in this study. *{If this is a monetary reward/payment, explain how this will be pro-rated should the participant choose to withdraw early. If this is not a cash payment, the IRB strongly suggests that the reward be given to the participant regardless of completion of the study.}*

If applicable, provide the following statement:

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

OR

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

This section may not apply to social/behavioral/educational studies or studies consisting of a single interaction. If not applicable, delete this section.

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS/SURVEYS?

Suggested language {should be revised to fit the study}:

Generally, tests/surveys done for research purposes are not meant to provide results that apply to you alone.

OR

You may be given feedback about the results from your tests or surveys done for purposes of this research.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

(If you are planning to contact these research subjects in the future regarding their potential participation in additional research studies, their permission to do so is recommended. If you do NOT plan to contact these research subjects regarding participation in additional studies, DELETE this section. Please note that if you are planning on creating a subject pool, a separate IRB application should be submitted.)

The research staff would like to contact you with information about participating in future studies. If so, it will be limited to *{specify frequency}* times per year.

Do you give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies? ☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

This statement may not be applicable: If you volunteer to take part in this study, you will be one of about _____ people to do so. (*If applicable, you may add the number of subjects)*

If the PI is a student, he/she should disclose this fact, and, add the following sentence: She/he is being guided in this research by _____ *{Advisor}.* There may be other people on the research team assisting at different times during the study.

Include the following statement if the study has a potential for commercialization. The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

Disclose what institution(s) (such as NIH, NCI, etc.) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. An example of such a statement would be as follows:

_____ *{name of institution/company}* is providing financial support and/or material for this study.

Note, if the IRB determines that disclosure of financial interest is necessary to protect the participants' rights and welfare, you may be asked to include a statement which informs participants of the investigator's financial interests in the study (i.e. the source of funding and funding arrangements for the conduct and review of the research, or information about a financial arrangement of the investigator and how it is being managed).

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

*One of the following statements is required if **any** identifiable samples or **any** identifiable private information is collected:*

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, clinical record number, or date of birth.

OR

All identifiable information (e.g., your name, clinical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

The researchers would like to store, use, and share your identifiable (*specify information and/or samples)* for future research. Having *information/samples* from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored *information/samples* to learn more about _____ (*cancer, diabetes, and other health problems*) or research additional scientific questions.

(Specify if requesting current and future access to the medical record) Researchers would like to have permission to look at your medical records from time to time *(or specify frequency)*. Researchers would collect general information related to your health such as test results, treatments, and doctor's notes. The confidentiality section below provides details about how we will keep your information private.

(Include if applicable) Researchers may use the genetic material (genes, DNA, RNA) in your sample to learn about the role genes play in heath and disease. Genetic studies help explain why traits or diseases are passed down in families. Results of genetic studies may also reveal information about your family members. Even if researchers do this type of research, the results will not be put into your health record.

(Include if applicable) Researchers may use your sample to create a "cell line" which is cells grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

(Include if applicable) Your cells may be used in laboratory studies to test treatments to see how well they work before using them in patients. Researchers may mix your cells with other human cells or implant them in laboratory animals such as mice.

(Include if applicable) The genetic testing may include whole genome sequencing. This means a researcher would map your entire set of genetic instructions. Genetic instructions are what make you unique. These tests involve scanning the genomes from many different people and looking for markers that scientists can use to predict the presence of a disease. Data obtained from analyzing your genomic information and your medical information may be put into scientific databases along with information from other research participants. Researchers will remove your name and other information that could be used to identify you before placing in the databases. (*If placing summary data in unrestricted access databases)* To advance scientific discovery, the researchers may put genomic summary data in public databases. (*If placing data in "controlled access" database)* The researchers may place your individual genomic data and health information in controlled databases. Controlled databases require researchers to apply for and get permission to use the data for a specific research project.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You are the subject or are authorized to act on behalf of the subject. You will receive a copy of this consent form after it has been signed.

_____ _____ **Signature of research subject** *or, if applicable, *research subject's legal representative* **Date** _____ **Printed name of research subject**
Remove this shaded section if not seeking IRB approval to obtain consent from a legally authorized representative _____ **Printed name of research subject's legal representative* **If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:* _____ _____
_____ _____ Printed name of [authorized] person obtaining informed consent Date