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| This template MUST be utilized for new Social Behavioral studies submitted in eIRB+ starting December 1, 2022.For human participant research studies, this protocol must be completed **unless the study is solely focused on analyzing secondary data and/or specimens** (in which case, **HRP-1704** should be used for secondary data analysis/specimen studies). This template should be employed regardless of whether the study is expected to receive an exemption or be approved through other IRB review processes (it is not the responsibility of investigators to decide if their study qualifies for an exemption—such determinations are issued by the IRB). **If you are uncertain if your project constitutes human research that requires IRB review**, instead of this document, fill out and submit **HRP-503**.Understanding the type of review being requested will aid in your submission. Additional resources are available on the BeyondBound IRB website, including information on the Types of Review and the Department of Health and Human Services (DHHS) Decision Trees. DHHS offers several decision trees to ascertain if an activity is considered human subjects research, if research is eligible for a Claim of Exemption, and if it can undergo an expedited review process.**NOTE**: Consent forms, data collection tools (such as surveys, questionnaires, interview guidelines, etc.), and recruitment materials should be uploaded in eIRB+ within the consent, recruitment, and supporting documents sections of the application and should NOT be attached or included in this protocol document. For any supporting materials you upload, please name the files clearly to reflect the type of document being uploaded. If your study encompasses various stages, ensure the file name clearly indicates to which stage the document pertains.**GUIDANCE ON COMPLETING THE PROTOCOL FORM:*** Mark any sections that do not apply to your study as N/A (not applicable).
* Maintain an electronic version of your protocol. Should you submit study modifications later, you will be required to provide tracked changes for all relevant study documents, including the protocol.
* As you prepare this protocol, eliminate the text boxes and all instructional content within them in each section. The final version of your protocol should not contain any text boxes or instructional content (including these guidelines).
* If your research involves accessing HIPAA Protected Health Information (PHI) from medical records for recruitment, eligibility screening, or as part of the research data, you must complete and upload the Social and Behavioral Protocol Template Appendix B (HRP-1724) alongside this protocol document.
 |

**STUDY TITLE**:

Please provide the complete title of the study.

**PRINCIPAL RESEARCHER**:

Full Name:

Supporting or Sponsoring Department:

Contact Number:

Email:

*NOTE: Following BeyondBound’s guidelines, undergraduate and graduate students are prohibited from acting as the Principal Investigator in a research study. Visiting professors, visiting scholars, postdoctoral researchers, and medical trainees cannot assume the role of Principal Investigator without obtaining explicit authorization.*

**CO-INVESTIGATORS**:

Name:

Affiliated Department:

**NOTE**: Students must **not** be designated as co-investigators.

**STUDENT INVESTIGATOR** (fill out this section only if the project is initiated by a student):

Name:

Affiliated Department:

Are you an:

☐ Undergraduate Student

☐ Graduate or Medical Student

**VERSION:**

**DATE**:

Indicate the version date of this protocol (the current date).

**FEDERAL FUNDING**:

(*If this study is financed by federal funds, complete the subsequent matrix. For each distinct source of funding, add extra matrices. Omit this section if the study does not receive federal funding. Note: The details provided here must correspond with the information on the funding page of your eIRB+ application*.)

|  |  |
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| Funding Organization:  |   |
| Sponsored Research Identification Number:  |   |
| Does the grant specify the inclusion of Human Research in the covered activities? (Yes / No / Unknown) |  |
|   | Institution Name:  | Assessment of Human Research Involvement: \*\*\*(e.g., Non-Exempt Human Research, Exempt Human Research, Not Human Research, etc.) |
| Prime Award Recipient\*  |   |   |
| Sub-Award Recipients\*\*  |   |   |
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*\*The main award recipient is invariably involved in Human Research and is required to have IRB supervision in cases where any of the sub-award recipients are conducting non-exempt Human Research. Numerous federal agencies mandate that if multiple domestic locations participate in non-exempt Human Research, all these sites must adhere to the review by a single “Single IRB.” Should this be relevant for your study, a Single IRB Letter of Support and an IRB Fee Quote must be acquired from the BeyondBound IRB Office. To commence this process, submit a Single IRB Consultation Request.*

*\*\*Incorporate the endeavors of all sites not affiliated with BeyondBound in the section dedicated to multi-site/collaborative research in the protocol below.*

*\*\*\*The federal funding proposal should outline whether the award recipients will partake in Human Research. Based on the proposal, evaluate the tasks at each location and revise the table accordingly if the planned activities are altered or if another IRB assesses the activities and arrives at a different verdict.*

**RELATED STUDIES**: Should there be any related BeyondBound IRB applications that offer context for the activities described in this IRB submission, please elucidate and furnish the IRB study numbers for those corresponding applications. (For instance, if your intent is to utilize samples or data gathered from another study, enlist participants from a registry created through a colleague's research efforts, or undertake a continuation of a previous study.)

