**GUIDELINES:**

* Should certain segments not be relevant to your study, you have the option to omit those sections. It's permissible to exclude subsections that do not pertain to your investigation.
* Incorporate the STU# from eIRB+ into the document's header.
* Insert the Version Date into the document's footer.
* Title the document with the protocol version date when saving and uploading it.
* Maintain a digital copy of this document in your records. This copy will be necessary for implementing amendments.
* During the development of this protocol, eliminate any instructions that are in italics and/or within brackets, ensuring they are not included in the ultimate edition of your protocol.

**PROTOCOL TITLE:** (Enter the complete title of the protocol.)

**PRINCIPAL INVESTIGATOR:**

Name:

Department sponsoring or supporting the research:

Contact Telephone:

Contact Email:

**VERSION DATE:**

(Enter the version date here and also in the document's footer.)

**STUDY OVERVIEW:**

| Investigational Agent(s)  (Drugs or Devices) |  |
| --- | --- |
| IND / IDE / HDE # |  |
| Indicate  Special Population(s) | ☐ Children  ☐ Children who are wards of the state  ☐ Adults Unable to Consent  ☐ Adults with Impaired Decision-making Capacity  ☐ Neonates of Uncertain Viability  ☐ Pregnant Women  ☐ Prisoners (or other detained/paroled individuals)  ☐ Students/Employees |
| Sample Size |  |
| Funding Source |  |
| Indicate the type of consent to be obtained | ☐ Written  ☐ Verbal/Waiver of Documentation of Informed Consent  ☐ Waiver of HIPAA Authorization  ☐ Waiver/Alteration of Consent Process |
| Site | ☐ Lead Site (For A Multiple Site Research Study)  ☐ Data Coordinating Center (DCC) |
| Research Related Radiation Exposure | ☐ Yes  ☐ No |
| DSMB / DMC / IDMC | ☐ Yes  ☐ No |

**FEDERAL FUNDING:**

(Fill out the following matrix for each distinct federal funding source supporting this study. Append extra matrices as necessary for each funding source. Omit this section if the study does not receive federal funding. Note: Ensure the details here align with those presented on the funding section of the eIRB+ application.)

| Funding Agency: |  | |
| --- | --- | --- |
| Sponsored Research ID#: |  | |
| Does the grant indicate that covered activities will include Human Research?  (Yes / No / Unknown) |  | |
|  | Institution Name: | Human Research Assessment \*\*\*  (e.g., Non-Exempt Human Research, Exempt Human Research, Not Human Research, etc.) |
| Prime Award Recipient\* |  |  |
| Sub-Award Recipients\*\* |  |  |
|  |  |  |
|  |  |  |

\*The primary recipient of the award is invariably involved in Human Research and must obtain IRB supervision if any of the sub-award recipients engage in non-exempt Human Research. Numerous federal bodies mandate that if multiple domestic locations participate in non-exempt Human Research, all locations must adhere to the evaluation by one "Single IRB." Should this be relevant to your investigation, you are required to secure a Single IRB Letter of Support and an IRB Fee Quote from the BeyondBound IRB Office. To begin this procedure, please submit a Single IRB Consultation Request.

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

\*\*\*The application for federal funding must detail whether the recipients of the award will partake in Human Research. Drawing from the application for funding, evaluate the tasks at each location and revise the table accordingly if there is a change in the planned activities or if a different IRB evaluates the tasks and arrives at an alternate conclusion.

**OBJECTIVES:**

(Outline the goals, specific aims, or objectives of the study. Specify the hypotheses that will be evaluated.)

