**Consent to Participate in a Human Research Study**

Instructions are highlighted in red text - eliminate all content in red and replace it with language relevant to your study.

The informed consent document's footer contains a "Consent Subtitle" area for identifying the specific subtitle and version of each consent document utilized in the study (e.g., Main, Genetic, Screening, Treatment Group, etc.). Abbreviate extended subtitles. If the study involves only one consent form, you may remove this section from the footer. The "Consent Version" is mandatory and serves as a tracking mechanism for any amendments to the document. The version must be formatted as a date (e.g., 17/03/2024). Ensure that the consent subtitle and version correspond with the file name of the document.

The consent form should be composed in a manner that is easy for a layperson to understand. Employ straightforward language and sentence construction while avoiding highly technical terminology. For assistance with simplifying the language, refer to the BeyondBound Informed Consent Language Database, which offers lay language explanations of risks and procedures in clinical research.

For specific contexts and procedures, refer to the IRB website and utilize the IRB-recommended language.

**Title of Research Study:** [Please provide the title of the research study and include the protocol number if available]

**Principal Investigator:** [Please enter the name of the principal investigator]

**Supported By:** [Enumerate all forms of financial and/or non-financial support for this research. If there is none, state "This research is supported by Beyond Bound IRB."]

**Financial Interest Disclosure:** [This section should be included only if there are financial interests to disclose. If none, omit this section.] The following statement is provided to allow you to assess whether these financial relationships may influence your decision to partake in this study:

[This should be included if the investigator is also the participant’s treating physician. If not applicable, remove this section.] Your physician, who is also leading this research study, is dedicated to both your healthcare and the progress of this study. You are entitled to discuss this study with someone not involved in the research team before deciding to participate.

**Key Information:**

The initial sections of this document contain a concise summary of this study aimed at assisting you in deciding whether to participate. Comprehensive details follow this summary.

Key Information Summary: This section presents an abridged overview of the essential information necessary for a reasonable individual to make an informed choice about participation in the research. More detailed information is available in the subsequent sections.

If the study follows a straightforward design, the information provided in the Key Information section need not be duplicated in the Detailed Information section. Studies of a simple design may include, for example, research involving only survey procedures or the collection of blood samples.

**Why am I being asked to participate in this research study?**

We invite you to participate in this research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Complete with the specific criteria or reasons that make participants suitable for the study.]

**What should I be aware of regarding a research study?**

* The details of this research study will be explained to you.
* Participation is entirely your choice.
* You have the option not to participate.
* You can initially agree to participate and later decide to withdraw.
* Your decision will not affect your relationship with us.
* You are encouraged to ask any questions before making your decision.

**Why is this research being conducted?**

1. The aim of this research is [Provide a non-technical explanation of the research's purpose understandable to those outside the medical field].
2. The background and rationale for the research problem are [Explain the context and reasons for the study].
3. The potential benefits to others or society are [Describe any possible advantages resulting from this research].
4. If the study involves investigational drugs and/or devices, it should be noted here, along with the clarification that 'investigational' implies the drug or device is not authorized by the USFDA or not approved for the condition being studied.
5. The FDA approval status of other drugs and devices utilized in the study should be clearly stated.

**How long will the research last, and what will I need to do?**

The duration of your participation in this research study is expected to be \_\_\_\_\_\_\_\_ [fill in the duration as appropriate: hours, days, months, weeks, years, or until a specified event occurs].

During this time, you will be required to \_\_\_\_\_\_\_\_\_ [provide a general overview of the study procedures, for example: “You will receive an investigational drug and are expected to attend three study visits.” Or “You will provide a total of three blood samples and complete questionnaires about your feelings and experiences.”]

For more comprehensive details about what participation involves, please refer to the section "What happens if I say 'Yes, I want to be in this research'?"

**Could participating in this study be harmful to me?**

[In this section, you should outline the most significant risks associated with the study, such as potential emotional discomfort from answering questions in a social-behavioral research project, or the primary side effects one might anticipate from a drug or device, similar to critical information a doctor would share with a patient.]

