Attachment H. Template Biospecimen Storage Consent Form

EMERGENCY EPIDEMIC INVESTIGATION DATA COLLECTIONS TEMPLATE INFORMED CONSENT DOCUMENT FOR STORING BIOSPECIMENS FOR FUTURE RESEARCH

This is the consent form template for creating your biospecimen repository informed consent document. You may use this biospecimen repository consent form as a stand-alone, or incorporate its provisions in the parent study consent document.
Delete this box and all other guidance boxes

Insert an identifier in the footer such as version number and/or date on the first page

If there are more than one consent form, identify each document by the population who will sign it, for example, "Adult Controls", "Parents" etc.

Title of Investigation:

CDC Lead Investigator:

IRB No. (if applicable):

Investigators are expected to write consent forms in simple language. The preferred reading level is 8th grade. Check the **instructional template** for guidance about assessing reading levels.

What you should know about this study

- You are being asked to participate in this study.
- This consent form explains the study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to give your specimens for future research. There will be no penalty if you decide not to give your specimens.
- You may decide to cancel your consent at any time. We will not be able to get back samples that we already have shared, but if you cancel, we will stop sharing your samples and information. If you cancel your consent, we will destroy your unused samples and your information.
- You will not own any product or idea created by researchers using your specimens and you will not receive any financial benefit from the creation, use or sale of such a product or idea.

Purpose of study

We would like to store your <<name the biospecimen, e.g., blood, skin sample, breast tissue, saliva, urine, etc.>> with information about you to use in future research. The samples may be used to learn about the body and to improve health. They also may be used to develop new medical products.

Procedures

<<Explain how the sample will be obtained. If this biospecimen consent is associated with another research study, explain the connection and that this part of the study is optional and that participation will not affect participation in the other study. You must also be clear whether the specimens will be used only by the study team, or will be shared with outside investigators.

The specimen will be stored in a repository at << *identify site of storage*>>. It will be used for future research. The specimens <<*will/will not*>> be shared with investigators outside this study.

<< *If they will be shared, you must explain who will make the decision about sharing, and what factors may be considered.*>> Before any researcher uses your specimen with your information, the study will be reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of doctors, scientists, and community members. It reviews research and protects the rights and welfare of research subjects.

We will keep the specimen << *indefinitely, or insert time period*>>. If we complete our research and no longer need to keep the specimens, we will destroy them. We will also destroy the specimens if we lose our funding for storage.

Risks/discomforts

In this section, clearly state how personal identifiers will be stored, whether the link between identifying information and biospecimen samples will be maintained or broken, and who will have access to the link.

There is a small risk that someone could link your specimen with you. For example, if your specimen is used for genetic research, someone outside the study could learn about your risk for certain diseases. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

We will protect your privacy by using codes. We will take things like name, address, and date of birth off of specimens. Your specimen will have a coded number that only the study team will know.

<<If you plan to share specimens with outside investigators>> The specimens given to outside researchers will not include your information. Outside researchers must promise not to use your DNA to identify you, and must agree to protect your data.

Certificate of Confidentiality (if applicable)

<<*Insert Appropriate Agency*>> has given us a Certificate of Confidentiality for this storage study. **This does not mean the government approves or disapproves of this investigation**. This Certificate adds special protection for research information that identifies you. It allows us to refuse to give out your information in some legal actions. Still, we may disclose information about you in other cases. For example, the government may see your information if it audits us.

Benefits

There is no direct benefit to you from allowing us to store your samples. The use of your samples in future research could help us learn more about human health and how to improve it.

Payment

There is no payment for participation.

Sharing your health information with others

Diagnostic, or clinically relevant, information produced in research labs that are not CLIA certified should not be given out to participants or their providers. If your study will produce test results that meet clinical standards, and you wish to give those results back to the participants, you may modify the language below. Be sure to address the need for clinical counseling or other support to ensure that the participant understands the test results.

Neither you nor your doctor will receive research information or test results from the research. Research information and test results will not be placed in your medical record or used in your care.

Choice for Future Research Use and Future Contact

The statements below provide a sample of what you may ask participants to consider. If you plan to use the specimens/data with personal identifiers, you need to give the participants a chance to choose among several choices, so that the decision to permit use with identifiers for certain purposes is clear. If data are anonymized and will subsequently linked with personal identifying information, provide information about how the link between personal identifiers and biospecimen samples will be made and who will have access to the identified data.

Your samples/data may help researchers at CDC and other institutions learn about, prevent, or treat health problems. Please read each statement below and think about your choice. Check either yes or no for each statement.

My samples/data may be used for future research to learn about, prevent, or treat <<identify specific disease or condition under study>>.

_____ Yes _____ No

My samples/data may be used for future research to learn about, prevent, or treat <<identify specific disease, if applicable>> or other health problems (e.g., cancer, heart disease, mental illness).

_____ Yes _____ No

My samples/data may not be used in future research unless researchers contact me to tell me about the study and ask my permission.

_____ Yes _____ No

My samples/data may not be used in future research, and I do not want researchers to contact me about future studies.

_____ Yes _____ No

Who do I call if I have questions, problems, or wish to cancel my consent?

Research conducted in an **international setting** must provide a local contact name and telephone number, address, and email, if available. If a local IRB is overseeing the study, replace the information below with contact information for the local IRB.

- Call the CDC Lead Investigator, <<insert name>>, at <<telephone number>> if you have questions or problems as a result of being in this study. Use this contact information to cancel your consent, or write to this address <<insert PI's address>>.

Keep the questions below on the same page as the signature lines.

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Add any of the following lines that are required; delete any that do not apply.

_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date
_____	_____	_____
Print name of Legally Authorized Representative (LAR)	Signature of LAR	Date

_____

Relationship of LAR to Participant

Include this Assent Statement in all studies involving children, unless using a separate Assent Form. Delete box and statement below if not applicable.

Assent Statement

_____
Print name of child participant

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

_____	_____	_____
Print name of Parent/Legal Guardian	Signature of Parent/Legal Guardian	Date
_____	_____	_____
Print name of Parent #2 for 45 CFR 46.406 studies	Signature of Parent #2	Date
_____	_____	_____
Print name of Witness (if needed and approved by IRB)	Signature of Witness	Date

Always include:

_____	_____	_____
Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Give one copy to the participant and keep one copy in study records