**BACKGROUND:**

*(Detail prior expertise and identify areas where current understanding is lacking.)*

*(Outline any pertinent preliminary information.)*

*(Discuss the academic or scientific groundwork for, justification for, and importance of the study, drawing from current literature, and how it will contribute to the expansion of existing knowledge.)*

STUDY ENDPOINTS:

*(Detail the main and additional study endpoints.) (Outline the primary and secondary safety endpoints.)*

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

*(Explain the intervention being studied and/or the investigational agent (for example, medication, device) under evaluation.)*

*(Management of Drugs/Devices: For studies involving pharmaceuticals or medical devices, outline your strategy for the safe storage, handling, and administration of these items to ensure they are exclusively utilized by participants and only by qualified researchers.)*

* *All experimental medication protocols are required to employ the IDS Pharmacy for the custody, distribution, and oversight of investigational medications, applicable to both inpatient and outpatient settings.*
* *In instances where the management of medications or devices within this study is governed by an existing, validated organizational SOP (for instance, Research Pharmacy SOP for the Management of Investigational Medications, etc.), this SOP should be cited in this section.*

(If the drug is under an Investigational New Drug (IND) application, or the device is subject to an Investigational Device Exemption (IDE) or qualifies for an abbreviated IDE (indicating it is a non-significant risk device), incorporate the following details:

* Specify the entity responsible for the IND/IDE/Abbreviated IDE.
* Describe the processes adhered to in order to meet the sponsor's requirements for research regulated by the FDA.

(Is this device considered a non-significant risk (NSR) under an Abbreviated IDE?)

* If affirmative, justify your assessment.
* Detail the locations where the research activities will be conducted.)

**PROCEDURES INVOLVED:**

(Detail and rationalize the research design.)

(Offer an explanation of all the procedures undertaken for the study and their timing, including those implemented for monitoring participant safety or reducing potential hazards.)

(Explanation:

* Methods employed to decrease the likelihood or severity of risks.
* Clarify which procedures are deemed routine medical care and which are specifically for research purposes. (For instance, if the regularity of CT scans aligns with standard medical practices, this should be noted)
* List all pharmaceuticals and devices utilized in the study, their intended uses, and their status regarding regulatory approval.
* Identify the source documents, including health or educational records, that will be accessed to gather information about participants. (Please attach any questionnaires, dialogue guides, and forms for data collection.)

(What information will be collected during the research, and what methods will be used to collect it?

* Should there be plans for extended observation after the conclusion of all research-related activities, specify the information that will be collected during this phase.)

(For Humanitarian Use Device (HUD): provide a comprehensive description of the device, an overview of its intended application, including any preliminary screening methods, the HUD process, and subsequent patient follow-up visits, examinations, or procedures.)

(If your project involves research-related radiation, please include a Radiation Dosimetry Form in the Supporting Documents segment of your application in eIRB+ and detail the quantity and frequency of radiation exposure.)

(Audio/Video Recording/Photography: If relevant, outline:

* the form of recording or photography being employed
* the reason such recording is essential for the study
* the ways in which the recordings or photographs will be used within the research framework (for example, solely for data analysis)
* the methods and locations for storage of the recordings or photographs, who will have access to them, and the conditions under which they will be deleted.)

**DATA AND SPECIMEN BANKING**

*(Should there be plans to bank data or specimens for future research, provide details on:*

* *the location where the specimens will be securely stored,*
* *the duration for which the specimens will be preserved,*
* *the method by which specimens will be retrieved,*
* *the individuals or entities authorized to access these specimens, and*
* *the information that will be stored or linked with each specimen.)*

*(Detail the protocol for the distribution of data or specimens, including: the procedure for submitting a distribution request, the approvals necessary for such a release, the parties eligible to receive data or specimens, and the specific data that will accompany the specimens.)*

*(In cases involving the collection and dissemination of genetic information, consult the relevant checklist and incorporate the details covered by the queries.)*

**SHARING RESULTS WITH PARTICIPANTS**

*(Outline the method by which the outcomes of the study or specific results relevant to individual participants [like outcomes from experimental diagnostic evaluations, genetic assessments, or incidental discoveries] will be communicated to participants (for example, through email notifications about published papers, newsletters, presentations either online or face-to-face) or to others (such as a participant's general healthcare provider). If there is a plan not to disclose the study findings to participants, explain the reasons for this decision.*

(Detail the process for disseminating the results.)

**STUDY TIMELINES**

(Detail the following aspects:

* the span of an individual's involvement in the research,
* the estimated time required to enroll all participants,
* the projected completion date for the primary analysis phase of the research.)

