Mount Sinai *The Tisch Cancer Institute*

INFORMATION SHEET

Dear Study Participant:

When you enrolled on a research study within the Mount Sinai Health System (MSHS), we told you we would let you know about any changes or additions to the original consent form that you read and signed. The purpose of this letter is to share with you new and/or updated information that has been added to all active trials within MSHS consent forms effective February 2023.

A summary of the new and/or updated information added to MSHS consent forms are listed below:

CONSENT SECTION	NEW/UPDATED INFORMATION
What is Involved	Instructions for the different types of study designs were extended. For example, if you were enrolled on a randomized clinical trial the updates expands on what this means for you. It now reads, "*No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or what study drug/device or procedure you get. It will be by chance, like flipping a coin*."
Pregnancy	Text has been modified to use language that is more inclusive. For example, the consent forms now use more gender-neutral language and terms, removed words such as "for women" and "for men" and changed text to second person (i.e., "you", "yours"). These changes were made to promote equitable research and to acknowledge subject diversity and sensitivity to differences and personal preference. Birth control instructions were also improved and the section for men has been renamed to semen/sperm and expanded on.

Use of your Data and/or Samples	Options about future use of your data and/or samples have been clarified. The updated language includes: "*If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them.* *However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed."*
Ending Participation in the Research Study	Removed imposing, legalistic language to support participant choice. For example, updated language included: *"You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted. If you decide to stop being in the study, please contact the Lead Researcher or the research staff.* *You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study.*

	Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study."
How the Institutional Review Board Can Help You	This section was added and states: *"This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:* o *Your questions, concerns, or complaints are not being answered by the research team.* o *You cannot reach the research team.* o *You are not comfortable talking to the research team.* o *You have questions about your rights as a research participant.* o *You want to get information or provide input about this research."*
Maintaining Confidentiality-HIPAA Authorization	Repetitive language was removed and shortened
All sections of the consent document	The use of the term "subjects" was replaced with "participants" and "Principal Investigator" was replaced with "lead researcher"

This information supplements the original consent form you read at the beginning of the study in which you participated. Unless specifically indicated otherwise in this document, all information contained in the original consent form that you signed is still true and remains in effect.

Your continued participation in a research study is voluntary. You may withdraw from the research now or at any time without penalty or negative consequences.

If you have any questions or concerns about this information, contact your principal investigator that is listed on your original consent form, research nurse or call 212-241-6756.

You can also speak with a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.