For an in-depth discussion of the potential risks associated with this study, please see the section titled **“Could participating in this study be harmful to me? (Detailed Risks).”**

**Will participation in this study benefit me personally?**

[This segment of the informed consent form should highlight any probable advantages for participants arising from their involvement in the research; however, the significance of these advantages should not be overstated. For further elaboration on the benefits, an additional section should be appended to the consent document later.]

[Incorporate if there are participant benefits. Otherwise, omit.] We cannot guarantee any direct advantages to you or indirect benefits to others from your participation in this research study. Nevertheless, potential advantages might include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Initially, list any immediate advantages for the participant, followed by any indirect benefits to others. Should the advantages linked to participation not extend beyond the duration of the research, mention this aspect here. Financial compensation for participating does not constitute a benefit.]

[Include if the study offers no participant benefits. Otherwise, remove.] You will not receive any personal benefits from your involvement in this study. We cannot assure any positive outcomes for others due to your participation in this study. Nonetheless, indirect advantages to others may include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Detail any possible benefits to others. Remember, financial compensation for taking part is not considered a benefit.]

[Applicable for studies involving incarcerated individuals] Participation in this research will not result in better housing or correctional program placements for you. Engaging in this study will not enhance your prospects for parole or early release.

**What are my options if I choose not to participate in this study?**

Your participation in this study is entirely at your discretion. It is your choice to join or decline. Should you decide not to engage, there will be no repercussions or forfeiture of benefits you normally would have.

[Add if alternative options exist.] If you opt out of this research study, you may consider the following alternatives: [Enumerate alternative procedures. For academic subject pools, outline alternatives to earn course credit. In the context of clinical trials, detail the standard treatments or options typically available to a patient. If relevant, include the provision of palliative care as an alternative.]

[Insert if no alternatives exist.] If you decide against participating in this study, your only alternative is to refrain from participation.

**Detailed Information:**

The subsequent sections of this document provide comprehensive information regarding this study, supplementing the details provided earlier.

**Whom Should I Contact?**

Should you have any inquiries, worries, or grievances, or if you believe the research has caused you harm, please communicate with the research team at [Include the research team's contact details here, ensuring to provide a phone number].

This study has undergone evaluation and received approval from an Institutional Review Board (IRB). For any discussions, you can contact them at (702) 708-1411 or through email at info@beyondbound.org.

* Your inquiries, worries, or grievances are not resolved by the research team.
* You cannot make contact with the research team.
* You seek to converse with an individual other than the research team members.
* You have questions about your entitlements as a research subject.
* You aim to receive further details or wish to submit suggestions regarding this research.

**How many participants will there be?**

We anticipate approximately \_\_\_\_\_ individuals from this location will participate in this research study, out of a total of \_\_\_\_\_ participants nationwide [or worldwide].

**What will happen if I agree to participate in this study?**

If you agree to be part of this study, here’s what you can expect, described in language that's easy to understand:

* Overview and Timeline: We will provide a clear outline of the steps involved in this study. If necessary, we'll include a timeline chart or diagram to illustrate the different stages, especially if the study requires multiple steps or visits.
* Medications or Biological Agents: Information about any drugs or biological treatments will be given, including their purpose and how they are administered.
* Medical Devices Used: Details about any medical devices that will be used, including their appearance, size, and function, will be provided. Diagrams or photographs of these devices might be included for better understanding.
* Healthcare Visits: Information on any required hospital stays, clinic visits, and follow-ups, whether in person or via phone or mail, will be outlined.
* Duration and Frequency of Visits and Procedures: We will specify how long each visit or procedure will take and how frequently they will occur.
* Blood Samples: If applicable, we will inform you about the amount of blood drawn (in understandable units) and how often it will be collected.
* Interaction with Healthcare Professionals: We'll let you know who you will be in contact with during the research.
* Research Location: Information on where the research will take place.
* Timing of the Study: When the research will be conducted.
* Experimental Aspects: Any procedures, therapies, or drugs that are experimental will be clearly identified.
* Frequency of Procedures: We will detail how often each procedure or treatment will occur.
* Research-Related Procedures: We will clarify which procedures, drugs, or devices are specifically for research purposes.
* Standard of Care: We will explain which procedures, drugs, or devices are part of your regular medical care.
* Future Research Participation: If applicable, we'll let you know if you'll be asked to participate in future research studies.
* Audio or Video Recording: If the research involves recording activities, we will inform you whether consenting to be recorded is mandatory for participation or optional.