**INCLUSION AND EXCLUSION CRITERIA**

(Explain the methodology for determining participant eligibility, including:

* the criteria for determining who will be included or excluded from the study cohort,
* state explicitly whether the study will include or exclude the following groups (individuals from the groups listed below should not be part of the research unless specified in your inclusion criteria):
  + Adults’ incapable of giving consent
  + Minors (infants, children, teenagers)
  + Pregnant individuals
  + Incarcerated individuals
  + Vulnerable groups
* If certain groups are omitted from the study, provide a comprehensive justification for their exclusion.)

**VULNERABLE POPULATIONS**

*(Should the study involve participants who are particularly susceptible to coercion or undue influence, provide a detailed account of the extra measures implemented to safeguard their rights and welfare. Please consult and reference the following specific checklists for guidance:*

* “CHECKLIST: Pregnant Women (HRP-412)” for protocols involving pregnant participants,
* “CHECKLIST: Neonates (HRP-413)” for studies including newborns,
* “CHECKLIST: Neonates of Uncertain Viability (HRP-414)” for research with newborns where viability is in question,
* “CHECKLIST: Prisoners (HRP-415)” for research involving incarcerated individuals,
* “CHECKLIST: Children (HRP-416)” for studies that include minors,
* “CHECKLIST: Adults with Impaired Decision-making Capacity (HRP-417)” for research involving adults who may not have the capacity to make informed decisions on their own behalf.)

**PARTICIPANT POPULATION(S)**

| Accrual Number: | Category/Group:  (Adults/Children Special/Vulnerable Populations) | Consented:  Maximum Number to be Consented or Reviewed/Collected/Screened | Enrolled:  Number to Complete the Study or Needed to Address the Research Question |
| --- | --- | --- | --- |
| Local |  |  |  |
|  |  |  |
| Study-wide |  |  |  |
|  |  |  |
| Total: |  |  |  |

**RECRUITMENT METHODS**

(Detail the timing, locations, and techniques for recruiting potential participants. Your approach to recruitment should specifically address and outline strategies to ensure the inclusion of individuals from diverse racial and ethnic backgrounds or under-represented groups relevant to the study. The objective is to create a recruitment strategy that is both inclusive and reflective of the population eligible for the study in its locale, while also considering the impact of the research on these communities.

(Explain the origin of the participant pool.)

(Outline the strategies that will be employed to identify prospective participants.)

(Describe the materials that will be utilized for participant recruitment. (Please include copies of these documents with your eIRB+ submission. For any advertisements, attach the final version of the printed materials.)

(For advertisements that will be broadcasted, include the final audio/video files. The wording of the advertisement may be submitted before recording to avoid re-recording due to unsuitable content, with the condition that the IRB reviews the final audio/video content.)

**COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES**

(Detail the compensation amount, schedule, and form for participant payments. (For example, through gift cards, ClinCard, or checks.)

(Should compensation be provided via check, it will be necessary to collect the participant's name, address, and Social Security Number to facilitate the issuance of a check for their participation. Payments made to participants are regarded as taxable income and must be reported to the IRS.)

(In the case of compensation through the [NAME OF INSTITUTION’S] ClinCard, specify the amount that will be credited to the card at each appointment.)

(For participants associated with the USDOD, it is important for them to consult with their supervisor regarding the acceptance of any research participation compensation.)

(If the investigator anticipates that the biological samples collected might contribute to or result in the creation of a commercial product, state whether participants will possess any entitlement to compensation or an ownership stake in relation to such developments.)

(Explain the timing and method through which participants will be notified about the research outcomes.)

**WITHDRAWAL OF PARTICIPANTS**

(Provide an explanation for:

* any foreseeable situations that may lead to the withdrawal of participants from the study without their agreement,
* the steps for orderly termination from the study,
* the processes to be implemented when participants choose to leave the study, including scenarios of partial withdrawal where certain procedures are discontinued while data collection may persist.)

**RISKS TO PARTICIPANTS**

(Itemize the potential risks, discomforts, drawbacks, or inconveniences to the participant arising from their involvement in the study. This should include an assessment for the IRB of the likelihood, severity, duration, and the potential for reversing these risks.)

(Consider the spectrum of risks including physical, emotional, social, legal, and financial aspects.)