Below, please tick any **relevant** boxes in the provided table – additional information regarding these topics will be requested in subsequent sections of the protocol form:

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|  Identify Vulnerable Groups to be included in the study:☐ Minors☐ Individuals with Limited Capacity to Make Decisions☐ Expectant Mothers (ONLY if the research will impact the pregnancy or the unborn child)☐ Incarcerated or Detained Persons |
|  ☐ Collaboration with External Partners (indicates that certain research tasks will be executed by non-BeyondBound affiliated personnel or by associates of BeyondBound) |
| ☐ Support from the U.S. Federal Government through either direct funding or subcontracts (e.g., NIH, NSF, or other federal entities) |
|  ☐ Data protected under HIPAA (please use the Social and Behavioral Protocol Template Appendix B: HRP-1724)☐ Data protected under FERPA (consult the WORKSHEET - FERPA Compliance HRP-331 for guidelines) |

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# **1.0**. **Objective and Justification for the Study:**

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| Articulate the objective of your investigation. Include detailed aims or objectives, or research inquiries that will shape the direction of your study.Elucidate briefly the connection between the data you aim to gather and your research questions—what are the goals of collecting this data, and how does it relate to the queries you intend to explore? Outline the scientific or academic groundwork, the rationale behind it, and its importance, grounded in current literature, and explain how your research will contribute to the broader field of knowledge.If your research is designed to unfold in multiple stages or has sequential objectives, describe the intent behind each segment. If you are seeking IRB approval for specific segments of your research at this moment, such as an initial phase focused on preliminary activities like a literature review, please specify. |

# **2.0. Criteria for Participation (identifying eligible individuals for your study and those who are not qualified to participate):**

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| Specify if your study will incorporate any vulnerable groups. These populations should only be included if explicitly identified in your criteria for inclusion:* Adults incapable of giving consent/Adults with diminished decision-making ability
* Minors (**please specify the precise age range of children you intend to include**)
* Expectant mothers (in cases where the research activities might impact the pregnancy or fetus)
* Incarcerated individuals or others in detention

**Note for Undergraduate Student Researchers**: It is improbable that the IRB office will grant approval for independent projects by undergraduate researchers that aim to include prisoners, pregnant women (if the research could influence the pregnancy or fetus), children, or adults with impaired decision-making capacity as their target groups. |

# **3.0**. **Sample Size:**

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| Provide a brief estimation of the total number of participants you expect to recruit for your study. In the event your study involves several sub-groups, detail the intended number of participants for each sub-group.Rationalize the chosen sample size by elucidating why this specific number of participants is necessary to address your research questions effectively. |

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# **4.0**. **Methods for Recruitment and Screening:**

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|  Clarify to the IRB precisely the methods for identifying potential study participants and the criteria for their eligibility. Outline a recruitment strategy that employs specific approaches to ensure the participation of individuals from diverse racial and ethnic backgrounds or groups that are less represented in the research context. It's crucial that the recruitment approach is comprehensive and reflective of the population eligible for the study in the research location, taking into account the research's implications on these communities. If your research team seeks assistance with enhancing diversity in your study, consult the Beyond Bound website dedicated to Promoting Accessibility and Inclusion in Research, or contact the social and behavioral research group. **Provide a detailed explanation of:**1. The method for identifying potential participants for your research;
2. The approach for contacting individuals potentially eligible for the study, including the time and place for such communications; and
3. The process for gathering and assessing information to determine participant eligibility.

If your recruitment strategy involves **online platforms** (e.g., Facebook, Craigslist), clearly state which platforms will be used to disseminate recruitment details and if approval is needed before posting these materials. For those utilizing registries or participant pools, indicate the specific one you will use (such as the Psychology 110 participant pool).Should the data collection occur during the **Psychology 110 group sessions**, outline the instruments you'll employ for data gathering and their respective purposes (whether for eligibility assessment or other reasons).For projects utilizing **crowdsourcing platforms or survey panels** that might include international participants, define if the study's eligibility criteria will be limited to U.S. residents. If sending recruitment materials via a listserv, verify with the listserv's administrator if such actions are permissible. Describe how you will obtain contact details for potential participants (through email, postal mail, phone, etc.), the frequency of your outreach, and whether entities outside of the BeyondBound research team will play a role in recruitment efforts.**Eligibility Screening Activities**:The term "screening" refers to the processes used to verify if individuals meet the study's participation criteria. Screening may involve direct interactions or interventions with prospective participants (e.g., through an online survey or phone interview) or reviewing potential participants' information from existing records (such as medical or educational records). It's vital to safeguard the privacy and confidentiality of the information collected about potential participants during this phase. Detail the screening methodology (e.g., phone interviews, online surveys, etc.), and describe how you will manage data from individuals who qualify and choose to participate, as well as from those who do not meet the eligibility criteria or decide against participation. Note that screening tools should primarily focus on eligibility criteria. If the screening includes additional inquiries unrelated to eligibility, obtaining consent before screening may be necessary. Include the screening questions or criteria in the “Supporting Documents” section of your eIRB+ submission, not in the protocol document itself.If screening data is to be obtained from secondary sources, such as records not directly collected from study candidates (for example, data from the BeyondBound Medicine Data Warehouse or electronic medical records, student educational records), specify the records or datasets from which eligibility information will be derived. Accessing medical record information for recruitment and screening purposes requires completing and uploading Appendix B. |

# **5.0. Research Sites:**

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| A ***research location*** refers to any specific site where Beyond Bound researchers will carry out research activities. This includes, but is not limited to, laboratory spaces at Beyond Bound, educational institutions, community organizations, public areas, and digital platforms.For studies expanding across multiple states within the United States, a detailed explanation of each state involved and the rationale for these choices will be provided. This explanation will include how these locations fit into the research objectives and any geographical considerations affecting participant recruitment or data collection.It is affirmed that all necessary approvals and permissions have been secured or will be obtained before commencing the project at each of the research sites. This is particularly pertinent for research conducted within K-12 educational settings, where certain school districts have established a comprehensive review process for research initiatives.In instances where data collection is facilitated through or derived from online or internet sources, the specific survey platforms or websites to be used will be explicitly stated (e.g., Qualtrics, Amazon Mechanical Turk, online forums, and support groups). Additionally, for research incorporating online activities, there will be a consideration for the potential of involving participants who reside outside the United States, and this aspect will be thoroughly addressed in the research design. |

# **6.0**. **Multi-Site or Collaborative Study:**

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| In the context of multi-site or collaborative research involving BeyondBound and external entities, reliance agreements are critical frameworks that designate which institution's Institutional Review Board (IRB) will oversee the ethical review of human research. BeyondBound will not assume the role of IRB of record for another entity without a formal agreement. When engaging in multi-site or collaborative research, the following details are required:* Identification of all institutions or individuals involved in the research.
* Description of the specific roles and activities undertaken by each participant.
* Determination of whether each entity will have its IRB review the activities or if a single IRB will oversee the entire project.

To adhere to IRB review and oversight requirements for multi-site or collaborative research, the following protocols will be followed:* No research activities will commence at external sites until they receive approval from their local IRB, or until a reliance agreement is fully executed between Beyond Bound's IRB and the external entities.
* External research teams will secure necessary approvals or permissions as per their local policies.
* Submission of IRB approval letters from external sites, evidence that IRB review is not required at external sites, or fully executed reliance agreements will be done alongside protocol updates through modification requests in the eIRB+ system.
* Any deviations from the study protocol or applicable regulations will be reported by local policies.

For projects where a single IRB acts as the IRB of Record:* Clarification on whether reliance is required by federal guidelines or sponsor mandates.
* Identification of the primary funding recipient if the research is federally supported.
* Proposal of which IRB will act as the central IRB for all sites.
* Specification of the type of reliance agreement to be utilized.
* Timelines for onboarding external sites or individuals, with a preference for reviewing Beyond Bound's site and the overall study first to prevent delays in initial approval.
* Strategies for communicating IRB approvals for modifications, sharing interim results, problems, or study closure with all parties involved, as detailed in the "Communication and Responsibilities" worksheet (HRP-830).
* Measures for ensuring data protection across all sites, compliant with local, state, and federal regulations.

For studies requiring a Single IRB setup due to non-exempt, federally funded research at multiple sites, Beyond Bound may necessitate reliance agreements. If Beyond Bound acts as the Single IRB, associated fees could apply. Further information on planning for a Single IRB can be found on our website.Beyond Bound's IRB also serves as the IRB of record and HIPAA Privacy Board for specific affiliated institutions. Collaborations with these entities do not require this section of the protocol to be completed by Beyond Bound members. |

# **7.0**. **Global Studies (involving data gathering beyond the borders of the United States and its territories, as well as through digital means)**

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| For guidance on IRB review of research that will be conducted outside the United States, refer to BeyondBound's website. The HHS Office of Human Research Protections updates annually a list of international laws and regulations governing human research, accessible at:<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>If your research is to be carried out internationally, please provide details on:* Will you seek review by a local IRB/research ethics committee in the country of your research? Not all countries have IRBs/research ethics committees, and in some places, they may only review biomedical studies. We recognize that obtaining a local IRB review might not always be feasible, but you should strive to get this review in the research country whenever possible. It's your duty to check if a local IRB/research ethics committee can evaluate your study in the intended countries for data collection.
* In locations lacking an equivalent board or group, researchers should engage with local experts or community leaders about the project to gain their endorsement for the research activities. The IRB requires a genuine effort to secure local support for the project and to submit documentation of this effort with your application.
* Consider the sociocultural dynamics that could influence the consent process in the research locations. For example, consider factors like low literacy rates or cultural norms that necessitate obtaining consent from a community or family leader.
* Address any compulsory reporting laws relevant to your research (for instance, laws mandating the reporting of child abuse and neglect).

NOTE: Collecting data **from individuals in the European Economic Area** (EEA) requires adherence to the General Data Protection Regulations (GDPR). This applies to distributing surveys/questionnaires to people in the EEA. If using a crowdsourcing platform or survey panel that may include participants from EEA countries, specify if the study will only include U.S. residents.NOTE: If handling sensitive data, adhere to robust **data security measures** for data collection, storage, and transmission. Be aware that data on electronic devices might be accessed by foreign officials or U.S. Customs and Border Protection. For best practices in data security during international travel, consult Beyond Bound's International Travel Data Security Guidelines and Data Protection Tips.**NOTE**: Federal export control laws may affect research endeavors domestically and internationally, including aspects like international travel, employment, collaborations abroad, and procuring equipment and materials. The Office of Foreign Assets Control (OFAC) lists several heavily embargoed countries. Before submitting proposals involving sanctioned countries or those under increased scrutiny, consult the Office of Export Compliance and International Compliance (ECIC).* Embargoed countries currently include Cuba, Iran, North Korea, Syria, and specific regions in Ukraine (Crimea, Donetsk region, Luhansk region, Sevastopol region), subject to change.
* Countries under military-end use restrictions include Belarus, Burma, Cambodia, China, Russia, and Venezuela, which may also change over time. For research conducted outside the U.S., consider consulting with the ECIC International Travel guidance page, irrespective of the destination country.
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# **8.0**. **Procedures Involved:**

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| Please indicate all the data collection methods you anticipate utilizing in your research:☐Individual interviews☐Group discussions☐Surveys/questionnaires☐Analysis of existing data (such as medical or educational records, data from governmental or private organizations, etc.)\*☐Observational studies☐Physiological assessments (examples include EEG, EKG, MRI scans)☐Collection of biological samples (examples include saliva, blood, hair, etc.)☐Use of digital tracking devices (examples include wearable fitness trackers, sleep monitors, etc.)☐Cognitive and behavioral tasks (such as problem-solving tasks, games involving strategy, etc.)☐Engagement in physical activities, including walking and other exercises☐Additional methods (if your data collection methods do not fit the categories listed above, please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ For each selected method above, provide a comprehensive description of the process and timeline for data collection. It’s essential to clarify the sequence of data collection and how it aligns with the overall study design. If your research encompasses **various segments**, each with unique procedures, please organize these details into a table or diagram to illustrate the chronological order of procedures segmented by study phase. Detail the expected **duration** of participation **for each activity** within the study and the total anticipated time commitment required from participants to complete all study activities. **If your research requires access to medical records classified as Protected Health Information (PHI) under HIPAA regulations, Appendix B must be filled out and submitted**. When your study involves **analyzing pre-existing data** not considered PHI under HIPAA, outline which datasets you aim to explore, their originating sources (for instance, educational records from a specific district, datasets from a governmental body, or another data provider like ICPSR), and the specific variables of interest. If the data to be received includes personal identifiers, justify the need for these identifiers, and specify whether you will keep the identifiers or anonymize the data. **Ensure to list the variables you will examine - this list may be added to your electronic IRB submission as an auxiliary document.**For projects employing **mobile applications** for data collection, consult the Beyond Bound IRB website for relevant guidelines. If incorporating **attention checks or incentives for performance**, describe these mechanisms and explain the consequences for participants who fail attention checks or do not meet criteria for incentives. \*If your investigation exclusively focuses on the analysis of secondary data, please use the Data and Specimen Analysis Protocol (HRP-1704) template. Exclusively for Student Researchers: Should your study involve potential risks to participants, outline your plan for regular consultation with your PI to ensure proper guidance and supervision throughout the research process. |

# **9.0**. **Studies Involving At-Risk Groups**

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| If your study involves individuals who might be more susceptible to coercion or undue influence, you must outline additional protective measures implemented to safeguard their rights and welfare. Such groups may include **minors, incarcerated individuals, adults with limited decision-making ability, and expectant mothers** if the research is anticipated to impact the pregnancy. This list is not exhaustive when considering potentially vulnerable groups.Protective strategies encompass, but are not limited to, aspects concerning: i) Recruitment: Detail the recruitment process for your study. For instance, will you approach potential participants individually or in groups, and will this be done in the presence of a parent/legal guardian/advocate?ii) Assent/Permission Process: Specify whether this will occur individually or in the presence of a parent/legal guardian. Elaborate on how the assent procedure will be adjusted to align with the developmental level and comprehension abilities of child participants. Provide thorough details on this process and the manner in which it will be recorded. It's expected that there will be a structured assent process with documentation for participants aged 7-17. For children under 7, describe your approach to verbally explaining the study in an age-appropriate manner.iii) Data Collection: Justify the suitability of your data collection method for these participants. Discuss whether it's appropriate for research interactions or interventions to be conducted privately with the participant.Consult the BeyondBound IRB Guidance on Research Involving Children, Parental Permission, and Child Assent to understand the ethical and regulatory considerations necessary for including minors in your research.If research team members have roles that could potentially lead to concerns about undue influence on participants (such as physician-patient, and teacher-student relationships), detail the measures you will implement to reduce the likelihood of coercion or undue influence.For assistance in ensuring all necessary information is provided for studies involving vulnerable populations, BeyondBound's IRB offers checklists. Note that these checklists are for the IRB office's use; refer to them for guidance only. |

# **10.0**. **DISSEMINATING FINDINGS TO PARTICIPANTS**

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| Outline the method through which outcomes of the study or specific results relevant to individual participants [including outcomes from exploratory diagnostic tests, genetic analyses, or unforeseen discoveries] will be communicated to participants. This could involve various approaches such as distributing summaries of published research through email, newsletters, presentations accessible online or in person. Additionally, describe if and how these findings might be relayed to others, for instance, a participant’s general healthcare provider. Should there be no plan to share the study findings with participants, offer a rationale for this decision.Elaborate on the communication strategy for disseminating the results.  |

# **11.0**. **Incomplete Disclosure or Deception:**

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| If your study involves partial disclosure (where information about the study's purpose is not fully disclosed during the consent process because full disclosure could significantly influence the validity of the study outcomes) or deception (intentionally misleading participants by giving them incorrect information or omitting certain details about the research during the consent process), please refer to the Guidance on Deception and Incomplete Disclosure on the BeyondBound IRB website.Should your research require the use of partial disclosure or deception, detail the nature of these methods and justify their necessity for the integrity of the research. Given that both deception and incomplete disclosure modify the information shared during the consent phase, the debriefing phase acts as a corrective measure to complete the consent process. Please prepare and upload a thorough debriefing script (HRP-1726). If debriefing is deemed suitable, describe your approach to executing the debriefing process. (The IRB Office offers examples of debriefing content in the Deception and Incomplete Disclosure Guidance on the BeyondBound IRB website.)NOTE: If your research strategy includes modifying the consent procedure due to the use of deception or incomplete disclosure, you must address this in Protocol Section 14 to request a modification of the consent process. |

# **12.0**. **Assent Process:**

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| **All the necessary templates for consent forms and instructions can be found on the Beyond Bound IRB website at**: https://beyondbound.org/Explain the method you will employ to secure informed consent (be it in written form, verbally, or digitally) from study participants, including the specific settings and timing for the consent process. If you intend to use varied consent methods across different groups of participants or at distinct stages of the study, provide a detailed account of the consent procedure for each group or phase.Consent is understood not simply as a formality but as a comprehensive process through which participants become fully aware of the study's methods, benefits, and potential risks. This awareness enables them to make a knowledgeable and voluntary decision about their participation.The **general** expectation is for participants to document their consent by signing a form once the study has been thoroughly explained to them, their queries have been addressed, and they have been afforded sufficient time to deliberate their participation.However, **exceptions** exist where it's impractical to obtain a participant's signature on the consent form (such as in studies that gather data over the phone) or where consent itself cannot be feasibly obtained (mainly in research analyzing existing data). With the growing use of electronic signatures for digital data collection (through platforms like REDCap, Qualtrics, etc.), the inability to collect a participant's signature on a consent form is not automatically presumed.**If you do not intend to collect signatures on the consent document, you must address this in Protocol Section 13. Should you seek a complete exemption from the consent process, or if you need to modify the consent procedure due to employing deception or partial disclosure strategies, Protocol Section 14 must be completed.****SPECIAL CONSIDERATIONS:****WHEN INCLUDING MINORS**: Obtaining parental consent and the child's agreement is mandatory unless the IRB approves a waiver for parental consent.The IRB mandates the documentation of the assent process for minors aged 7 to 17 years, except under specific conditions that justify assent waiver. The assent procedure should be adapted to match the reading and comprehension abilities of the children targeted for study participation. For participants younger than 7 years, describe your plan for verbally communicating the study's nature in an age-appropriate manner.Consult the IRB Guidance on Research Involving Minors, Parental Consent, and Child Assent for definitions and regulatory criteria relevant to this context. **STUDENT EDUCATIONAL RECORDS (FERPA**): If your research involves accessing identifiable student educational records protected under FERPA, this law mandates obtaining a consent form signed and dated by either the student or their parent, contingent on the student's educational level. For further details on FERPA, visit<https://studentprivacy.ed.gov/?src=fpco>.If you do NOT intend to secure consent for accessing student educational records, you must verify with the records' custodian if accessing the records without consent from the student or parent is permissible.For Beyond Bound, to access **identifiable BeyondBound student educational records** **for research** without obtainingstudent consent, you must fill out a FERPA Studies Exception Agreement(obtainable from the BeyondBound Registrar’s Office), submit it to theBeyondBound FERPA officer, and include the approved agreement in the“Supporting Documents” section of your IRB application.**NON-ENGLISH SPEAKING PARTICIPANTS**: Clarify the language(s) used by those obtaining consent and the languages understood/spoken by the potential participants. Outline your strategy to ensure that both oral and written communications provided to participants not proficient in English (whether within the United States or abroad) will be in their preferred language.Describe the process for selecting a qualified translator if translation services are needed.If translating your recruitment, consent, or data collection materials into other languages, it's advisable to first secure IRB approval for the materials in English and then submit the translations as a study modification. Include the translated documents along with a Certificate of Translation - Template for Non-English Documents.INDIVIDUALS WHO LACK THE CAPACITY TO CONSENT: If your study will include individuals potentially unable to consent, detail your approach for evaluating their consent capacity. Should your study involve multiple interactions with participants, their capacity to consent must be reassessed at each encounter, as their ability to consent may vary over time.In cases involving adults who cannot consent, permission for the individual's research participation must be obtained from a Legally Authorized Representative (unless consent waiver has been granted by the IRB). For guidance on identifying a Legally Authorized Representative, consult SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013). |

# **13.0**. **Exemption from Participant Signature Requirement on Consent Document:**

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| Several circumstances may render the collection of a participant's signature on the consent form impractical. For instance, in scenarios where consent and data collection are conducted via phone or online platforms, securing a participant's signature can become challenging and may complicate the consent process. Additionally, in research exploring illegal behaviors or subjects that carry social stigma, requiring a signature on the consent form could heighten risks to participants. Moreover, when a signature represents the sole piece of identifying information being gathered, acquiring a waiver could be advisable to ensure participant anonymity. Furthermore, in international contexts or within specific cultural groups, the practice of signing consent forms might not align with local customs or expectations.**Should you decide against collecting participant signatures on the consent document, please provide your rationale.** |

# **14.0**. **Exemptions and Modifications to Consent Details:**

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| In certain research projects, foregoing the process of obtaining consent may be considered suitable (for instance, studies focusing solely on the analysis of secondary data). Additionally, for some studies, it might be essential to withhold specific details during the consent process to ensure the feasibility of the research and the integrity of the data collected, such as in studies employing deceptive methods. Should you seek a full exemption from obtaining consent OR a modification of the consent procedure, please justify why:* + 1. The research presents no more than minimal risk to participants.
		2. The study could not feasibly be conducted without the proposed exemption or modification.
		3. If the study involves identifiable private information or biospecimens, it could not feasibly be conducted without utilizing such information or biospecimens in an identifiable manner.
		4. The exemption or modification will not negatively impact the participants' rights and welfare.
		5. Whether you intend to offer participants any relevant information post-participation (for example, debriefing participants).

