**SUPPLEMENTAL CONSENT LANGUAGE (insert in the consent form/script to be used for your study, as appropriate)**

**Focus Groups:**

**In the section titled “How will the researchers protect my information?“, add the following:**

“Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.”

**==============================================================================**

**If the study is a clinical trial that will register and report results on ClinicalTrials.gov:**

A description of this clinical trial will be available on 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.

**==============================================================================**

**If the study either has NIH funding or will apply for a Certificate of Confidentiality (without NIH funding):**

**In the section titled “How will the researchers protect my information?“, add the following:**

**Certificate of Confidentiality:**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**==============================================================================**

**If the study will enroll prisoners:**

**In the section titled “Will being in this study help me in any way?” include the following:**

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.

**==============================================================================**

**If the study will use incomplete disclosure and/or deception as research techniques:**

**If you intend to withhold information about the real purpose of the study or purposely give participants false information about some aspect of the research (i.e., incomplete disclosure or deception), include one of the following statements in the “Key Information” section of the consent. There are occasionally situations where the potential harms to participants from debriefing may outweigh the benefits of disclosure – those situations will be rare; if you plan not to debrief participants regarding the use of deception/incomplete disclosure, you must explain in the protocol document why you think the harms of debriefing could outweigh the benefits. For further guidance on the use of deception and incomplete disclosure in research, see the NU IRB’s guidance document at:** <https://www.irb.northwestern.edu/files/2020/01/Guidelines-for-Research-involving-Deception-or-Incomplete-Disclosure-2019-05-07.pdf>

For scientific reasons, this consent form does not include complete information about the research questions or topics being tested. You will be fully debriefed following your participation in the research, and you will have the right to withdraw your consent at that time. If you withdraw your consent, your personal information will be deleted.

**OR**

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation, and you will have the right to withdraw your consent at that time. If you withdraw your consent, your personal information will be deleted.

**==============================================================================**

**If your study may lead to disclosure of information relating to sexual misconduct that involves at least one member of the NU community (including sexual harassment and violence):**

I (or the Principal Investigator on this study) may be required by law to report to appropriate NU authorities any information you provide to me that indicates sexual misconduct, including sexual assault, sexual exploitation, dating violence, domestic violence, stalking, and sexual harassment. Therefore, I cannot promise you complete confidentiality of any information you share with me about experiences of sexual misconduct.

**==============================================================================**

## What else do I need to know?

[Include for greater-than-minimal research. Otherwise, delete. The language should not be changed except as indicated.]

[Include if study is unfunded, PI-initiated, or federally funded]

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

[Include if study is industry sponsored. If you need to deviate from this language, then please contact Sponsored Research (SR) and obtain written documentation that the template language is not consistent with the clinical trial agreement and that the language must be altered. The written documentation should then be uploaded into the eIRB+ application.]

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

[Describe any compensation available for research-related injury dictated by the Clinical Trial Agreement or contract.]