Randomization (if applicable; otherwise, delete): If the study involves randomization, you'll be informed that the treatment assignment is by chance, similar to flipping a coin. You and the research team will not choose the treatment. You will be told your chances of receiving each possible treatment.

Remember, your participation is voluntary, and you can withdraw at any time without penalty.

* [Double-Blinded Research, add]: If this study is double-blinded, both you and the study physician will remain unaware of the specific treatment you are receiving to maintain impartiality.
* [Single-Blinded Research, add]: In the case of single-blinded research, you will not be informed about the treatment you are receiving, though your study physician will have this information.

[Include if the study is known or likely to involve whole genome sequencing]

Genes consist of DNA, inherited from our parents. DNA (Deoxyribonucleic acid), is the molecule carrying one's unique genetic blueprint. Genes hold the information dictating how our bodies develop and function. The complete set of a person’s DNA constitutes their genome.

Your DNA is distinct to you. Examining your genes through DNA can offer insights into your present or potential health conditions. Sequencing is a method that deciphers, or “reads,” an individual's entire DNA. This research may include the process of whole genome sequencing.

[If genetic results will not be returned to participants, include the following:]

Neither you nor your healthcare provider will receive the outcomes of any genetic assessments carried out during this research.

[Include if results will be returned to participants and/or their physicians]:

Remember, research differs from clinical healthcare. The genetic information derived from this study is subject to the same scrutiny as results from clinical diagnostics typically ordered by your healthcare provider. However, it is essential to verify any genetic findings from this research through confirmed clinical testing. Additionally, genetic tests that identify DNA variances have their limitations.

Should you have queries or concerns regarding any genetic test results, consulting a genetic counselor is advisable. You may request a referral to a genetic counselor from the research team or your personal physician. For any health-related questions or concerns, please consult with your doctor.

**What will be my duties if I participate in this study?**

[Remove this segment if the study is not a clinical trial.]

If you decide to participate in this study, you will need to: [Detail the specific responsibilities required of the participant.]

**What if I decide to withdraw after agreeing to participate?**

You are free to exit the study at any point without any negative consequences.

[Include if there are negative implications to withdrawing from the study. Otherwise, omit.] Should you choose to withdraw from the study, [Explain the negative implications of leaving the study.]

Upon deciding to withdraw, please inform the lead researcher so that they can [Detail the steps for a structured withdrawal by the participant, if any.]

Deciding not to participate or to discontinue your participation will not result in any penalties or loss of benefits you are otherwise entitled to. Specifically, your decision will not adversely affect your current or future medical care, [Include if relevant] your academic status (for students at educational institutions), or your current or future employment (for employees at the institution or its affiliates).

[Include for research regulated by the USFDA. Otherwise, remove.] If you cease participation in the study, data already collected may not be removed from the study's records. You will be asked whether you allow the investigator to use data obtained from your regular medical care. [Note: The consent form must not offer the option to have data removed.]

If consented, this data will be treated as part of the study's research data. [Note: If a participant withdraws from the interventional segment of a study and does not agree to the continued collection of related clinical outcome information, the researcher is prohibited from accessing the participant’s medical records or other confidential information that requires the participant’s consent for the study-related purposes. Nonetheless, the researcher can review data related to the participant already collected for the study.]

[For research not regulated by the USFDA, clarify the handling of data collected up to the point of participant withdrawal. Explain whether participants will need to specify how much they wish to withdraw and if they will give permission for continued data collection through interactions or access to private identifiable information. For instance, a participant may choose to withdraw from the experimental aspect due to intolerable side effects but may consent to continue with follow-up procedures and data collection.]

**Detailed Risks: Could participating in this study pose any risks to me?**

[Appropriately describe the following risks, if relevant. If possible, indicate the likelihood and severity of each risk. Risks associated with procedures may be summarized in a table.]

* Physical risks: Describe any potential physical harm or discomfort that may arise from the research.
* Psychological risks: Outline any possible mental or emotional impacts resulting from participation.
* Privacy risks: Detail any potential threats to your privacy as a result of participating.
* Confidentiality risks: Explain the chances of your personal information being accidentally disclosed.
* Legal risks: Discuss any legal implications or risks that might occur from participation.
* Social risks: Mention any possible social repercussions or stigmatization that could result from participating.
* Economic risks: Highlight any financial costs or economic impacts that could be incurred by participating.
* Group or community risks: Describe any risks that your participation may pose to your community or demographic group.

It is important to differentiate between the risks specifically associated with research activities and those related to procedures or treatments you would receive even if not participating in the research. Generally, do not consider the outcomes of animal studies, except in cases where no other risk information is available and their inclusion would contribute to a clearer understanding.

[Distinguish between the risks presented by participation in the research and the risks associated with any procedures or treatments that would occur regardless of participation in the research. Also, in general, do not include results of animal studies, unless there is no other known risk information and inclusion would aid with understanding.]

This research may hurt you in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise, delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include this paragraph for studies using identifiable, personal information.]

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **“What happens to the information collected for the research?”.**

[Include for research that will collect/store data and samples for future research. Otherwise delete.]

We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero.

If your research requires adherence to GDPR, you must specify which collected data could be identified, the rationale behind its collection, and the duration of its retention. For further details, refer to the GDPR Guidance and Worksheet HRP-335.

[Applicable to Department of Defense (DoD) studies involving DoD-affiliated participants where there's a potential impact on their duty fitness (e.g., health, job performance capability, data confidentiality).] This study may affect your duty fitness. It is advised to consult with your command or respective DoD Component before joining.

[Include for DoD-related studies, if relevant.] There is a potential risk in this study of losing your clearance, credentials, or other specialized access or responsibilities.

**In this study, it's important to understand the potential impacts on reproductive health and sexual activity.** [This information is particularly pertinent for individuals who are pregnant or may become pregnant, and for studies that could pose risks to an embryo or fetus or when the effects on pregnancy remain unclear. Exclude this portion if it is irrelevant to the research context.]

This study's protocols may negatively impact a pregnancy or fetus in identified manners. [Remove this statement if the study presents no recognized risks.]

Furthermore, the study could potentially affect a pregnancy or fetus in ways not yet understood, with effects ranging from trivial to critically severe. [Exclude this information if the study's pregnancy risk profile is already established.]

Participants are advised against pregnancy during the study; this may also extend to fathering a child, breastfeeding, or donating gametes, depending on the specific conditions of the study. Include, if necessary, the recommended timeframe for waiting before attempting to conceive or father a child following the end of participation.

[Retain this section if relevant:]

Should you be engaged in sexual activities, it is advised that both you and your partner utilize a reliable form of contraception throughout the duration of this research. As per guidelines from the World Health Organization and the United States Center for Disease Control and Prevention, the foremost effective contraceptive methods are total sexual abstinence, permanent sterilization (applicable to both sexes), the use of intrauterine devices (IUDs), and contraceptive implants. Subsequent in efficacy are methods like contraceptive injections, oral pills, vaginal rings, or skin patches. While male and female condoms are considered acceptable, they rank lower in effectiveness.