Debriefing is generally relevant for research that incorporates deception or partial disclosure. If debriefing is not applicable to your study, indicate "debriefing does not apply to this study. |

# **15.0**. **Monetary Remuneration:**

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| There's no obligation to offer compensation to research participants. Should you intend to provide compensation, outline any financial or alternative rewards you plan to offer to participants. Detail the compensation approach, including the monetary value or other forms of compensation for specific activities, along with the timing of such compensation. If a lottery/raffle method will be employed for compensation, explain how many participants will be compensated and the procedure for distributing the rewards.Discuss the provision of prorated compensation in scenarios involving multiple research activities or early participant withdrawal from the study. For studies requiring several sessions or interactions, the IRB advises distributing compensation at consistent intervals, not solely upon study completion. If children are among the participants, indicate whether compensation will be given to the parent or directly to the child.Identify any expenses for which participants might be liable as a result of their research involvement, such as parking fees, costs associated with using personal phones, etc. For studies posing more than minimal risk to participants, outline the compensation available for research-related injuries.For a more comprehensive discussion on compensating research participants, refer to the Beyond Bound IRB Guidance on Research Participant Payment. |

# **16.0**. **Audio/Video Recording/Photography**

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| Specify the recording method you intend to employ, the justification for its necessity within the scope of your research, and whether participation in the recording aspect of the study is compulsory or voluntary.Explain the intended applications of the recording(s) in your study, such as exclusively for data examination or for both analysis and public dissemination (including presentations or publications). If there's a possibility of using the recordings or visuals in public forums or for publishing purposes, acquiring explicit permission from participants for these specific uses is mandatory.Detail the procedures for the storage and security of the recordings, including the location of storage, individuals authorized to access them, and the protocol for their eventual disposal. Should the participation in audio/video recording be a requisite for involvement in the study, a justification for this requirement must be provided. Furthermore, it is imperative to clearly state this requirement in the consent documentation. |

# **17.0**. **Prospective Advantages of the Study:**

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| Outline any anticipated advantages that your study may yield, clarifying if participants should not expect any direct benefits from their involvement. Expand on the broader benefits that the research might offer to society or specific groups.Remember, the act of participating in the study and any **financial remuneration** received for participation do not qualify as benefits of the research and **should not be presented as such** **during the consent process**. |

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# **18.0**. **Possible Hazards to Participants:**

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| Identify any risks, discomforts, or inconveniences that participants might encounter due to their involvement in the research, including the likelihood, severity, duration, and potential for reversing these risks.Consider risks across various dimensions, including physical, emotional, social, legal, financial, as well as potential negative impacts on communities or groups. It's important to acknowledge that a breach of confidentiality represents a typical risk in social and behavioral studies.For research designed to elicit adverse emotional responses or expose individuals to distressing content, outline the strategies implemented to alleviate any resultant discomfort. For further guidance on managing studies involving deceptive practices or partial disclosure, consult the **IRB Guidance for Research Involving Deception or Incomplete Disclosure**. |

# **19.0. Measures to Safeguard Participant Privacy and Ensure Data Secrecy:**

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| **Participant Privacy**: Detail the measures you will implement to safeguard participants' privacy interests. "Privacy" pertains to an individual's control over their interactions and the personal information they share. For instance, will sensitive questions asked during interviews be conducted in private settings to prevent being overheard?**Confidentiality of Data/Biospecimens**: Explain your strategy for ensuring the confidentiality of data/specimens throughout your study's duration, encompassing collection, data handling (including transfers), and storage phases. Describe the security measures (such as authorized access, password protection, encryption, physical safeguards, and the separation of identifiers from data) you will apply during collection, transmission, and storage to maintain stringent data security.NOTE: According to the policy of the BeyondBound, research projects that gather health information are required to submit data security details as part of the **Research** **Supplemental Submission (RSS)** **if you, as the Principal Investigator,** **are associated with FSM OR if NMHC (or an affiliate) is a research location**. FSM necessitates completing the RSS upon submitting a new study in the RSS section of the eIRB+ application. FSM IT Security will review the RSS details, independently from the IRB approval process. **IRB reviewers will** **NOT see the RSS information – you must also include comprehensive data security details within this protocol section.**Address the following points as relevant to your research:* Will participant identifiers (such as names, addresses, phone numbers, email addresses, etc.) be included with the data/specimens? Is there a plan to remove identifiers at some stage? Note that participants might be recognizable from video or audio recordings.
* If direct participant identifiers are not collected, will a coding system be utilized?
* Where will the code key be stored, and who will have access to it?
* If audio recordings are transcribed, do you plan to erase the audio files post-transcription?
* Describe the process for moving data from the collection site to storage.
* Outline the storage method and location for data/specimens, the retention duration, and the disposition of these materials after the study concludes. (Note: Under BeyondBound policy, research data must be retained for at least 3 years following study completion, though specific circumstances may dictate different durations. Consent documents containing HIPAA authorizations must be kept for a minimum of 6 years after the study's end.)

For comprehensive guidelines on proper research data security practices, consult Beyond Bound IT’s website.  |

# **20.0**. **Strategy for Data Oversight to Safeguard Participant Well-being:**

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| You are required to complete this section if your research falls into one of the following categories:* A clinical trial, or
* The collection of data that may reveal potential harm to participants (for instance, expressions of self-harm or harm towards others, or indicators of child, spousal, elder, or other abuse or neglect).

Outline your strategy for regularly reviewing and assessing the data collected to identify any risks or harm, ensuring the safety of participants and others involved. The monitoring frequency should align with the nature of the data collected and the associated risk level. For instance, if there's a possibility that participant feedback might indicate a risk of self-harm or harm to others, detail your monitoring approach for such risks and your response plan for instances where harm is indicated. It's essential to have team members with the appropriate qualifications to conduct these assessments if your study will directly evaluate such sensitive information. If your research involves evaluating suicidality, consult the Guidance on Suicidality in Human Research Protocols and adequately address this in your plan. Nevada state law and BeyondBound policy mandate all employees, students, volunteers, and third-party contractors of BeyondBound to report any suspected instances of **child abuse or neglect**. **Regarding studies potentially uncovering** **disclosures of sexual misconduct**: If your study's target population is likely to disclose incidents of sexual misconduct involving members of the BeyondBound community, such contingencies must be anticipated in your research protocol and informed consent documentation. Sexual harassment and sexual violence, as forms of sex discrimination, are prohibited under a federal law known as Title IX. Beyond Bound employees are obligated to report any known instances of sexual misconduct to the BeyondBound Office of Equity, especially if any party involved is a member of the Beyond Bound community. This encompasses sexual assault, sexual exploitation, stalking, dating and domestic violence, and sexual harassment. This reporting obligation is specific to BeyondBound employees. Student researchers informed of such matters should consult with their Principal Investigator (PI), who is then responsible for contacting the Office of Equity.  |

# **21.0**. **Prolonged Storage and Dissemination of Data and Samples**

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| Should your research involve the long-term storage and subsequent sharing of data or specimens for future studies, detail your strategy for both the preservation and distribution of these materials. If the intention is to deposit the data into a repository, specify the chosen repository or database and the rationale behind this selection.Given that numerous funding bodies and scholarly journals mandate data sharing, indicate if this requirement pertains to your project and describe the approach to data dissemination.For data housed in internal repositories, mention any pertinent STU numbers. Clarify if the shared data or specimens will contain identifiers.  |

# **22.0**. **Credentials of Research Team to Conduct the Study:**

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| Detail the credentials of the research team that affirm their capability to undertake this study. The IRB seeks to understand the team's specific areas of expertise, history of research involvement, pertinent certifications, and any other qualifications relevant to conducting the proposed research effectively.For projects carried out internationally or those involving at-risk groups, expound on your qualifications (including training, prior experience, and supervisory roles) for conducting such research, as well as your familiarity with the local study environments, cultural norms, and societal structures.Note: Should an individual team member be identified by name, any subsequent change to this individual will necessitate IRB approval beforehand. Conversely, if team members are designated by their roles (such as coordinator, research assistant, co-investigator, or pharmacist), replacements can be made without IRB pre-approval, assuming the new individual possesses the outlined qualifications necessary for their respective position. |