

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 for standard clinical care. More often, biological samples are collected to help diagnose or monitor your health condition. After being used for your care, leftover materials from the samples are normally discarded or destroyed. With your permission, these leftover materials will be sent to the UCLA BioBank for research instead of being discarded.

What is the UCLA Biobank?

The UCLA BioBank collects biological samples from as many people as possible. It then codes the samples and removes personally identifiable information. The BioBank then sends the samples, along with previously obtained de-identified medical data, to qualified 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 leftover or additional biological samples) will have no impact on your clinical care. 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.

How will my privacy be protected?

UCLA will remove your name and other identifying information prior to providing your tissue for research. A list of names and corresponding code numbers will be kept separate from coded samples and data. Only authorized UCLA staff can access this list. Those working on the research projects will not have access.

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

Jane Smith

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Researchers who study your samples will not know who you are. The BioBank will only give them a code number that lacks 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 release limited information to other parties and none of the information will include identifying information.

The BioBank has a Certificate of Confidentiality by the National Institute of Health. This certificate protects against forced disclosure of personally identifiable information in any civil, criminal, administrative, legislative, or other proceeding whether at the federal, state or local level.

Your privacy will 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.

Why do we need an extra tube of blood?

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 any biological samples from 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 are 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 place genetic and other non-identifiable information about you and your

health conditions, along with information from their research studies, into a scientific database. This increases knowledge and can help speed the pace of future research discoveries.

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 university 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 agree to participate in the Institute for Precision Health Pilot program for Return of 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 health. If you do not want to be notified of any results, UCLA 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 clinician are concerned that you have a condition that requires genetic testing, we encourage your doctor to order a clinical genetic test. Participating in the Precision Health research project does not replace the need for a clinical genetic test.

Are there financial factors I should consider?

You will not be charged or paid for donating your samples. 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 small chance that someone could obtain information connecting the sample to you. Since only you have your unique genetic makeup, information on your ancestry, ethnic group or other people with your disease might be identified and connected with your sample. There is also a small chance of accidental release of information from your health records. 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.

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 release information about yourselves.
- b.** You consent to 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 ensure 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 change your mind.

To stop the use of your sample or data 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.

Any researcher who received your samples will be asked to destroy them. Please note that we cannot retrieve materials 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.

To reach UCLA Precision Health, please call 310-206-6907 or visit uclahealth.org/precision-health.