## Title of research study: ***[insert title of research study here with protocol number, if applicable]***

## Investigator: ***[insert name of principal investigator]***

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes participants eligible for the research.]

## Why is this research being done?

[Tell the participant the purpose of the research. Explain the background of the research problem.]

## How long will the research last?

We expect that individuals will spend \_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event] participating in the proposed activities.

## How many people will be studied?

We expect about \_\_\_\_\_ people will participate in this research study.

## What happens if I say yes, I want to be in this research?

[Tell the participant what to expect using lay language and simple terms.] [Include if there are alternatives other than participating. Otherwise delete.] You are free to decide whether you wish to participate in this study. Instead of being in this research study, your choices may include: [List alternatives procedures. For student participant pools describe alternatives for course credit.]

## What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

## Is there any way being in this study could be bad for me?

[Delete this section if there are no risks or discomforts.]

 [Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks

## Will being in this study help me in any way?

[Delete this section if there are no benefits]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

 [Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. The results of this study may be used in reports, presentations or publications but your name will not be used.

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

***[If data will be retained after the study for future research, explain where the data will be stored, who will have access to the data, and how long the data will be retained.]***

## What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

## Who can I talk to?

If you have questions, concerns, or complaints, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by the CCSNH IRB. You contact them at CCSNHIRB@ccsnh.edu if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no requirement for written documentation of consent.]

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. |
|  |  |  |
| Signature of participant |  | Date |
|  |  |
| Printed name of participant |
|  |  |  |
| Signature of person obtaining consent |  | Date |
| Printed name of person obtaining consent |  |  |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the named participant to take part in this research. |
|  |  |  |
| Printed name of participant |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
| Printed name of person obtaining consent |  |  |

***[Add the following block if you will document assent of the participant.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.
 |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Parental Permission for Children**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
| Printed name of person obtaining consent |  |  |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |