**Agreement to Participate in Research**

**Instructions and alternate phrases are presented in red text – remove all red text and replace it with relevant content specific to your research. If your study involves gathering data from electronic health records for recruitment screening and/or analysis and you plan to acquire HIPAA Authorization from participants, please use the consent form template (HRP-1721) which includes HIPAA Authorization terminology.**

**Consult the Additional Consent Language Document for extra wording required in your consent form if your study:**

* Intends to utilize focus groups for data collection
* Is a clinical trial that will be registered and its results reported on ClinicalTrials.gov
* Receives funding from the [Organization]
* Seeks a Certificate of Confidentiality to safeguard identifiable sensitive information from obligatory disclosure (e.g., through a subpoena)
* Plans to include prisoners as participants

**This consent form template SHOULD NOT be used IF:**

* Your research involves children as participants – instead, utilize the designated parental permission and child assent forms
* Your study involves experimental drugs or devices

**Title of Research Study:** [insert your study's title here]

**Principal Investigator:** [insert Principal Investigator's name]

**Student Investigator:** [If relevant, insert the name of the student researcher conducting this as part of a degree/certificate program]

**Supported By:** [Indicate all forms of financial and in-kind support (e.g., access to facilities and equipment) for this study. If your study receives no external funding, mention your school or department] This research is supported by \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Conflict of Interest Disclosure:**

[Include if applicable. Otherwise, remove this section.] We disclose the following to allow you to determine if this relationship impacts your willingness to participate in this research: [detail the conflict of interest and measures taken to mitigate its impact.]

[Include if the research is conducted by the participant’s healthcare provider. Otherwise, remove.] The healthcare provider overseeing this study [or If your healthcare provider is leading this study, it's important to know that they are...] is dedicated to both your health and this research. You are entitled to discuss the study with an independent advisor not involved in the research prior to deciding on participation.

**Collaborating Institutions:** [Delete if not applicable]

**Essential Information Regarding this research study:**

This section provides a brief overview of the study, assisting you in deciding about participation. More detailed information follows in this document.

* The objective of this research is \_\_\_\_\_.
* Participation involves \_\_\_\_\_\_\_\_\_ [offer a concise description of what will be required of participants, e.g., completing a survey and attending a follow-up interview].
* The expected duration of your involvement is \_\_\_\_\_\_\_\_ [specify the total time commitment and number of visits].
* The primary potential risk includes \_\_\_\_\_\_\_.
* Participating in this study may primarily benefit you by \_\_\_\_\_\_\_.

If your study involves **deception and/or partial disclosure**, you must include here a note stating that the information provided at this stage is incomplete. Refer to the Additional Consent Language Document for appropriate wording. If the study is a **clinical trial**, information regarding the registration and results reporting on ClinicalTrials.gov must be included here. Refer to the Additional Consent Language Document for the necessary phrasing.

Why have I been invited to this research study?

You are being considered for this study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Detail the circumstances (e.g., being a student parent) or criteria (e.g., age 18-45) qualifying participants for the study. Address any significant exclusion criteria relevant. Ensure consistency with the criteria outlined in your study protocol.]

**How many will participate in this study?**

It is anticipated that approximately \_\_\_\_\_ individuals will participate. If conducting the study across multiple sites, indicate: Around \_\_\_\_\_ participants will be recruited through BeyondBound out of an estimated total of \_\_\_\_\_ participants across all collaborating institutions.

What should I be aware of regarding research study participation?

* You will be fully informed about the study. [Omit if not applicable.]
* The choice to participate is entirely yours.
* You may opt not to participate.
* You can agree to participate now and choose to withdraw later.
* Your decision will not affect you negatively.
* You are encouraged to ask any questions before making a decision.

You are not obliged to answer any questions you prefer not to. [Include this point for studies involving surveys, interviews, and/or focus groups]

**What does agreeing to participate entail?**

* Explain to the participant what to expect in straightforward terms.
* Detail the research activities and procedures, ideally in the order they will occur. If the study involves multiple steps/visits, consider including a chart or table.
* Outline the length and frequency of study visits, activities, and interactions.
* Identify with whom the participant will interact.
* Specify the timing and location of the research activities.
* Clarify what is part of standard practice and what is research-specific.
* When applicable, detail if and how audio or video recordings or photographs will be used in the research. Explain whether these are mandatory or optional.
* [For studies with randomization to groups:] Your assignment to a study group will be random, akin to a coin toss. Neither you nor the research team will choose your group. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [an equal/one out of three/so on] likelihood of placement in any given group.

