**University of North Carolina at Chapel Hill**
**Information about a Research Study**
**Adult Participants** [If using more than one adult form, identify adult group.]

DELETE THIS AND ALL OTHER INSTRUCTIONS IN ITALICS AND YELLOW HIGHLIGHTS.

ADDITIONALLY, YOU SHOULD DELETE ANY INFORMATION REQUESTED THAT DOES NOT APPLY TO THIS STUDY.

The consent form must be written in 2nd person (e.g., You are being asked to take part in a research study about…).  Complex terms and concepts must be described or defined in lay language and the consent form overall should be understandable in a language at a level that subjects can comprehend including an explanation of scientific and medical terms (e.g., renal = kidney, cardiac = heart). Define all abbreviations the first time they are used. Also, the page numbering already inserted in the footer should be maintained to show what each page is out of the total number of pages (e.g., 2 of 4).

**Consent Form Version Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_
**IRB Study #** 17-0238
**Title of Study**: Test Application To Generate IRB Templates
**Principal Investigator**: Celeste Cantrell
**Principal Investigator Department**: UNC Hospitals - UNCPN
**Principal Investigator Phone number**: (919) 843-5018
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**Funding Source and/or Sponsor:** NIH National Institute of Mental Health (NIMH); North Carolina Division for Heart Disease and Stroke Prevention; UNC-CH North Carolina Translational and Clinical Sciences (NC TraCS) Institute

**Study Contact Telephone Number**: (919) 966-2755
**Study Contact Email**: griese@email.unc.edu

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.

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)

**What are some general things you should know about research studies?**

You are being asked to take part in a research study.  To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future.   You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below.  It is important that you understand this information so that you can make an informed choice about being in this research study.

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 study?**
Describe the general purpose of the study and include relevant background information. Describe in layman terms why the study is being done and what is the background. For biomedical studies, describe relevant information on safety and/or efficacy.  What are the main aims of the study and how will these be determined?
The purpose of this research study is to \_\_\_\_\_\_\_\_

**Optional**.  Include a description of target population or selection criteria if it is relevant to study participants.
You are being asked to be in the study because \_\_\_\_\_\_\_\_

**Are there any reasons you should not be in this study?**
You should not be in this study if \_\_\_\_\_\_\_\_\_\_\_

**How many people will take part in this study?**
Approximately total number people at this institution (OR) multiple institutions will take part in this study.

**How long will your part in this study last?**
Indicate the length of time of the individual participant’s active involvement.  Include expected time needed for visits as well as the overall length of time. Tell participants whether there is any follow-up.  For stored specimens, indicate length of time of specimen storage.

**What will happen if you take part in the study?**
This is the procedures section.  Describe in lay language, step-by-step, what will be required of or done to the research subject.  Be concise.  Avoid describing study procedures in lengthy narrative form.  If there are multiple steps, use headers, bullets, tables, pictures whenever available. This may include, but need not be limited to:

* **Overall design**:  Procedures to be performed, including frequency and follow-up.
	+ Describe diary cards, questionnaires, surveys, if any.
	+ For studies that involve questionnaires or interviews, include a statement informing the subject they may choose not to answer a question for any reason.
	+ For any procedures indicate whether they are a requirement of participation in the study.
	+ In research involving patients as subjects, provide the name of the physician responsible for the patient's welfare during the study.
* **For Randomization**: Explain to the subjects that they will be assigned by chance, like flipping a coin, to a study group.  Explain the study groups.
* **For Blinding**: Explain what this means and that a subject’s treatment arm can be determined by the PI in case of emergencies.
* **For Specimens**:  Describe specimens to be collected, including frequency and size/amount. Describe what will be done with the specimens, including plans for destruction of the specimens upon completion of this research project. If specimens will be stored for as-yet-unknown tests, see Stored Samples Policy and Consent Form.
* **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 from being in this study?**
Choose or modify ONE of the following groups of sentences as appropriate to the specific study:
Research is designed to benefit society by gaining new knowledge.  There is little chance you will benefit from being in this research study.

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be \_\_\_\_\_\_\_\_\_\_\_

**What are the possible risks or discomforts involved from being in this study?**
For each research procedure and/or intervention (e.g., drug administration), describe immediate and long-term physical, psychological, and social risks/discomforts. Describe how the researchers are minimizing the risks/discomforts.  If there are no known risks state this fact.
There may be uncommon or previously unknown risks. You should report any problems to the researcher.
Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study.  [Be sure to indicate who will pay for the pregnancy tests.]
**What are the risks to a pregnancy or to a nursing child?**
Use sentences below as they apply to this specific study.
We do not know the effect of the study drug on babies before they are born, or on nursing children.  Many drugs can get into the mother's milk. You should not breast feed your child while taking the study drug.

If you are a woman and you are planning to get pregnant, you should not be in the study. If you are a man, you should not father children while in the study.  If you or your partner becomes pregnant during the study you should notify the researcher right away.

**If you choose not to be in the study, what other treatment options do you have?**
Delete this section if only option is not to participate.
For example:  For some terminally ill patients considering a treatment trial, supportive care only may be an alternative.  Others may receive drug out of research study.
You do not have to be in this research study in order to receive treatment. The other procedures or treatments that are available include

**MRI and Gadolinium**
As part of the MRl procedure you may receive a dye called gadolinium. Gadolinium makes it easier to see details on the MRI pictures. If you have any problems with your kidneys, you may be at risk for a condition called Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF). NSF has been reported to occur between 2 days and 18 months following injection of gadolinium. There is no known treatment for NSF. Some people have even died from this. Signs and symptoms of NSF may include:  burning, swelling, hardening or tightening of the skin, blood vessels and internal organs (heart, lungs, live; yellow spots on the white part of the eyes; joint swelling and stiffness; pain in the hip bones or ribs; muscle weakness.

Your doctor will check how well your kidneys work before you are given gadolinium. Depending on how well your kidneys work, you may be given a reduced dose or you may not be able to take gadolinium at all.  NSF has not been reported in people with normal kidneys.

Risks associated with radiation exposure:
If the Radiation Safety Sub-committee reviewed this study, replace the following text with the language they provided to you.
If your study includes 5 or fewer scans of adult subjects, as specified in this document,  the following language should be included.  Insert the number of scan and type of procedure by replacing the bolded text).

This research study involves exposure to radiation from (**insert maximum number scans and type of procedure**). Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

The average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth’s air and soil. The dose that you will receive from participation in this research study is less than amount you receive from these natural sources in one year.

The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

**What if we learn about new findings or information during the study?**
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

The imaging we are using in this research study is not the same quality as imaging that you may have as part of your health care. The images will not be reviewed by a doctor who normally reads such images (such as a radiologist). As a result, you may not be informed of any unexpected findings. The results will not be placed in your medical record.  Occasionally the technologist or principal investigator may notice something abnormal on the imaging.  If this does occur, the images will be reviewed by a qualified doctor to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified.  Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

 Do you wish to be informed in case of clinical/relevant unexpected findings?  Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings.  If you do not initial in the box, you will be notified of any findings.
  \_\_\_\_\_\_ I do not wish to be notified.

**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)

**How will information about you be protected?**
Indicate how privacy and confidentiality will be protected.  Briefly but as clearly as possible describe the key procedures for protecting the privacy and confidentiality of the individual’s data, such as:

* How records will be secured.
* Who will have access to individually identifiable data (e.g. research collaborators, sponsors, etc.).
* Whether names or ID numbers will be used (if codes or numbers are assigned, describe how the linkage file will be secured).

Participants will/will not be identified in any report or publication about this study.  We may use de-identified data and/or specimens from this study in future research without additional consent.

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 study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

* Describe what will be done with tapes.
* Include plans for storage during use and what will be done after transcription, e.g., how long the tapes will be kept.
* Advise participants that audio and video recordings may be requested to be turned off, if that is true for the study.
* Include the following:

Check the line that best matches your choice:

\_\_\_\_\_ OK to record me during the study

\_\_\_\_\_ Not OK to record me during the study

Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in a locked file cabinet. After the focus group tape has been transcribed, the tape will be destroyed, and the list of names and numbers will also be destroyed.

[Where applicable, advise participants that they do not need to reveal their name, or that they may use a fictitious name.]
[Describe how you will help ensure that the bilingual interpreter will maintain confidentiality.]

**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.

[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.