(If relevant, specify:

* any procedures that might pose risks to participants which are not currently predictable.
* any procedures that could present risks to an embryo or fetus in the event that the participant is or becomes pregnant.
* any potential risks to individuals who are not part of the study.)

**POTENTIAL BENEFITS TO PARTICIPANTS**

(Outline the possible advantages that participants might gain from their involvement in the study, including an analysis of the likelihood, scale, and persistence of these potential benefits for the IRB's review.)

(Mention if there are no direct benefits to participants. Exclude any societal or third-party benefits.)

**DATA MANAGEMENT AND CONFIDENTIALITY**

(Detail the plan for data analysis, encompassing statistical methods, power calculations, and the rationale behind the chosen sample size.)

(Explain the measures to be implemented for data protection (such as training for those with access, authorization procedures, password safeguarding, encryption, physical security measures, confidentiality agreements, and the decoupling of identifiers from data) throughout data handling, utilization, and sharing.)

(If relevant: consult the HRP-335 GDPR Data Protection Worksheet for extra directives when gathering data from subjects in the European Economic Area.)

(Describe the quality control measures that will be applied to the collected data.)

(Explain the approach for the management of data or specimens across the study:

* Detail the type of information that will be recorded or linked with the specimens.
* Describe the storage solutions and methods for both data and specimens.
* Specify the duration for which data or specimens will be retained.
* Identify individuals or groups with access to the data or specimens.
* Name the person or entity accountable for managing the data or specimens' receipt or dispatch.
* Outline how data or specimens will be transported.)

(NOTE: For research associated with the School of Medicine, refer to their Data Storage Policy that delineates authorized data storage platforms based on data sensitivity, the capacity for dependable data backup and recovery, and the management and customization of data access permissions.)

**PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS**

(This segment is necessary for research that entails more than minimal risk to participants.)

(Elaborate on:

* The strategy for regular assessment of the data gathered, focusing on both potential harms and benefits, to ascertain ongoing participant safety. This strategy may involve the formation of a data monitoring committee (DSMB/DMC/IDMC), along with a procedure for communicating the findings from this committee to both the IRB and the project sponsor.
* The regularity of DSMB meetings.
* The specific data to be examined, which should include information on safety, adverse events, and effectiveness.
* The method of safety data collection (for instance, through case report forms, during study visits, or via telephone communications with participants).
* The timetable for data collection, indicating the commencement of safety data accumulation.
* The individuals responsible for data review.
* How often the cumulative data will be evaluated.
* The statistical methodologies employed to analyze safety data to identify potential harm.
* Any circumstances that would necessitate an immediate halt to the research activities.)

**PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS**

(Outline the measures that will be implemented to safeguard the privacy interests of participants. The term "privacy interest" pertains to an individual's preference to control their engagement and the disclosure of their personal information.)

(Detail the actions you will undertake to ensure participants are comfortable with the research environment, considering the inquiries posed and the procedures conducted. The term "at ease" does not relate to physical discomfort but rather to a participant's perception of invasiveness resulting from questions, examinations, and procedures.)

(Specify the conditions under which the research team may access any forms of information pertaining to the participants.)

**COMPENSATION FOR RESEARCH-RELATED INJURY**

(For studies presenting more than minimal risk to participants, outline the compensation available in case of an injury related to the research activities.)

(Include any contract language pertinent to compensation for injuries sustained through research participation.)

**ECONOMIC BURDEN TO PARTICIPANTS**

Detail any financial responsibilities that will fall on participants due to their involvement in the research.

**CONSENT PROCESS**

(Specify whether consent will be obtained and if so, describe:

* The location where the consent process will occur.
* Any period of reflection offered between presenting the potential participant with information and obtaining their consent.
* Procedures in place to confirm consent on an ongoing basis.
* The responsibilities of the individuals named in the application as participants in the consent process.
* The languages utilized by those obtaining consent and those understood by the prospective participant or their legally authorized representative.
* The duration allocated for the consent discussion.
* Measures to reduce the risk of coercion or undue influence.
* Actions to ensure participants' comprehension of the information provided.)
* If relevant: For obtaining consent from individuals within the European Economic Area, consult the GDPR Guidance to understand participant rights and the dual-step consent process, including the utilization of the GDPR Compliance Consent Document template (HRP-590).

**NON-ENGLISH-SPEAKING PARTICIPANTS**

(Specify the languages, aside from English, that are understood by prospective participants or their representatives.)

(If the study plans to enroll participants who are not proficient in English, detail the strategy to guarantee that both the oral and written information furnished to these participants is presented in their language. Also, mention the language that individuals obtaining consent will use.)

**WAIVER OR ALTERATION OF CONSENT PROCESS**

(consent will not be obtained, required information will not be disclosed, or the research involves deception)

(Ensure you have reviewed the guidance on “(Waiver or Alteration of Consent Process)” thoroughly to provide adequate details for the Institutional Review Board (IRB) to evaluate these considerations. Enumerate the criteria for a waiver or alteration of the consent process and explain how your study fulfills each criterion.)

(If the study includes a waiver of the consent process for anticipated emergency research, make sure to review the “Waiver of Consent for Emergency Research” guidelines to supply all necessary information for the IRB to assess these aspects.)

* Participants who have not reached adulthood (such as infants, children, and teenagers)
* Outline the criteria utilized to assess whether a potential participant is below the legal age of consent for treatments or procedures involved in the study, according to the laws of the jurisdiction where the research will be conducted (For example, individuals under 18 years of age).
* For studies taking place within the state, consult the “(HRP-013)” to understand which individuals are classified as “children” under state regulations.
* For studies conducted outside the state, provide details identifying the individuals who are considered below the legal age of consent for treatments or procedures involved in the research, in accordance with the laws of the jurisdiction where the study will occur. Consulting a legal advisor or authority to review your protocol alongside the definition of “children” in (HRP-013)” is one approach to acquiring this information.
* Explain the approach to obtaining parental permission, which may include:
* Requiring consent from both parents unless one parent is deceased, unknown, incompetent, not reasonably accessible, or when only one parent holds legal responsibility for the child's care and custody.
* Allowing consent from one parent even if the other parent is alive, known, competent, reasonably accessible, and shares legal responsibility for the child’s care and custody.
* Detail whether consent will be sought from individuals other than the parents, who these individuals might be, and describe the method used to verify their legal authority to consent on behalf of the child’s general medical care.
* Specify if assent will be sought from all, some, or none of the children involved. If assent is required from certain children, identify these groups.
* When obtaining assent from children, describe if and how this assent will be recorded.
* Outline the strategy to secure informed consent once a child participant reaches 18 years of age.
* Refer to the IRB Guidance on Children as Research Participants, Parental Permission, and Child Assent for comprehensive insights on the additional ethical and regulatory issues to consider when planning to include children in your research.
* Adults with Impaired Decision-making Capacity
  + Detail the methodology for assessing an individual's capacity to consent. The IRB permits the individual gathering assent to note assent on the consent form itself and does not standardly demand separate assent documentation nor typically necessitate adults with compromised decision-making abilities to sign assent forms.
* Adults Unable to Consent
* Enumerate the individuals from whom permission will be sought, arranged according to priority. (For instance, durable power of attorney for healthcare, court-appointed healthcare guardian, spouse, and adult children.)
* For studies conducted within the state, consult the “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to understand who qualifies as a “legally authorized representative” in the state.
* For research undertaken outside the state, present information identifying the persons legally empowered to consent on a prospective participant's behalf for their involvement in the research procedures. Consulting with a legal advisor or authority to review your protocol in conjunction with the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” can be an effective strategy for gathering this information.
* Explain the procedure for obtaining assent from adult participants, including:
* Whether assent will be required from all, some, or none of the participants. If only some participants are to assent, specify which ones will need to assent and which ones will not.
* If assent will not be sought from some or all participants, provide a rationale for this decision.
* Describe how the assent of participants will be recorded. The IRB permits assent to be documented directly on the consent form and does not usually ask for separate assent forms nor require participants to sign assent documents.
* Humanitarian Use Devices
* For the application of Humanitarian Use Devices (HUDs), detail the method by which patients will be informed about the possible risks and advantages of the HUD, as well as any procedures related to its usage.
* Process to Document Consent in Writing
* Explain the procedure for documenting participant consent in a written format.
* If your study involves no more than minimal risk to participants and does not include any procedures for which written consent is typically required outside the research context, the IRB may waive the requirement for written consent documentation.
* (If documenting consent in writing is part of your protocol, remember to include this detail in your EIRB+ Application.) If you intend to obtain consent without documenting it in writing, provide a consent dialogue or script. Consult the “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to verify you've supplied adequate information. The “TEMPLATE CONSENT DOCUMENT (HRP-502)” can be utilized to draft the consent document or script.
* Setting
  + Describe the locations or venues where the research will be carried out by your team.
  + If acting as a Lead Coordinating Center or Data Coordinating Center, elucidate BeyondBound’s role in this study. For definitions, refer below.
  + Discuss the structure and participation of any community advisory board involved.
  + For studies conducted outside of your organization and its affiliates, address:
  + Site-specific norms or regulations impacting the research.
  + The framework for scientific and ethical review outside of your organization.
* Lead Coordinating Center:
  + A Lead Coordinating Center is identified as a location offering the administrative, clinical, and technical support and leadership necessary for the planning and management of multi-site collaborative research within a multi-center trial.
  + The principal investigator is tasked with overseeing all site monitoring, as well as coordinating the recruitment, screening, enrollment, and retention of participants, ensuring data and safety monitoring, managing data collection and analysis, adhering to protocol-directed procedures and guidelines, and the timely identification, reporting, and addressing of adverse events.
* Data Coordinating Center:
  + A Data Coordinating Center is described as a location responsible exclusively for the aggregation and storage of data collected from all sites participating in a multi-site trial.