**Will participation benefit me?**

We cannot guarantee personal benefits from your participation. However, potential benefits might include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [first describe any direct benefits to you, followed by potential benefits to others. Financial incentives should not be considered benefits – these will be described later.]

**Could participation cause any harm?**

List foreseeable risks, detailing likelihood and severity if known. Potential risks include:

* Physical
* Psychological
* Privacy (Note: Studies involving participants from the European Economic Area must comply with GDPR for consent and data security.)
* Legal
* Social
* Economic
* Community or group harm

[Include this section into the consent document for all studies collecting potentially identifiable data:] A general risk in research is the potential breach of confidentiality. We will take extensive measures to minimize this risk, as detailed later in this document.

**What if I decide not to participate or wish to withdraw later?**

Participation is voluntary. You can choose not to participate or to withdraw at any time without consequence to your relationship [including academic grades, standing, healthcare services, etc.] with BeyondBound [mention any other affiliates involved in your study here].

[If there are alternatives to participation:] Instead of this study, your options might include: [List alternatives and standard options for participants not choosing to participate.] If the study recruits from student pools: Outline approved alternatives for earning course credit without study participation.

If you leave the study, it will not be held against you.

What happens to my data if I withdraw?

Upon withdrawal, you may be asked if your collected data can still be used.

OR

If you withdraw, any data collected will be destroyed.

**How will the research team safeguard my data?**

Outline the methods that will be implemented to ensure the privacy and confidentiality of participant details. This includes the application of encryption techniques, separating identifiable details from the broader research data, and maintaining only anonymized records of interviews or group discussions. For insights into effective research data protection strategies, refer to [Institution] IT department's guidance.

If your research receives **funding from the [Organization] or intends to request a Certificate of Confidentiality,** it is mandatory to incorporate specific statements regarding the safeguards and constraints associated with the Certificate of Confidentiality – consult the Additional Consent Language Document for the appropriate terminology related to the Certificate of Confidentiality.

If your research involves the utilization of **focus groups** for gathering data, refer to the extra wording provided in the Supplemental Consent Language Document, which must be included here concerning restrictions on privacy and the confidentiality of participant data within the context of focus group discussions.

**Who will have access to the information collected during this research study?**

Measures will be taken to restrict the use and sharing of your personal details, including records related to the research study, to individuals who require this information for review purposes. Absolute confidentiality cannot be guaranteed.

There may be instances during or after the study when your information might be accessed or used by others apart from the research team. Situations may involve:

* Officials from [Institution], governmental bodies, funding entities, auditors, and the Institutional Review Board might need to access the study data to ensure it is conducted safely and correctly.
* Collaborative researchers from other institutions participating in this study. [include this point ONLY if relevant to your research]
* The research team may disclose information to the appropriate authorities for health and safety reasons – for instance, if there is an indication of potential harm to yourself or others, or for public health concerns. [include this point ONLY if it applies to your study]

[Incorporate one of the following statements in studies that might discover or are likely to reveal information regarding **child abuse or neglect**. All employees of [Institution] (including faculty, staff, and student employees) are mandated by Nevada’s law and [Institution] policy to report suspected instances of child abuse and/or neglect. Students, volunteers, and external contractors are also obligated by [Institution] policy to report suspected cases of child abuse and/or neglect. Visit BeyondBound's website for more details.]

If current or ongoing child abuse or neglect comes to our knowledge, we might be legally or policy-wise required or allowed to report this information to the authorities.

OR

We will not inquire about child abuse, but if you disclose instances of child abuse or neglect to us, we might be legally or according to policy required or allowed to report it to the authorities.

If your study could reveal information that falls under Federal laws concerning sexual harassment and sexual violence, include statements in the consent form regarding Title IX reporting obligations – see the Supplemental Consent Language Document for the correct consent language on Title IX responsibilities.

[When relevant, clarify if assessment, educational, or clinically significant research findings, including individual results, will be shared with participants, and if so, under what conditions.] Most assessments in research are purely for investigative purposes and do not have immediate implications for [development, education, or healthcare.] Should the research outcomes be significant for your health, the researchers will/will not reach out to share their findings with you.

