ADDITIONAL CONSENT TERMS (to be included in the consent document/script applicable to your study)

**Focus Groups**:

In the segment titled “Methods of Protecting Participant Information,” include:

“While we request all group members to honor each participant's privacy and keep discussions confidential, we cannot assure this will happen. Consider this when deciding on the information you choose to share within the group.”

**For clinical trials to be listed and reported on ClinicalTrials.gov:**

This clinical trial will be posted on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/) as mandated by U.S. legislation. This site will exclude any personally identifying details. At most, it will display a summary of the findings. You are free to explore this website at any convenience.

**For studies with NIH funding or applying for a Certificate of Confidentiality (without NIH funding):**

In the segment titled “Methods of Protecting Participant Information,” include:

**Certificate of Confidentiality:**

This study benefits from a Certificate of Confidentiality from the National Institutes of Health. Consequently, the researchers are prohibited from revealing or utilizing any information, documents, or samples that might identify you in any legal or administrative action unless you provide explicit consent. This includes a wide range of proceedings such as federal, state, or local civil, criminal, administrative, legislative, or others, for example, responding to a court subpoena.

However, certain identifiable details could still be shared beyond the research team: This Certificate does not prevent obligatory disclosures as per federal, state, or local laws, such as mandatory reporting of child or elder abuse, specific infectious diseases, and imminent threats to oneself or others. It also does not preclude audits or program evaluations by sponsoring U.S. federal or state government agencies, nor does it limit disclosures mandated by the federal Food and Drug Administration (FDA). Furthermore, the Certificate doesn't restrict the use of your information for additional research if allowed under federal rules.

Researchers may disclose your information with your permission, for instance, to insurers, medical providers, or others not involved in the study. The Certificate of Confidentiality does not restrict you from freely sharing details about your research participation nor does it limit access to your personal information.

**If the study enrolls prisoners:**

In the section “Will participation in this study benefit me in any manner?” include:

Participation in this study will not influence your housing or correctional program placements, nor will it enhance your prospects for parole or release.

**If the study will employ incomplete disclosure and/or deception as research methods:**

Should you plan to omit details about the true objective of the study or deliberately provide participants with incorrect information regarding some aspects of the research (i.e., incomplete disclosure or deception), incorporate one of the following statements in the “Key Information” section of the consent. Situations where the potential harm from debriefing surpasses the benefits of disclosure will be exceptional; if you decide against debriefing participants about the use of deception/incomplete disclosure, you must justify in the protocol document why you believe the debriefing harms outweigh the benefits. For additional advice on employing deception and incomplete disclosure in research, refer to the BeyondBound IRB’s guidance document at: https://beyondbound.org/

For scientific reasons, this consent form does not reveal all details about the research questions or subjects being examined. You will receive a comprehensive debrief after your participation, at which point you can choose to revoke your consent. Should you withdraw, your personal data will be removed.

OR

We cannot disclose all aspects of this study beforehand, but if you agree to participate under these conditions, we will thoroughly explain the process post-participation, allowing you the option to withdraw your consent at that time. Upon withdrawal, your personal data will be erased.

**If the study might expose information regarding sexual misconduct involving a BeyondBound community member:**

I (or the Principal researcher of this study) might be legally obligated to report any disclosed information suggesting sexual misconduct, including sexual assault, sexual exploitation, dating and domestic violence, stalking, and sexual harassment, to the appropriate BeyondBound officials. Therefore, I cannot assure complete confidentiality for any shared information regarding sexual misconduct experiences.

**Additional Information to Consider:**

[Include for research exceeding minimal risk. Otherwise, omit. The wording should remain unchanged unless specified.]

[Include if the study is is not funded, initiated by the Principal Researcher, or federally funded]

Should you experience sickness or harm from participating in this study, whether through medications, devices, or any procedures used, it is advised that you seek medical assistance from your preferred healthcare provider or medical facility. It is important to inform the study's lead medical professional about any health issues or injuries immediately. The hospital [university, researchers] will not cover the cost of medical treatments necessitated by adverse outcomes from your involvement in this research. However, this does not preclude your right to seek compensation for such medical care.

[Include for studies funded by corporations. Should there be a necessity to alter this wording, you are required to get in touch with Sponsored Research (SR) and secure a formal document indicating that the original wording conflicts with the clinical trial agreement, necessitating a change. This document should subsequently be included in the eIRB+ submission.]
 If the study's devices, medications, or procedures cause you harm or illness, the study's funding entity may cover the reasonable medical expenses for treating such conditions.

Eligibility for this financial support is contingent upon the agreement of BeyondBound's lead researcher and the funding party, if relevant, that the health issue is directly connected to the study's interventions and is neither due to pre-existing conditions, the natural course of your illness, nor non-compliance with the study doctor's instructions. Should there be charges billed to your insurance, you might be responsible for any applicable deductibles and co-payments. It's advisable to consult with your insurance provider regarding potential charges.

[Outline any potential compensation for injuries related to the research as specified in the Clinical Trial Agreement or contract.]