**Template Informed Consent Document for Biospecimen Banking**

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for discussion by the Arizona Biospecimen Consortium[[1]](#footnote-1)\*

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**Consent to Participate in a Biospecimen Repository**

Research is the key to developing new treatments and cures for disease. Medical information and biospecimens are very useful for research. You can support research by giving us permission to use your or your child’s medical information and biospecimens for research. If you are consenting on behalf of your child, all of the references to “you” or “your” below refer to your child.

Human specimens include samples of blood, skin, bones, hair and other parts of the body. You have been given this consent form because *[insert holder of biospecimen bank]* wants to include your specimens in a biospecimen repository, or a “biospecimen bank,” to use for future research. The *[insert name of biospecimen bank]* is located at *[insert location of repository]*.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a law designed to protect the confidentiality of your health information. This document seeks your permission to include your health information in the *[insert name of biospecimen bank]* to use for future research, and describes your rights about your health information.

**How will your specimens be collected?**

*[Insert description of how specimens will be collected. For example, if they will only be excess tissue after treatment or diagnostic procedures, you could say: “You have had or are scheduled to have tests or procedures performed at [institution]. After these tests or procedures are completed, there may be leftover specimens that would be thrown away. Instead of having these leftover specimens thrown away, you can agree to let [institution] keep your specimens in the biospecimen bank for research.”]*

**Who will keep your specimens?**

*[Insert discussion of who holds the research repository and how the repository is operated. Include a discussion of where the specimens will be stored, and who will have access to the specimens. Include a description of how long specimens will be kept. (Note that there is nothing in present federal law that requires a time limit for collection or retention; however, the NPRM has proposed changes to how long a consent can support future collection.)]*

**What type of information about me will be stored and what confidentiality protections are in place?**

[*Insert explanation of what type of information is collected (such as the participant’s medical records or other more limited parts of the record, such as laboratory results). This should also state whether identifiable or coded information will be maintained with the specimens or in a separate database, whether research results will be linked to specimens, and whether clinical data will be provided to the biospecimen bank in connection with the specimens (including whether that clinical data will be collected over time). It should state the name or specific identification of the persons or class of persons authorized to make the disclosure of PHI to the biospecimen repository (such as the participant’s physicians and treating hospitals).]*

*[Option 1: Insert for specimens linked to medical record information]*

If you agree to participate, information about medical care you received in the past *[and that you will receive in the future]* will be collected from your medical record (such as test results, diagnoses, medications, immunizations and dates related to your care). This information may relate to treatment for sensitive conditions, such as HIV/AIDS, sexually transmitted and other communicable diseases, drug, alcohol or substance abuse, and mental health treatment, and may include genetic information. Demographic information about you (such as name, address, age, gender, race and family history) also will be collected.

We will collect this information from *[insert sources of information. Include “your health care providers” generically if you intend to collect medical records from other sources, such as the participant’s primary care provider]*.

The information stored in the biobank will not include information that can directly identify you, such as your name, social security number, address, telephone number. Your biospecimens will be labeled with an identification number (a code).

Your name, address, phone number, and other identifying information will be kept separate from your biospecimens in a secure computer database at *[insert location of database].* This secure computer database will include the identification number assigned to your biospecimens, which can be used to link you to your biospecimens if necessary. At *[insert name of biospecimen repository],* only the manager of the repository and other trusted personnel will have access to the information in this secure database. It is possible that agencies that regulate research, such as the Food and Drug Administration or the Office for Human Research Protections, will have access to this information, but they usually will not need to know your identity.

*[Option 2: Insert for Unlinked Specimens.]*

Once the specimen is collected, it will be separated or unlinked from your name or other ways to identify you. This will protect your identity and preserve anonymity. However, once you provide the specimen, you will not be able to withdraw your specimens from the bank because we will not know which specimen is yours.

*[Insert if the participant will not be informed about research results:]* Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your medical record and it will not affect your care.

*[Insert if the repository will be recontacting the participant’s providers in the future to obtain more information about the participant:]* In the future, people who do research may need to know more about your health. While the *[insert name of repository]* may give them information about your health, we will not give researchers your name, address, phone number, or any other information that will let the researchers know who you are.

**What type of research will be done with your specimens?**

*[Insert discussion of what types of research will be conducted with the specimens collected. Example language: “Your medical information and biospecimens may be used for research relating to health, disease prevention, medical advancement, and other scientific purposes. This may include research on cancer, cardiovascular disease, stroke, diabetes and other metabolic disorders, neuroscience, urology, and other areas. Sometimes specimens are used for genetic research (about diseases that are passed on in families).]*

*[Insert description of data sharing for NIH-funded GWAS studies: “To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in the Biobank, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by [institution], some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.’[[2]](#footnote-2)]*

**How will researchers get your specimens?**

Researchers from universities, health organizations and private companies conduct research using biospecimens. They will contact the *[insert name or repository]* and request specimens for their research. A committee will review the way these studies will be done and decide if the studies have scientific or educational merits before we give your specimens to the researchers.

**What are the benefits of participating**?

The benefits of research using specimens for research include learning more about what causes diseases, how to prevent them, and how to treat them. The research that may be done with your specimens is not designed specifically to help you. It might help people who have diseases in the future.

**What are the risks of participating?**

*[Insert explanation here if there are any risks associated with the physical collection of the specimens. For example, if there is a blood draw, consider inserting: “Having your blood drawn may cause mild bruising, swelling, and pain at the site at which the blood was taken. There is also a very small risk of infection at the site within the few days after the blood draw.”]*

*[Insert if the specimens are linked to the participant: [Insert holder of biospecimen bank] has extensive precautions in place to prevent any unauthorized disclosure of personally identifiable information. However, if there is an accidental disclosure of information that can be used to identify you, it could affect your insurability, employment, family relationships or other legal rights. You should know that there are measures in place to prevent this from taking place. State and federal law, such as the Genetic Information Nondiscrimination Act (GINA), prohibit health insurance companies and larger employers from discriminating against people based on their genetics. There may be unforeseeable risks that are not known at this time. However, you will be informed of any new risks as they become known.]*

Once your health information is released to researchers, it may no longer be protected by the HIPAA law, although other confidentiality safeguards apply. If you have questions about your rights or how your health information will be protected, you can ask *[insert contact information].*

**How many other people have participated?**

Over *[insert number]* other people have participated in the *[insert name of biospecimen repository]*.

**Can you change your mind later?**

Yes. If you decide now that your specimens can be kept for research, you can change your mind at any time. You may cancel your permission at any time by sending a written notice to *[insert contact information]*. If you cancel your permission, your *[insert type of serum/tissue]* and the information about you will be taken out of *[insert name of biospecimen repository]* and destroyed. However, your cancellation will not apply to information that has already been distributed for research purposes. *[Explain if the repository will contact recipient investigators when a participant withdraws participation and what happens.]* Unless you cancel this authorization, it will not expire. If you decide not to participate, it will not affect your care or any other benefits to which you are entitled.

**Will you receive compensation?**

No, you will not receive compensation for contributing your specimens to this research. *[Insert name or repository]* may share your specimens with researchers at universities, health care organizations and private companies. As part of such activity, the researchers may obtain patents or other legal licenses relating to possible diagnostic or treatment methods, which may lead to financial benefit for them. They do not have plans for you to share in this economic benefit. You do not waive any legal rights by signing this document.

**Your Participation is Voluntary**

The choice to let us keep your specimens for future research is up to you. You are not required to sign this form. If you decide not to sign this form or if you cancel it in the future, it will not affect your medical treatment, payment or eligibility for benefits, or enrollment in a health plan.

**Where can I get more information?**

If you have questions about your rights or how your health information will be protected, you can ask *[insert contact information].*

**Signature**

I have been given a copy of all *[insert total of number of pages]* pages of this form. I have read this form or it has been read to me. I understand the information and I have had all my questions answered. I agree to participate in the Biospecimen Repository.

Signature of Participant Date

Printed Name of Participant

Printed Name of Person Collecting the Consent

**If Participant has a Personal Representative (someone who is authorized to make health care decisions on behalf of the Participant), the Personal Representative should sign:**

Signature of the Personal Representative

Printed Name of Personal Representative

Date

Please describe why you have authority to make health care decisions on behalf of the Participant. (For example, are you the Participant’s spouse or parent? Did the Participant name you as health care power of attorney?)

1. \* This Template Informed Consent Document for Biospecimen Banking is for educational purposes and is not intended to be legal advice. Please consult your legal counsel for questions concerning your particular circumstances. Kristen acknowledges the assistance of Naomi Jorgensen, Coppersmith Brockelman PLC, in preparing this document. [↑](#footnote-ref-1)
2. *See* The Electronic Medical Records and Genomics (eMERGE) Network Consent & Community Consultation Workgroup Informed Consent Task Force, Model Consent, http://www.genome.gov/Pages/PolicyEthics/InformedConsent/eMERGEModelLanguage2009-12-15.pdf. [↑](#footnote-ref-2)