[If data or specimens are to be stored for future research after the study concludes, explain where and how these will be stored, who will access them, and the duration of their retention.]

[For studies involving genetic information, refer to the Supplemental Consent Language Document concerning the Genetic Information Nondiscrimination Act (GINA) for additional necessary language.]

**How might the information gathered in this study be disseminated in the future?**

The data collected about you during this research by [Institution] will be retained for the purposes of study documentation and possibly for inclusion in future research endeavors. Should the collected study data include identifiable participant information: Your name and any other details that could directly identify you will be securely stored separately from the rest of the data collected from you in this research.

For studies that extend over time, it is noted: The researchers might reach out to you again as a continuation of this research effort.

Data that does not identify individuals from this study could be distributed to the broader research community, including journals where study findings are published, and to databases and repositories that support research activities. [If participant identifiers are collected, include the following statement]. We will either remove or encrypt any personal data that could directly identify you prior to sharing the study data. Even with these precautions, the complete anonymity of your personal data cannot be assured.

If there is an intention to keep or distribute identifiable data for research purposes not yet determined, a separate application for IRB review must be filed, including a detailed protocol, consent forms, and additional documentation (such as a research registry). If the Lead Researcher (PI) of this investigation wishes to offer participants the opportunity to be contacted for future studies led by this PI, such an option should be outlined at the conclusion, including the following statement: The PI is interested in keeping your contact details to invite you for future research opportunities. This information will not be circulated among other investigators but will be kept solely for possible future research projects under this PI. Your consent for such contact will be sought at the conclusion of this form. Participation in this present study does not require your agreement to the future use of your identifiable data for subsequent research.

[Omit if there are no intentions to distribute identifiable data]The outcomes of this research may be communicated in scholarly articles and presentations, but will exclude any data that could identify you, unless you explicitly consent to the disclosure of your identifying information in such scholarly communications.

**Will I receive any compensation for my participation in this study?**

For your involvement in this research, you will be compensated with [specify the type, for example, cash, gift voucher, cheque] and the total sum you will receive. If applicable to your study, please clarify the following points:

* If compensation will be adjusted based on certain conditions (such as if a participant leaves the study early before completing all required procedures).
* If there is any additional payment, such as a bonus, or if any part of the compensation depends on the decisions/actions of the participant or a group of participants.
* For studies utilizing a raffle or lottery system, detail the total amount and number of payments to be given, the likelihood of winning (if known), the estimated time of the draw, and the method for informing winners.
* If participants will be reimbursed for travel, parking, or other expenses incurred by taking part in this research.
* If the research involves a student subject pool, clearly state the amount of course credit that will be given to participants.

Should there be any costs to participants for joining in the research (for example, expenses for parking and transport), those should be outlined here.

If there is no compensation or reimbursement for taking part in this research, it should be noted: Participation in this study does not include any payment or reimbursement.

**Whom can I contact?**

Should you have any inquiries, issues, or complaints, you are encouraged to get in touch with the Principal Investigator [Name and contact details] and [any other researcher, such as a student, where applicable]. [For international studies, mention the international dialing code for the research team's contact numbers, along with details of a local collaborator, if present.]

This study has received approval from an Institutional Review Board (“IRB”) – a committee dedicated to safeguarding the rights and welfare of research participants. You may reach out to the IRB at (646) 217-0403 or via email at info@beyondbound.org if:

* Your concerns or complaints are not addressed by the research team.
* You are unable to contact the research team.
* You wish to speak to someone other than the research team about your experience.
* You have questions about your rights as a participant in research.

You seek to offer feedback or obtain further information about this research.

For studies conducted internationally: include the international calling code for the IRB's contact number. For studies reviewed by an IRB or ethical committee in the host country, include the contact details for that body as well as for the BeyondBound IRB.

**Optional Elements:**

 [If applicable, insert any optional components of the research here. If not relevant, please omit this section.] This study might encompass various optional activities, signifying that your participation in these specific aspects is not obligatory for your overall involvement in the research. To indicate your willingness to partake in these optional activities, kindly initial next to each activity you consent to.