**PROTECTED HEALTH INFORMATION (PHI AND HIPAA)**

(HIPAA pertains to Protected Health Information (PHI), which is any health information that can be linked to an individual and is created or kept by a covered entity (such as healthcare providers, hospitals, doctor's offices, healthcare clearinghouses, and health plans) or their business associates.)

(If your research does not engage with medical record information held by a covered entity and if the data produced from the research will not enter the medical record, then HIPAA regulations do not apply.)

(Please specify the following:

* Does the study entail the generation, utilization, or sharing of Protected Personal Health Information? HIPAA Authorization:
* Will HIPAA Authorization be secured from all or certain participants?
* If HIPAA Authorization will not be obtained, describe the alternative measures that will be employed.)

**MODIFICATION OR ADJUSTMENT OF HIPAA CONSENT REQUIREMENTS**

* Enumerate the following categories of Protected Health Information (PHI) that will be utilized:
  + Individual names
  + Geographic Details: All geographic details smaller than a state level, including addresses, cities, counties, precincts, ZIP codes, and equivalent geographic identifiers, with the exception of the first three numbers of a ZIP code provided that, according to the most recent data available from the Census Bureau: (a) The geographic area resulting from merging all ZIP codes sharing the same initial three numbers exceed 20,000 residents. (b) For any geographic areas with a population of 20,000 or less, the first three digits of their ZIP code will be altered to 000.
  + Dates and Age: All components of dates (excluding the year) that are associated with an individual, such as birthdate, admission and discharge dates, and date of death; along with all ages over 89 and all date components (year included) indicating such age, with the provision that these ages and components may be consolidated into a single category for ages 90 and above.
  + Telephone numbers
  + FAX numbers
  + Social Security numbers
  + Numbers of medical records
  + Numbers identifying health plan beneficiaries
  + Numbers of accounts
  + Numbers of certificates/licenses
  + Identifiers and serial numbers of vehicles, including numbers of license plates
  + Identifiers and serial numbers of devices
  + URLs for the World Wide Web
  + Numbers of Internet Protocol (IP) addresses
  + Identifiers of biometrics, including fingerprints and voice patterns
  + Photographs showing the full face and similar images
  + Any other number, characteristic, or code uniquely identifying an individual, except as the Privacy Rule may allow for re-identification purposes.
* (Examine the need for a Waiver of HIPAA Consent and provide specific justifications related to your protocol if HIPAA is applicable and you do not intend to secure a signed HIPAA Consent. Detail the criteria here and describe how each criterion is fulfilled.)