[Only include if applicable. Please remove if no research information nor the consent form will be entered into subjects’ medical records. Please note if you are creating a medical record for the subject as part of the research study, this language should remain.]

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

Under North Carolina law, researchers are required to report information about the abuse or neglect of a child or disabled adult to local or state authorities.

Under North Carolina law, confidentiality does not extend to certain communicable diseases, such as TB, HIV, hepatitis,or other illnesses that put others at risk. If the researchers become aware that subjects have such an illness, they are required to report it to state authorities.

Include one of the statements below if your study will utilize unencrypted messaging (e.g., unencrypted e-mail or text messaging].

[Option 1-Most Common] The study team would like to message you by (insert technology(ies); e.g. text messaging or e-mail); e.g. text messaging or e-mail), however you may say “no” to receiving these messages and still participate in this study.  If you say “yes”, messages may contain personal information about you and may be sent or received by the study team’s personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.  This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form.  After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

\_\_\_\_\_ Yes, I consent to the study team utilizing the following (insert mechanism; e.g. cell phone number, email) to send communication: \_(List e-mail, cell-phone #)\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ No, I do not consent to receive un-protected communication from the study team.

[Option 2-Only for Studies Designed to Investigate Messaging] As the purpose of this research is to study (insert technology(ies)), by signing this consent on the last page of this form you are giving permission for the study team to contact by the mechanism identified below that you provide.  This communication may contain personal information about you and may be sent or received by the study team member’s personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.

This information may include information such as reminders and notification requests to contact the study team.  If you do not want to receive un-protected communication that may contain personal information, then you should not consent to participate in this study.

If you have lost access to your device, please notify the study team using the study contact information on the first page of this consent form.  After the study is complete and all research activities concluded, or you withdraw from the study, you will no longer receive un-encrypted (un-protected) communication specific to this study.

The study team may use the following (insert mechanism; e.g. cell phone number, email) to send communication: \_(List e-mail, cell-phone #)\_\_\_\_\_\_\_\_\_\_

**Will you receive results from research involving your specimens?**
[Delete if separate consent for 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.

[Include in any study that includes specimens] 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.

**What will happen if you are injured by this research?**

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 sil@unc.edu for questions regarding alterations to injury language.

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.

**What if you want to stop before your part in the study is complete?**
Modify the paragraph below, if necessary, to fit the study. Explain the consequences of a subject’s decision to withdraw and the procedures that will be followed for the orderly termination of participation.
You can withdraw from this study at any time, without penalty.  The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

**Will you receive anything for being 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.

In order to process payments, the University may share certain identifiable information about you, such as name and contact information, with third parties that the University retains to process payments on its behalf.  If you do not want to agree with sharing your information with these third parties, then you will be unable to receive payment/compensation for participating in the study.

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS.  You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation.  If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099.  Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation.  Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S.  This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation.  However, you may still choose to participate in this study.

**Will it cost you anything to be in this study?**

If you enroll in this study, you will have costs which include:

* List the additional costs, such as parking, child care, travel, clinic or diagnostic fees.
* List the additional tests/visits/procedures to be performed for research purposes only. Describe who will be responsible for paying the cost of research tests, procedures, visits, etc. that are not standard of care.
* Clearly explain what the likely costs will be for participation in this research study and who will be responsible for those costs  e.g. “… billed to you and/or your insurance.”   Or “… paid by the sponsor.
* Describe specific items or procedures that may/may not be covered.  Include clinic fees, transportation, and parking fees (if known).
* Address clearly who will be responsible for the payment of the costs of standard treatment in the research study, e.g., “These costs will be billed to you or your insurance carrier."

**What if you are a UNC student?**
You may choose not to be in the study or to stop being in the study before it is over at any time.  This will not affect your class standing or grades at UNC-Chapel Hill.  You will not be offered or receive any special consideration if you take part in this research.

**What if you are a UNC employee?**

Taking part in this research is not a part of your University duties, and refusing will not affect your job.  You will not be offered or receive any special job-related consideration if you take part in this research.

**Who is sponsoring this study?**
When appropriate, the last sentence should be modified/expanded to disclose the nature of any potential conflicts of interest relating to this study, financial or otherwise.
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.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if you have questions about your rights as a research participant?**
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, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.