In the event of pregnancy during the research or within a specified number of months following the conclusion of the study, it is imperative to inform the research lead or a team member at the earliest opportunity. This may necessitate your withdrawal from the study; however, alternate treatment or research avenues may be explored and discussed with you accordingly.

Incorporate this section when applicable: If you or your partner are recognized as postmenopausal, the use of birth control is not obligatory during your involvement in this study, given the rare occurrence of pregnancy in postmenopausal individuals. However, if pregnancy does occur while engaged in the study or within a certain number of months following its completion, promptly inform the study's leading physician or another member of the research team. It may be necessary to halt your participation in the study; nonetheless, alternative treatment methodologies may be reviewed and discussed with you as needed.

For those who are postmenopausal or whose partners are, using birth control is not typically required during the study, given the low likelihood of pregnancy. Nonetheless, if pregnancy occurs during the study or within a specified timeframe afterward, it is imperative to inform the research team promptly. You might need to cease participation, and other options may be discussed as needed.

**Will it cost me anything to participate in this research study?**

[Include for research that will NOT result in any costs to the participants. Otherwise, delete.] Taking part in this research study will not lead to any costs to you.

[Include for research that may result in additional costs to the participants. Otherwise, delete.] Taking part in this research study may lead to added costs to you. [Specify which procedures/drugs/devices will be covered by the study, and specify which will be billed to the participant/insurance.]

[Include for a clinical trial. Otherwise, delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

**Will being in this study help me in any way?**

[Delete this entire section if there are no benefits and the research is not a clinical trial.]

[Include if there are benefits to participation. Otherwise, delete.] While there is no guarantee of personal benefit, participating in this research may provide certain advantages. These may include: [Detail potential advantages for the participant, followed by any benefits for others. Should the benefits not extend post-research, note them here. Note: Financial compensation for participating does not constitute a benefit.]

[Include for a clinical trial with no direct participant benefits. Otherwise, delete.] You may not receive any direct benefit from participating in this research. Benefits to others cannot be guaranteed but may include: [Explain potential benefits for others. Remember, financial compensation is not considered a benefit and will be covered in a different section.]

[Include if the research involves prisoners] Participation in this study will not affect your housing or program status within the correctional facility. Engaging in this study will not enhance your prospects for parole or early release.

**Here's how your information will be handled in this research:**

Efforts will be implemented to restrict the use and sharing of your personal data, including records from this research study and your medical information, to individuals who need to access this data. Absolute confidentiality cannot be guaranteed. Entities that may review and replicate your data include the Institutional Review Board (IRB) and other representatives from this institution. [Expand this list with any additional entities such as the US Department of Health and Human Services, the research sponsor, contract research organizations, the sponsor’s agents, and other collaborating entities, especially if the research is supported or conducted by the Department of Defense (DOD) or the Department of Health and Human Services (DHHS). Mention that DOD representatives have the authority to review research records in DOD-related research.]

[Include the appropriate statement regarding mandated or permitted reporter language if relevant. In scenarios where the research is expected to or may incidentally uncover information on child or elder abuse or neglect, the State requires or allows researchers to report such findings to the appropriate authorities:] If instances of current or ongoing child [or elder] abuse or neglect come to light, we might be mandated or authorized by law or institutional policy to report this information to the relevant authorities.

Alternatively,

A limitation to our pledge of confidentiality arises if, in good faith, we are allowed by law or policy to report instances of child [or elder] abuse or neglect.

Alternatively,

We will not probe specifically for information regarding child [or elder] abuse, but if such information is disclosed to us, we might be required or authorized by law or policy to report it to the relevant authorities.

[Detail any other confidentiality constraints that may arise due to potential legal issues, such as the discovery of illegal drug use or sensitive information like an HIV status, indicating that such findings could be reported to the appropriate entities.]

[Applicable for studies with participants from the European Economic Area: If collecting data from participants in this region, ensure a data protection plan compliant with the General Data Protection Regulation (GDPR) is in place. Refer to Worksheet HRP-335 for instructions.]

