Health Research Ethics Board (Biomedical Panel) Guidelines on Participant Withdrawal from a Research Study

During the course of a research study, a human participant may voluntarily withdraw from the study or may be actively removed from a study for reasons outlined in that study’s protocol. HREB’s position on these two scenarios is as follows.

Guiding Principles:

*Participants must not feel in any way coerced or unduly influenced to continue to participate in research. Nor must they suffer any disadvantage or reprisal for withdrawing (Article 3.1).*

*After participants inform the researcher that they wish to withdraw or continue in the study in a graded fashion, they should not be asked for their reason(s)for this decision in any manner that constitutes coercion, undue influence or reprisal.*

1. Participant voluntarily withdraws from a study

Respect for persons is an important core principle necessary to the ethical conduct of human participant research. An important application of that principle is that consent to participate in or withdraw from a research study be given voluntarily and without fear of prejudice.

Notification of withdrawal can be given verbally by the participant to any member of the research team. The study team shall not require a written request from the participant, nor shall they require that the participant provide a reason for the withdrawal. If a Sponsor requests that a researcher make reasonable efforts to ascertain the reason(s) for withdrawal, researchers shall only ask participants in a manner that affords them the freedom to unconditionally refuse and does not in any way pressure or badger them to give an answer or make them believe they will suffer a disadvantage or reprisal for withdrawing. In circumstances where the Principal Investigator is

also the participant’s health care provider special care must be taken to

ensure that the participant does not fear losing access to their health care

upon voluntary withdrawal from a study. Where it may be reasonably

expected that a participant may feel so threatened, the study team should

avoid asking the withdrawing participant for a withdrawal reason.

In addition, a participant lost to follow-up is considered by the HREB to have voluntarily left the study and shall be treated in the same manner as a participant who has actively given notice of their desire to leave the study. Practically, a participant who does not respond to two telephone calls and a registered letter can reasonably be considered lost to follow-up and withdrawn from a study. Other definitions may be defined in a study’s protocol and would be subject to HREB approval.

Once a participant has withdrawn from the study, it is assumed that the following will occur:

1. All study related activities shall cease except those required for the safety of the participant. This includes, but is not limited to, the further collection of health information and activities such as future determination of vital status.
2. Upon withdrawal from the main study, the participant is also considered withdrawn from all optional substudies and all subsequent use of their data and samples not related to the study’s prime objectives.

The study team may provide the participant with a series of options that may allow participation in the study in a more limited manner (graded withdrawal). This could include provisions for future contact, future use of data for secondary purposes and for continued participation in substudies. All options for such limited participation shall be by written informed consent and the possibility of such graded options for study withdrawal shall be made clear in the original consent document. Under no circumstances shall a participant be required to sign a document stating their desire to fully withdraw from a study. The consent for limited study participation after withdrawal from a study is considered voluntary and as such may be withdrawn at any time as described above. The HREB template for graded withdrawal options is attached.

1. Participant is actively withdrawn from a study

If it is necessary that a participant leave or be removed from a study, the study team shall inform the participant of the reasons for this withdrawal. Otherwise, the processes for managing this this type of withdrawal shall be identical to those for voluntary withdrawal.

<*PLACE ON SITE LETTERHEAD*>

Withdrawal Consent Form

**Title of Study:**

**Principal Investigator:** Phone Number:

**Co-Investigators:**

You previously agreed to participate in this research study, but now have told us that you would like to withdraw your consent to participate. As stated in the original consent you signed, you are free to withdraw from this research, without giving a reason, and this will in no way affect the care that you are entitled to receive at this Institution. You do not need to sign this form to withdraw from this study.

The purpose of this form is to see if you would agree to continue to attend follow-up visits and/or to allow information about you to be collected for the study. If this is ok with you, please check the boxes below to indicate your decision:

🞏 I agree to allow the study doctor to contact me at regular intervals to collect study-related information about how I am doing.

🞏 I will not be contacted by the study doctor, but I agree to allow the study doctor to collect study-related information about me and my health from medical records.

If applicable (ie: participant consented to optional studies of samples):

🞏 I agree to allow any samples that have been previously collected (through any optional sub-study) to continue to be used for the study purposes outlined in the original consent(s).

If you have questions or concerns about your rights as a study participant including your right to freely withdraw from this study, you may contact the **Research Ethics Office**, at **780-492-2615**.

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Participant’s Name Signature and Date

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Person obtaining consent Signature and Date

*A signed copy of this consent form will be given to the participant.*