Example Optional Components

I consent I do not consent

\_\_\_\_\_\_\_ \_\_\_\_\_\_\_ The investigator is permitted to utilize [indicate type of recording: audio, video, and/or photographs] featuring me for educational purposes or in scholarly articles, where revealing my identity could facilitate a deeper comprehension of the study. I acknowledge that I may be identifiable in these materials.

\_\_\_\_\_\_\_ \_\_\_\_\_\_\_ The investigator may retain my contact details for the purpose of reaching out to me regarding future studies led by the Principal Investigator.

**NOTE:** Below are signature blocks suited for various consent scenarios. The first is for instances where the participant will physically sign the consent document. There are also blocks for scenarios involving verbal consent without in-person interaction, obtaining consent online, or seeking consent from a legally authorized representative for individuals whose decisional impairments prevent them from providing informed consent themselves. Select the appropriate signature block for your study and remove the others. **If your study will use different consent methods** (e.g., some participants will sign the form in person, while others will participate online), you must provide a consent form suitable for each consent method.

When obtaining the participant’s signature:

**Signature for Adult 18 or Older Capable of Providing Consent**

Your signature below signifies your agreement to participate in this research.

Signature of participant Date

Printed name of participant

Signature of person obtaining consent Date

Printed name of person obtaining consent

**Signature for Witness of Consent Process**

Include the following if the consent process will be observed by a witness (e.g., the participant is illiterate, visually impaired, or physically unable to sign). Otherwise, remove this section.

My signature confirms that the consent document, assent process, and all provided information were accurately explained to and seemed to be understood by the participant, and that the participant freely gave their consent.

Signature of Witness to Consent Process Date

Printed Name of Person Witnessing Consent Process

Electronic Consent (akin to written consent but acquired remotely via an electronic platform)

To secure valid consent electronically, a verifiable electronic signature must be collected. Include fields for the participant to digitally input their name and the date in the consent form.

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**Verbal Consent**:

There may be situations where obtaining a participant's signature on a consent form is impractical, such as when consent and data collection occur over the phone or via Skype, or in studies of sensitive topics where a signature could increase risk to the participant. In research conducted abroad, signing a consent form may not align with the cultural norms of certain groups or communities. Your study protocol must justify why participant signatures are not being collected.

If obtaining a signed or electronic signature is not feasible, you must meet the criteria for a federal waiver of documentation of informed consent (HRP-411 – CHECKLIST Waiver of Written Documentation of Consent).

Should participant signatures not be collected, remove the above signature block and utilize this document as an information sheet. Before commencing data collection, review the consent details with the participant and verbally confirm their agreement to participate. If verbal consent will be audio-recorded, this must be specified in the protocol document.

Do you agree to participate? Record participant’s response: Yes No

Participant name or study ID number (if participant names are not recorded on the consent form to minimize risks, record the study ID number instead):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent Date

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Online Consent (obtained without a signature - not an electronic signature):

If a signed consent or electronic signature is not being collected, you must fulfill the requirements for a waiver of documentation of informed consent. Justify this in your protocol according to the federal waiver criteria (HRP-411 – CHECKLIST Waiver of Written Documentation of Consent).

For consent processes occurring online, remove the primary signature block above and use the following instructions:

If you desire a copy of this consent for your records, you have the option to print it directly from the screen. If printing is not possible and you wish to have a copy, please reach out to the Principal Investigator using the contact information provided above.

To participate, click the “I Agree” button to proceed to the survey.

If you choose not to participate in this study, click “I Disagree” or close the browser window.

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For Adults with Limited Capacity to Consent:

In circumstances where adults are unable to provide consent (for instance, those with diminished decision-making capabilities or during emergencies), directly obtaining informed consent may not be feasible. Under these conditions, the IRB may allow for consent to be granted through the individual’s legally appointed representative. However, it is important to attempt to gain the assent of the participant to the greatest extent achievable. For additional details regarding the engagement of legally authorized representatives, refer to the BeyondBound Standard Operating Procedures concerning Legally Authorized Representatives, Minors, and Guardians (HRP-013). Your research protocol must outline any intentions to include participants lacking the capacity to consent, and the following signature block is to be used when consent for study participation is provided by a legally authorized representative:

By signing below, you authorize the participation of the named individual in this research study.

Printed Name of Participant

Signature of Legally Authorized Representative Date

Printed Name of Legally Authorized Representative Date

Signature of Individual Obtaining Consent Date

Printed Name of Individual Obtaining Consent Date