Procedures for Participant Group <Insert Participant Group>

Number of Participants for this group:

-

Inclusion/Exclusion for this group:

-

Recruitment Methods for this group:

- Participants will be recruited through _____
- Please see the following documents for recruitment: _____

Screening for this group:

- Participants will be screened through _____
- Please see the following documents for screening materials: _____

Sign-Up and Scheduling for this group:

- Participants will sign up through _____
- Please see the following documents for how sign up occurs: _____

Lab Visit Experience for this group:

- Length of Lab Visit:
- Number of Lab Visits in Total:
- Activities the Participant Will Experience During Lab Visit <insert lab visit number>:
    - <insert interaction/activity 1 and refer to necessary documents>
    - <insert interaction/activity 2 and refer to necessary documents>
    - <insert interaction/activity 3 and refer to necessary documents>
    - <insert interaction/activity 4 and refer to necessary documents>
    - <insert interaction/activity 5 and refer to necessary documents>
    - <insert interaction/activity 6 and refer to necessary documents>
    - <insert interaction/activity 7 and refer to necessary documents>
    - <insert interaction/activity 8 and refer to necessary documents>
    - <insert interaction/activity 9 and refer to necessary documents>
    - <insert interaction/activity 10 and refer to necessary documents>

Devices Used in the Research for this group:

Refer to Guidance: Devices Used in Research and Use of Apps and Software in Research

- <Insert Device Name>:
    - State if the device is homegrown or off the shelf
    - State if the device is used on label and as approved or not
    - State if the device is being used simply as a tool for data collection in the research or if the device is being tested for safety and efficacy.
    - State how the device is donned and doffed
    - State what data the device is collecting/recording or if it's just communicating to other devices
    - For experimental devices:

        - Add this statement: There is a label on the experimental device with the statement "Caution, Investigational device. Limited by Federal (or United States) law to investigational use." *Then make sure to label the experimental device.*
        - Additional Information in the Informed Consent about the experimental device includes: _____
        - Add the statement that the "Researcher will not promote the experimental device"
    - For each device discussed, please complete the "Medical Devices Used in Research - Form" for necessary IDE and risk determinations.

Risks Associated with each lab activity for this group:

- <insert lab activity>: This activity is necessary to answer the research question because _____. The risk associated with this activity includes _____. The probability of this risk occurring is ____ because this risk is mitigated by ____.
- <insert lab activity>: This activity is necessary to answer the research question because _____. The risk associated with this activity includes _____. The probability of this risk occurring is ____ because this risk is mitigated by ____.
- <insert lab activity>: This activity is necessary to answer the research question because _____. The risk associated with this activity includes _____. The probability of this risk occurring is ____ because this risk is mitigated by ____.
- <insert lab activity>: This activity is necessary to answer the research question because _____. The risk associated with this activity includes _____. The probability of this risk occurring is ____ because this risk is mitigated by ____.

Compensation for this group:

- Participants will be compensated ____ amount for ____ time. If the participant stops participating, they will receive ___ amount.

Clinical Trials Information:

- State what health outcomes are being researched. They can be physical or behavioral.
- If health outcomes are NOT being researched, add a brief statement as to what is being researched and how it differs from researching a health outcome

Do I need to submit a Data Access and Security Plan in addition to answering questions on the IRB application?

- NC State classifies the data associated with this protocol as <select one: green, yellow, red, purple>
    - Note: If collecting red or purple data, you need to submit a Data Access and Security Plan.
- If you are only collecting red or purple data for the purpose of payment, then discuss how that information is handled (ideally the researchers do not interact with it and that information is given straight to accounting/HR),