Standard Consent Form for Adult Participants

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Participants *[If using more than one adult form, identify adult group.]*
Social Behavioral Form

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…). Also the page numbering already inserted in the footer must be maintained to show what each page is out of the total number of consent form pages (e.g., 2 of 4).

IRB Study #_____ *(Leave blank if new submission.)*
Consent Form Version Date: _____ *(Enter or update for all submissions.)*

Title of Study:

Principal Investigator:
UNC-Chapel Hill Department:
UNC-Chapel Hill Phone number:
Email Address: ***Optional***
Co-Investigators: ***Delete if not applicable.***
Faculty Advisor: ***Delete if not applicable.***
Funding Source and/or Sponsor:

Study Contact telephone number:
Study Contact email:

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 refuse to join, 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. Be brief.
The purpose of this research study is to learn about

(Optional) *Include if it makes sense to tell participants why they are being approached.*

You are being asked to be in the study because

Are there any reasons you should not be in this study?
Delete entire section if not applicable. *Include if there are exclusion criteria about which participants will know, and that may be unknown to the investigator.*
You should not be in this study if

How many people will take part in this study?
If you decide to be in this study, you will be one of approximately number people in this research 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?
Describe in lay language, step-by-step, what will be required of, or done to, the research participants. Be concise. If the procedures are all to be listed in the consent form and there are multiple steps, use headers, bullets, tables, pictures when appropriate.

- *If it is important for the participants to know prior to consenting that the study involves randomization, explain that they will be assigned by chance, like flipping a coin, to a study group. Explain the study groups.*
- *Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.*
- *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 Addenda*.*

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. You may not benefit personally from being in this research study.

Research is designed to benefit society by gaining new knowledge. You may also expect to benefit by participating in this study by

What are the possible risks or discomforts involved from being in this study?
For each research procedure, 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.

How will your privacy 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. 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 purposes such as quality control or safety.

- ***For studies having a federal Certificate of Confidentiality:***
  - *Insert language provided by the federal agency that issued the certificate or ask your IRB for appropriate language.*
- ***For studies that involve video or audio recording:***
  - *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
- ***For studies that involve group interviews or focus groups***
  - *Advise participants that they do not need to reveal their name, or that they may use a fictitious name.*
  - *Advise participants that they must agree not to reveal anything they learn from group discussions or other activities.*
- ***For studies that involve an interpreter:***
  - *Describe how you will help ensure that the bilingual interpreter will maintain confidentiality.*

What will happen if you are injured by this research?

This section may be omitted if the study involves no more than minimal risk and no chance of personal injury. *To the extent they are known, describe any medical treatments for injury that might be available or where the subject can obtain further information.*

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

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?
*Choose **ONE** applicable sentence:*
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 not receive anything for taking part in this study.

You will be receiving for taking part in this study.

Will it cost you anything to be in this study?
Use this section if there are no costs.
There will be no costs for being in the study

Use this section if there are costs: describe costs such as transportation costs to research site, etc.
Your costs will include

What if you are a UNC student?
Delete entire section if not applicable.
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.

Delete if not applicable. *You will receive _____ hours of departmental research credit. If you leave early, this credit will be prorated as follows:*

What if you are a UNC employee?
Delete entire section if not applicable.
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.

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, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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.

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Title of Study:

Principal Investigator:

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.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

Only include the following section if consent obtained in-person.

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

Parental Permission Form for Minors

University of North Carolina-Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study
Social Behavioral Form

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…). Also the page numbering already inserted in the footer must be maintained to show what each page is out of the total number of consent form pages (e.g., 2 of 4).

IRB Study #_____ *(Leave blank if new submission.)*
Consent Form Version Date: _____ *(Enter or update for all submissions.)*

Title of Study:

Principal Investigator:
UNC-Chapel Hill Department:
UNC-Chapel Hill Phone number:
Email Address: ***Optional***
Co-Investigators: ***Delete if not applicable.***
Faculty Advisor: ***Delete if not applicable.***
Funding Source and/or Sponsor:

Study Contact telephone number:
Study Contact email:

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

You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason. Even if you give your permission, your child can decide not to be in the study or to leave the study early. ***Delete last sentence if not applicable.***

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child 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 and your child can make an informed choice about being in this research study.
You will be given a copy of this permission form. You and your child 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. Be brief.

