**University of North Carolina at Chapel Hill**
**Consent for Storing Biological Specimens With Identifying Information**
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DELETE THIS AND ALL OTHER INSTRUCTIONS IN ITALICS AND YELLOW HIGHLIGHTS. The consent form must be written in 2nd person (e.g., You are being asked to take part in a research study about)

**Consent Form Version Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_
**IRB Study #** 17-0238
**Title of Study**: Test Application To Generate IRB Templates
**Principal Investigator**: Dr. Principal Investigator
**Principal Investigator Department**: Office of Human Research Ethics
**Principal Investigator Phone number**: (919) 966-3113
**Principal Investigator Email Address**: email@email.unc.edu

**Faculty Advisor**:
**Faculty Advisor Contact Information**:

**Funding Source and/or Sponsor:** NIH National Institute of Mental Health (NIMH); North Carolina Division for Heart Disease and Stroke Prevention

**Study Contact Telephone Number**: (919) 966-3113
**Study Contact Email**: email@email.unc.edu
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**CONCISE SUMMARY**

The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project’s scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Please keep the 'Concise Summary' header and text box border around this section.

Examples of model summary statements are available on the IRB website. [Click here to view examples](https://research.unc.edu/files/2018/01/Concise-Summary-Examples.pdf)

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this consent form, we mean you or your child.

**What are some general things you should know about research?**
Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research. If you are a patient with an illness, you do not have to be in research in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this specimen repository or "biobank?"**
Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or "biobank."

The purpose of this particular repository or biobank is to: describe purpose for the specimen collection and storage and what you hope to learn from the stored samples.

* Inform subjects of the purpose of the repository.
* Inform subjects what specimens are to be collected and/or stored (i.e. blood, tissues, teeth etc).
* Provide a specific description of the research to be conducted with the specimens if known.
* Describe the types of genetic research that may be done in the future, e.g, looking for relationships between genes, the environment, and people's habits or diet, and different diseases. (May omit if there is certainty that genetic research will never occur, but this may be unlikely).

**How will the specimens be collected?**

* Provide specific details about how the specimen will be collected, OR
* If specimen already exists from previous clinical sources or research studies, inform subjects.
* Describe specimens to be collected, including frequency and size/amount.

**What will happen to the specimens?**
Address specific areas about how the sample will be used and stored:

* Provide a clear description of the operation of the specimen repository
	+ Where will the specimen be stored?
	+ Who will have access to the link?
	+ When will the specimens be destroyed?
* Inform subjects of conditions under which data and specimens will be released to other investigators.
* **For Whole Genome Sequencing (WGS):**A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).  (may be omitted if not applicable)

**What are the possible benefits to you?**
Benefits to you are unlikely. Studies that use specimens from this repository may provide additional information that will be helpful in understanding (specify if repository focus known).

**What are the possible risks or discomforts involved with the use of your specimens?**
Describe immediate and long-term social, physical, and psychological risks/discomforts related to the specimen collection and storage. Address all risks that are applicable.

* Social risk: describe the impact for the subject if a breach of confidentiality occurs, especially if research involves sensitive topics.
* Unknown risk: Subjects should be informed that there may be risks that at this time are unknown.
* Physical risks: If new samples are being collected include the physical risk associated with the sample collection for research purposes.
* In addition, use the following.

There is a risk of breach of confidentiality. If this research involves genetics, there is also a potential risk for some of your relatives and other members of your ethnic group, since they share some of your genetic makeup.

**Will there be any cost to you for storage of the specimens?**
There will be no cost to you for the storage and use of the specimens for research purposes.

**Will you receive anything for the use of your specimens?**You will not receive anything for taking part in this study.

Describe payment or gift and schedule for their receipt. Address how payment will be prorated in the event the participant withdraws from the study prior to completion.   Include information about any reimbursement for parking, transportation, etc.
You will be receiving \_\_\_\_\_\_\_\_ for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

**Who owns the specimens?**
Insert any contract, grant or agreement language related to specimen ownership or modify the following boilerplate.

