**[Insert Study Title]**

***[Include this section only if applicable]* Conflict of Interest**

* *If the investigator is recruiting potential subjects from their own patients and/or from patients in a clinical program under their direction, it is recommended that the investigator disclose this dual-role in the informed consent.*

**\**Suggested Text\**** Your health care provider may be an investigator on this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this project. You are not obligated to participate in any research project offered by your clinician. Your participation in this research study is voluntary and you do not have to participate. The decision to not participate will not affect your clinical care now or in the future.

* *If the SCNM IRB recommends that you disclose a conflict of interest to subjects, please include the language recommended here so the IRB can review and make a final determination.*

***\*Suggested Text - Include the following if the subject will be receiving study drug, device or biologic at home\**** Please keep the study drug [or device]out of the reach of children or others who may not be able to read or understand the directions on the label. Do not let anyone else take the study drug besides you.

***[This section is required only if applicable - delete paragraphs/sentences that do not apply]*What are the reproductive risks?**

**If you are a woman:** Participating in this research may involve risks to pregnant women and/ or an unborn baby which are currently unforeseeable. To protect against possible side effects of the study drug, if you are pregnant or nursing a child you may not take part in this study. If you are a woman of childbearing ability, you and the study doctor must either agree on a method of birth control to use or you must agree to be abstinent (i.e., not have sex) throughout the study.

* *If applicable, specify the time period after stopping study treatment or completing study that contraceptive control should continue.*
* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, abstinence, etc., if applicable).*

If you think that you have become pregnant during the study, you must tell the doctor immediately. ***[Add the following when true:]*** If you become pregnant, your participation will be stopped.

**If you are a man:**  To protect against possible side effects of the study drug to an unborn baby, you must not get a partner pregnant while taking the study drug and for [Insert the number of days/weeks/months] after the last dose.

You and the study doctor must agree on a method of birth control to use throughout the study or you must agree to remain abstinent, as applicable.

* *Describe acceptable forms of birth control (i.e., oral contraceptive, double barrier method, etc., if applicable).*

**Will I be told about new information that may affect my decision to participate?**

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

**What about privacy and confidentiality?**

*[Include section only if applicable]* **Focus group or group discussion**

We will ask everyone in the focus group [alt text: group discussion] to respect the privacy of other participants and to treat anything said in the group as confidential. However, please remember there is no guarantee that other participants will cooperate.

*[This section is required when appropriate]* **What if I lose the ability to make decisions during the study**?

Either due to your condition or due to the study procedures, you may become unable to continue to provide consent to continue in the study.

Your ability to consent will be evaluated by the investigator at each study visit.

To prepare for this possibility, you may want to prepare an advanced directive (such as a durable power of attorney for health care) indicating who you would like to make health care decisions, including treatment and research decisions for you in such an instance. If you do not have this type of document, the researchers will refer you to someone who can help you create this document.

***[The statement below is required for the following types of clinical trials: 1) controlled, clinical investigations of drugs and biologics subject to FDA regulation, excluding Phase I trials and 2) controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, but including pediatric postmarket surveillance of devices ordered under section 522 of the Federal Food, Drug and Cosmetic Act.]***

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. law.  This web site will not include information that can identify you.  At most, the Web site will include a summary of the results.  You can search this Web site at any time.

*[Include section only if applicable]* **research shows the subject has a communicable disease, e.g., HIV/AIDS, TB.**

 “If the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.”

*This section is required if SCNM students are being recruited:***What if I am an SCNM student?**

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at SCNM. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

*[This section is required if SCNM employees are being recruited]***What if I am an SCNM employee?**

Your participation in this research is in no way a part of your employment duties, and your refusal to participate will not in any way affect your employment with SCNM, or the benefits, privileges, or opportunities associated with your employment at the SCNM. You will not be offered or receive any special consideration if you participate in this research.

***[A signature is a required element of consent – you must apply for a waiver of documentation if not included]*Signature of Subject or Legally Authorized Representative** [*delete “or Legally Authorized Representative” if not applicable]*

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

***[OPTIONAL]***

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Signature of Witness (include only if required by IRB) Date (must be same as subject’s)

 \_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Witness (include only if required by IRB)

[OPTIONAL]

 \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness (include only if required by IRB) Date (must be same as subject’s)

 \_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Witness (include only if required by IRB)