[For NIH-funded studies: Include this statement as the research operates under a Certificate of Confidentiality, otherwise, remove it.]

This study is protected by a Certificate of Confidentiality issued by the National Institutes of Health. This implies that researchers are prohibited from releasing or utilizing information, documents, or samples that could identify you in any legal actions or proceedings without your explicit consent. They are also barred from providing them as evidence unless you have agreed. This protection applies to a wide range of proceedings, including federal, state, or local civil, criminal, administrative, legislative, or other legal actions, such as responding to a court subpoena.

However, there are specific exceptions to this protection you should be aware of:

* The Certificate does not exempt mandatory reports required by federal, state, or local laws, such as the obligation to report child or elder abuse, certain communicable diseases, and threats of harm to yourself or others.
* The Certificate does not prevent a sponsoring United States federal or state government agency from auditing records or evaluating programs.
* It does not preclude disclosures mandated by the Food and Drug Administration (FDA).
* It does not restrict the use of your information for further research as permitted under federal regulations.
* You can authorize the release of information about you, for example, to insurance companies, healthcare providers, or others not associated with the study. The Certificate does not prevent you from voluntarily sharing details about your participation in the research nor does it restrict your access to your personal information.

[If applicable, include details on the storage, access, and duration of retention for data or specimens kept after the study concludes.]

[Add if identifiable private information or samples are collected:] If identifiers are removed from your identifiable private information or biological samples gathered during this study, they may be utilized for future research or given to another investigator for further studies without additional consent from you. Refer to the section “Will my data or samples be used for future research?” for more details.

[Include if the research sponsor may cover medical costs:] In instances where the sponsor covers your medical expenses, it may be necessary to provide the sponsor with your personal details such as your name, date of birth, and Medicare ID or social security number.

[For clinical trials] The sponsor, monitors, auditors, the Institutional Review Board (IRB), the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may receive direct access to your medical records to facilitate and oversee the study. By consenting to this document, you allow such access. While the findings of this research may be published, your identity and personal details will remain confidential.

[Applicable for certain FDA-regulated and NIH-funded trials] Details about this clinical trial will be posted on http://www.ClinicalTrials.gov as mandated by U.S. legislation. This website will safeguard your anonymity; it will not feature information that could identify you directly. Instead, it may display a summary of the study's findings. You are free to access this website at any point to obtain information.

[For studies involving prisoners] Should you be a prisoner, your medical records might also be disclosed to appropriate criminal justice entities as required and authorized by law.

[Recommended for inclusion in your consent form] It is advisable to inform participants that the data and/or samples collected from them may be utilized for future research. This is becoming a common requirement from certain sponsors and is increasingly expected by various academic journals across different fields. Omitting this section now could limit your ability to share data later without re-obtaining consent from participants.

[If retaining data or specimens for future research] This research involves collecting your data and samples for potential use in future studies, which may address similar or entirely different diseases, conditions, or scientific inquiries. These future studies might be conducted by our institution or others globally, including commercial organizations. The aim is to facilitate broader research efforts. We intend to store your data and samples for [Specify duration as per the study protocol]. Future researchers will need to obtain permission from our institution, and their proposals may undergo an Institutional Review Board (IRB) review.

[For coded data and biospecimens] We commit to maintaining your privacy to the fullest extent. Your data and samples will be coded to safeguard your identity when shared with other researchers. The coding key, accessible only to the study team [or specify the custodian of the code key], will be kept secure, ensuring that your identifying information is protected.

[For unlinked data and biospecimens] Before sharing with other researchers, your name and any personal identifiers will be removed from the data and samples you contribute. It will not be straightforward for researchers to reconnect your personal information with the data and samples provided.

[For mandatory sharing of data and specimens] By participating in this study, you consent to the sharing of your data and samples. You may withdraw your consent at any time; however, if your data and samples have already been shared with researchers, they may continue to be used. If you prefer your data and samples not be used in other research, opting out of this study is recommended.