The purpose of this research study is to learn about

(Optional) *Include if it makes sense to tell participants why they are being approached.*
Your child is being asked to be in the study because

Are there any reasons your child should not be in this study?
Delete entire section if not applicable. *Include if there are exclusion criteria about which parents will know, and that may be unknown to the investigator.*
Your child should not be in this study if

How many people will take part in this study?
If your child is in this study, your child will be one of approximately number people in this research study.

How long will your child's 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 parents whether there is any follow-up. For stored specimens, indicate length of time of specimen storage.

What will happen if your child takes part in the study?
Describe in lay language, step-by-step, what will be required of, or done to, the research participants. Be concise. If the procedures are all to be listed in the consent form and there are multiple steps, use headers, bullets, tables, pictures when appropriate.

- *For studies that involve questionnaires include a statement informing the parent that the child may choose not to answer a question for any reason.*
- *If it is important for the parents to know prior to giving permission that the study involves randomization, explain that the participants will be assigned by chance, like flipping a coin, to a study group. Explain the study groups.*
- *Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.*
- *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 study. If specimens will be stored for as-yet-unknown tests, see* Stored Samples Policy and Consent Form Addenda.

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. Your child may not benefit personally from being in this research study.

Research is designed to benefit society by gaining new knowledge. You may also expect your child to benefit by being in this study by

What are the possible risks or discomforts involved from being in this study?
For each research procedure, 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.

How will your child's privacy 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. 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.

- ***For studies having a federal Certificate of Confidentiality:***
  - *Insert language provided by the federal agency that issued the certificate or ask your IRB for appropriate language.*
- ***For studies that involve video or audio recording:***
  - *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 parents 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
- ***For studies that involve group interviews or focus groups***
  - *Advise parents that the child does not need to reveal her/his true name, and may use a fictitious name.*
  - *Advise parents that the child must agree not to reveal anything learned from group discussions or other activities.*
- ***For studies that involve an interpreter:***
  - *Describe how you will help ensure that the bilingual interpreter will maintain confidentiality.*

What will happen if your child is injured by this research?

This section may be omitted if the study involves no more than minimal risk and no chance of personal injury. To the extent they are known, describe any medical treatments for injury that might be available or where the subject can obtain further information.

All research involves a chance that something bad might happen. This may include the risk of personal injury. In spite of all safety measures, your child might develop a reaction or injury from being in this study. If such problems occur, the researchers will help your child get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such

reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

Will your child receive anything for being in this study?
Choose ***ONE*** *applicable sentence. If the second sentence is selected, then:*

- *Describe payment or gift and schedule for their receipt.*
- *Indicate if parents will receive payment or gift separate from child.*
- *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.*

Your child will not receive anything for taking part in this study.

Your child will be receiving for taking part in this study.

Will it cost you anything for your child to be in this study?
Use this section if there are no costs.
There will be no costs for being in the study

Use this section if there are costs: describe costs such as transportation costs to research site, etc.
Your costs will include

What if you are a UNC student?
Delete entire section if not applicable.
You may choose not to give permission for your child 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 your child takes part in this research.

What if you are a UNC employee?
Delete entire section if not applicable.
Your child's taking part in this research is not a part of your University duties, and refusing to give permission will not affect your job. You will not be offered or receive any special job-related consideration if your child takes part in this research.

What if you or your child has questions about this study?
You and your child have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints or concerns, you should contact the researchers listed on the first page of this form.

What if you or your child has questions about your child's 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 or your child has questions or concerns about your child's 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.

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Title of Study:

Principal Investigator:

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Participant (Child)

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

Only include the following section if permission obtained in-person.

_____ _____
Signature of Research Team Member Obtaining Permission Date

_____
Printed Name of Research Team Member Obtaining Permission