Any blood, body fluids, or tissue specimens obtained for this purpose become the exclusive property of (specify organization that owns, e.g,. the University of North Carolina at Chapel Hill, name of drug company or other sponsor, etc. Individual researchers do not own specimens, and should not be listed.). This organization may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

**How will information about you be protected?**
Indicate how privacy and confidentiality will be protected.

* Include protection of identifiable data.
* Describe methods to be used: coding, etc.
* Describe how the records will be secured.
* Include who may have access to the records, if names will be used, or if there will be ID numbers only, and a linkage file.

[if applicable] Information from your medical records may be stored along with your specimens(s). You will be asked to sign a separate form ("HIPAA authorization") to allow researchers to review your medical records.

[if applicable] The specimens may be shared with researchers at this or other institutions (include name of other institutions, if known). Research studies may be done at many places at the same time. Your personal identifying information will not be sent to other researchers.

You will not be identified in any report or publication about research using your specimens. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

**What is a Certificate of Confidentiality?**
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

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 an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

[This short version of the language may be used for research enrolling subjects in the international setting. Please delete the version that will not be used.]

**What is a Certificate of Confidentiality?**
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

Describe how you will help ensure that the bilingual interpreter will maintain confidentiality.

[Delete if using a separate consent for specimens or if this does not apply to your study and you know data will never be submitted to a data sharing repository (e.g. dbGaP for genome-wide association study (GWAS))]

**Will my genetic information be shared?**Your blood and tissue samples contain genes that are made of DNA unique to you. 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 this study, 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 this 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 information 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 as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential.

[Delete if no genetic testing will take place under the known aims of the main study. If the possibility of genetic testing is limited to future, unspecified research on stored specimens, the language can be covered in the stored specimens consent document.]

Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

**Will researchers seek approval from you to do future studies involving the specimens?**
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. We may use de-identified data and/or specimens from this study in future research without additional consent.  However, in some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

**Will you receive results from research involving your specimens?**
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.  The use of your samples may result in commercial profit.  You will not be compensated for the use of your samples other than what is described in this consent form.

**Will I receive any other clinical results?**
Other clinically relevant results of this research will be communicated with you (describe which test results, when, and under what conditions). (if applicable)

**Can you withdraw the specimens from the research repository?**
If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your remaining specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

**What will happen if you are injured by this research?**
Omit this section if the specimens have already been collected.

OPTION A – no commercial sponsor:

All research involves a chance that something bad might happen to you.  If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.  Any costs for medical expenses will be billed to you or your insurance company.  You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form.  They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

OPTION B:  Injury language for industry **sponsored** studies. This section cannot be modified without the approval of the Office of Clinical Trials. If alternative language is approved by OCT please upload the SIL approval letter in PI attachments.   Failure to do so may result in approval delay. Contact OCT at 919-843-0832 if you have questions.

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care.

The Sponsor of the study has agreed to pay all reasonable medical expenses for the treatment of reactions, illnesses or injuries related to the use of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study tests and/or procedures, except to the extent such expenses are due to the negligence of the study staff or due to your current disease or condition unless it is made worse because you are taking part in this study.

The Sponsor has not set aside funds to pay for lost wages or any other losses or expenses. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

To pay these medical expenses, the Sponsor will need to know some information about you like your name, date of birth, and social security number. This is because the Sponsor has to check to see if you have health care insurance through Medicare, and if so, report to Medicare the payment the Sponsor makes toward your medical expenses. We will not collect your social security number for this purpose unless you are injured and a claim is submitted to the Sponsor to pay medical expenses.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form.  They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**Who is sponsoring this research?**
This research is funded by (name of Drug Company, the National Institutes of Health, etc.). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

When appropriate, the last sentence should be modified to disclose the nature of any potential conflicts of interest relating to this study, financial or otherwise.

**What if you have questions about this research?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights as a research subject?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB\_ subjects@unc.edu.

**Subject’s Agreement (adult or minor subjects):**Keep signatures with body of form. If this section is on separate page include header with title of study and name of PI.

I have read the information provided above (if child 14 or younger, insert instead This information has been explained to me).  I have asked all the questions I have at this time.  I voluntarily agree to participate.  I agree to my specimen(s) being stored with the identifying code(s).

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Research Subject |   |
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Parent/Guardian Agreement (If applicable)

I have read the information provided above.  I have asked all the questions I have at this time.  I voluntarily agree to allow my child to participate by allowing their specimen(s) to be stored with the identifying code(s).

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