**Can I be withdrawn from the study without my consent?**

[Omit this section if it does not apply.]

[If applicable, include this section] The lead researcher or the sponsor reserves the right to withdraw you from the study without your consent. Reasons for such removal could include [list specific reasons pertinent to the study].

[Applicable if there's potential for removal] Should there be any new developments that could impact your well-being, health, or continued participation, you will be informed promptly.

**What additional information is necessary?**

[Retain for research exceeding minimal risk levels. If not applicable, remove. Modify only as specified.]

[Applicable if the research is not sponsored, initiated by the principal investigator, or supported by federal funds]

Should you experience illness or injury related to this study (due to medications, devices, or procedures), it is important to obtain medical care from your chosen healthcare provider or facility. It is crucial to inform the study's leading physician about any health issues or injuries.

The institution [university, research team] is not responsible for medical expenses incurred due to adverse effects from participating in this study. Nonetheless, this does not prevent you from pursuing reimbursement for necessary medical treatment resulting from such adverse effects.

[Applicable if the research is backed by industry sponsors. For deviations from this wording, consult with Sponsored Research (SR) and secure written approval that the standard language conflicts with the clinical trial agreement requiring alterations. Upload the written approval into the eIRB+ system.]

In the event of an injury or illness resulting from participation in this study, such as from the study device, medication, or required procedures, the study's sponsor may cover the reasonable medical costs to address such conditions.

Eligibility for this coverage requires confirmation from the Northwestern University principal investigator and, if relevant, the study sponsor, that the injury or illness is directly connected to the study-related interventions and not due to pre-existing health issues, the natural advancement of your condition, or non-adherence to the study physician’s instructions. Should your insurance be charged, you might have to cover any related deductibles and copayments. It's advised to discuss potential costs with your insurance provider.

[Applicable for Department of Defense (DoD) studies with more than minimal risk] Throughout the study's duration and beyond its completion, you might be entitled to healthcare services for injuries related to the research at a military treatment facility. [Insert further details regarding how this organization will support participants with injuries related to the research, especially those resulting directly from actions by DoD-associated staff]

[Detail the compensation for research-related injuries as outlined by the Clinical Trial Agreement or contractual terms.]

[Include if the research involves genetic information] The Genetic Information Nondiscrimination Act (GINA) is a federal regulation that typically prohibits discrimination by health insurers, group health plans, and employers with 15 or more employees based on genetic data. Specifically, under this act:

* Health insurers and group health plans are not allowed to request genetic information obtained from this study.
* These insurance entities cannot use your genetic data to decide on your coverage eligibility or pricing.
* Employers with a workforce of 15 or more cannot base employment decisions—such as hiring, promotion, or termination—nor determine employment conditions on the genetic information obtained from this research.

Note, however, that GINA does not offer protection against genetic discrimination by life, disability, or long-term care insurance providers.

[Retain if participants are not compensated] You will not receive financial compensation for participating in this study.

[Retain if there is compensation for participation] Should you decide to participate in this research, you will be compensated with \_\_\_\_\_\_\_\_ [state the amount] for your involvement and the time you invest. [Specify if compensation is dependent on completing the study visits.]

For payments issued by check from BeyondBound, note: BeyondBound’s Accounting Services will require your name, address, and Social Security Number to process a check as compensation for your participation. [Remember, payments from the study are taxable and must be reported to the IRS. You will receive a Form 1099 if your total payments exceed $600 within a year.]

[Include if compensation is provided via the [NAME OF INSTITUTION]] You will receive $xx per attended session, up to a total of $xx. This compensation is intended to offset the costs associated with your time and travel for the study.

The [NAME OF INSTITUTION] will provide a [TYPE OF COMPENSATION], a debit card specifically for clinical research participants. Upon completion of a qualifying visit, compensation will be authorized and credited to your card, becoming accessible within one day. The funds are yours to spend as you see fit.

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