**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Focus Group for 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…)

**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

**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)

**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.

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. 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?**
Your participation in this focus group will last approximately one hour.

**What will happen if you take part in the study?**
The group will be asked to [UPDATE]. No questions will be directed to you individually, but instead will be posed to the group. You may choose to respond or not respond at any point during the discussion. The focus group discussion will be audiotaped so we can capture comments in a transcript for analysis.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge.  You will not benefit personally from being in this research 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?**
We do not anticipate any risks or discomfort to you from being in this study. Even though we will emphasize to all participants that comments made during the focus group session should be kept confidential, it is possible that participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can, but remain aware of our limits in protecting confidentiality.

**How will information about you be protected?**
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.

We may use de-identified data from this study in future research without additional consent.

**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?**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

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?**
It will not cost you anything to be 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.

**Participant’s Agreement**:

I have read the information provided above.  I have asked all the questions I have at this time.  I voluntarily agree to participate in this research study.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Research Participant |   |
|  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Research Team Member Obtaining Consent | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Research Team Member Obtaining Consent |  |