UNIVERSAL CONSENT FOR BIOLOGICAL SAMPLES

In support of precision health

Frequently asked questions

What is a biological sample?

A biological sample is any bodily fluid or tissue (e.g., blood, saliva, urine, skin or other tissues) that may be collected when you go to the doctor or have a medical procedure. More often, these samples are collected to help diagnose or monitor your health condition. After being used, anything that's left over is thrown away or destroyed. With your permission, these leftover materials will be sent to the UCLA BioBank for research instead of being thrown away.

What is the UCLA Biobank?

The UCLA BioBank collects biological samples from as many people as possible. It then codes the samples and removes any information that could identify you. The BioBank then sends the samples, along with some of your health information, to approved researchers who will use the information to find new ways to prevent, detect and treat health problems.

Will my consent decision affect my care?

No. Your universal consent decision (opting in or out of donating your biological samples) will have no impact on your clinical care. For patients over the age of 18, if you say YES to the collection of an additional blood tube and/or saliva sample, the clinical staff will need to know in advance in order to collect the additional sample. No matter what you decide, it will not affect your relationship with UCLA Health or the services you are receiving.

Why do we need an extra tube of blood?

For patients over the age of 18, having an extra tube of blood (up to 2 teaspoons) or in some cases saliva provides us with enough volume for multiple research purposes and permits certain research not possible on leftover samples.

How will samples be collected?

We will collect some biological samples from some of your future routine clinical lab work done at any UCLA Health laboratory. With your permission, we may: 1) use leftover biological specimens from any future routine lab work done at any UCLA Health laboratory, 2) collect an extra tube of blood as part of a future blood draw or IV placement during a routine visit, and/or 3) collect saliva if you are at a clinic that collects samples for precision medicine.

***You will not need to undergo any additional needle sticks, tests or procedures.**

How long will my samples be stored?

Your samples will be stored indefinitely.

How could my samples be used for research?

Your samples may be used for a variety of research purposes (e.g., cancer, heart disease, diabetes) and for product development.

Examples:

a. Genetic research

Your sample may be used to study how genes affect health or respond to treatment. Genes contain pieces of DNA that control how our cells and bodies develop and work. The DNA code is what you inherit from your parents and pass on to your children. Researchers can use a number of methods, including whole genome sequencing, to look at parts or all of your DNA code.

b. Scientific databases

Researchers also put genetic and other non-identifiable information about you and your health conditions, into a research database. This increases knowledge and can make future research discoveries happen more quickly.

c. Other uses

Researchers may use your samples to create new products useful for research or clinical treatment. Your sample may include cells that can be made to grow indefinitely in the laboratory, called a “cell line,” or your sample could be used to develop or test new treatments.

Who will conduct research on the samples?

Only researchers and research projects approved by a UCLA research-review process may receive samples for research. Most samples will go to UCLA researchers, but we may also choose to share samples with researchers from other universities, government researchers and researchers from private companies that work on developing new tests or treatments.

Will I get any results from research done with my samples?

You will not get any results back unless you let the UCLA Atlas Genetic Screening Program know that you want to receive genetic results. The research community will not know who you are but the UCLA BioBank will be able to work with your healthcare team to notify you only if there are results that may affect your care. Please know that there is often a delay of months to years before a result is available. For patients under the age of 18, results may not be available before they turn 18 years old. If you do not want to be notified of any results, the UCLA Atlas Genetic Screening Program will publish a newsletter that provides overall information about new discoveries made from the samples. If any results are returned to you, a genetic counselor will be available to provide more information on your results either in person or over the phone. If you or your doctor are concerned that you have a medical condition that requires genetic testing, we encourage your doctor to order a clinical genetic test in order to get you answers sooner. Please know that this does not substitute the need for a clinical genetic test.

Are there financial factors I should consider?

You will not be charged for donating your samples and you won’t receive any money for doing so. If there is commercial value, it will belong to UCLA and its collaborators. You will not be paid if any new products, tests or discoveries result from any research performed with your samples.

Who benefits from biological samples?

Your samples will be used to advance science and better understand specific diseases. In the past, some UCLA samples have developed new treatments for serious diseases. The research discoveries in the future may allow for more personalized therapies for patients — a primary goal of precision health at UCLA.

Are there any risks?

There are no physical risks. There is a very small chance that someone could obtain information that would connect the sample to you. Since only you have your unique genetic makeup, information about your ancestry, ethnic group or other people with your disease might be identified and connected with your sample. There is also a small chance that information from your health records could be accidentally released. Currently, only large state and federal agencies have the ability to identify individuals just based on a complete DNA profile. We cannot predict how future technology might affect confidentiality.

Federal and California laws provide certain protections against discrimination based on genetic information.

Some people may have moral, religious or cultural concerns about some kinds of research.

How will my privacy be protected?

UCLA will remove your name and other information that could identify you before sharing your samples for research. A list of names and matching code numbers will be kept separate from coded samples and data.Those working on the research projects will not have access to any information that link your samples to you.

Jane Smith → becomes → **1493526807**

The samples are kept in locked freezers in locked buildings. All information is kept secure on password-protected computers located behind a firewall.

Researchers who study your samples will not know who you are. The BioBank will only give them a code number without any identifying information. UCLA Health and its BioBank must follow state and federal laws and UCLA policies that require protection of your information. The BioBank will only give out limited information to other collaborators and none of the information will include identifying information.

The BioBank has a Certificate of Confidentiality by the National Institute of Health. This certificate prevents UCLA from sharing any information that could identify you in any civil, criminal, administrative, legislative, or other proceeding whether at the federal, state or local level.

Your privacy will always be protected whether you choose to share your leftover sample or donate an additional tube of blood and/or a saliva sample for research. If you would like to be contacted for future research, then we may contact you for other research opportunities that may or may not relate to a biological sample you may have given.

Your specimens and information about you are/is protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your specimens or information about you for any legal proceeding, even if the court asks.

The Certificate allows us to use your specimens and information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect specimens and information we share with them. There are limits to this protection. The Certificate does not protect your information when:

a. You or your family voluntarily share information about yourselves.

b. You agree to the specific release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).

c. A federal agency audits or evaluates research that it funds.

How do I withdraw from the UCLA BioBank?

Your participation in the UCLA BioBank is voluntary. If you agree to participate but change your mind, we will honor your request. To make sure you have the time to think over your decision carefully, there will be a 10-day window from the time you sign the consent to the time your sample becomes available for researchers. Even after the 10-day window, you can still change your mind at any time.

To stop the use of your sample or health information in a study, you may return to the same location where you first completed the consent to change your consent decision. You may also stop the use of your sample or data by contacting the BioBank at 310-825-4136.

For patients under the age of 18, we can only withdraw a consent for the patient over the phone if the parent or guardian who initially completed the process is the one contacting the BioBank.

Any researcher who received your samples will be asked to destroy them. Please note that we cannot get back any samples that have already been used by researchers.

Whom do I contact with questions?

Any questions related to your rights as a research subject, contact the UCLA Office of the Human Research Protection Program at 310-825-5344.

For general questions or to learn how to navigate the consent application, please call 310-794-0981 or email UniversalConsent@mednet.ucla.edu.

To reach the UCLA Atlas Genetic Screening Program, please call 310-780-1333 or email ATLASROR@mednet.ucla.edu.

To learn more about the Universal Consent, please visit our website at uclahealth.org/patient-resources/universal-consent.