**ELIGIBILITY FOR CONDUCTING RESEARCH AND ACCESS TO RESOURCES**

* (Outline the resources at your disposal for undertaking the study, including, as applicable:
  + Provide evidence of the practicability of enlisting the necessary number of appropriate subjects within the stipulated recruitment timeframe. For instance, what is the total number of potential subjects accessible to you? What proportion of these potential subjects is required for enrollment?
  + Specify the amount of time you intend to allocate to the execution and completion of the study.
  + Detail the infrastructure and facilities at your disposal.
  + Highlight the availability of medical or psychological support for participants who may need it due to the expected outcomes of the research.
  + Explain your methodology for ensuring that all individuals involved in the research are thoroughly briefed on the study protocol, the investigative procedures, and their respective roles and responsibilities.
  + Multi-Center Investigations (Fill out if your institution is the primary site and/or the central data management hub)
  + Overall Participant Numbers for the Study
  + If the research involves multiple centers, provide the aggregate number of participants to be recruited across all locations.)

**RESEARCH CONDUCTED ACROSS MULTIPLE LOCATIONS OR IN COLLABORATION:**

When research activities are undertaken by researchers at BB along with those from other institutions, or by independent external researchers, the following details must be provided:

* Identify the institutions or persons engaged in the research project.
* Describe the specific roles or tasks these institutions or persons will undertake in the study.
* Clarify whether each participating institution or individual will have their activities reviewed by their respective IRB, or if a single IRB will act as the reviewing IRB of Record for all involved.

If there's uncertainty about the process for IRB review and oversight in your multi-site or collaborative research project, please confirm adherence to the following principles:

* No research activities will commence at external locations until local IRB reviews have been conducted or reliance agreements have been completely established.
* External sites will obtain necessary approvals or permissions in line with their own local guidelines.
* Upon availability, IRB approval documents from external locations, evidence indicating that IRB review is not required at these sites, or fully finalized reliance agreements will be submitted along with the latest protocol revisions.
* Any deviation from the study protocol or relevant regulations will be reported as per the governing local policy.

Should a single IRB act as the IRB of Record for all entities involved in the research (a practice known as reliance), a comprehensive reliance strategy must be outlined:

* Determine whether reliance is a requirement as per federal regulations or a mandate from the sponsor.
* Identify the primary recipient of federal funding, if applicable.
* Name the designated IRB of Record for all sites involved.
* Describe the form of reliance agreement that will be implemented.
* Specify the timeline for onboarding participating entities. When BB is suggested as the IRB of Record, the preference is to initially review the BB site and the overall scope of the study, with the subsequent inclusion of other entities through amendments incorporating fully signed reliance agreements. Incorporating other entities during the initial review might postpone the initial approval process.
* Outline the process for communicating changes in study procedures to all participating entities, ensuring approval before any implementation. Detail how updates, including issues, interim findings, or study conclusion, will be shared with all entities. Refer to the WORKSHEET: Communication and Responsibilities (HRP-830) for more information.
* Describe the measures that will be taken to ensure participant data protection. All entities must adhere to data security measures, including secure data transmission, in compliance with relevant local policies, state statutes, and federal laws.

*Reliance agreements are official documents that enable an IRB, institution, or individual to depend on the IRB review conducted by another institution for human research oversight. The BB IRB will consent to act as the IRB of record for another institution, IRB, or individual only when a mutual agreement has been established. For additional details, please visit our website at: https://beyondbound.org/*

*For non-exempt, federally funded human research that occurs across multiple sites, it might be necessary to form a Single IRB through reliance agreements. Should BeyondBound function as the Single IRB, certain fees could be applied. Further information is available on our website: https://beyondbound.org/*

*It is important to note that federal export control regulations may affect research activities conducted both domestically and internationally, including aspects such as international travel, employment, collaboration with foreign colleagues, and the procurement of equipment and supplies. These regulations include strict embargoes by the Office of Foreign Assets Control (OFAC) on several countries. Researchers are advised to consult with the Office of Export Compliance & International Compliance (ECIC) prior to submitting their proposals if their research involves countries under sanctions or considered to be at a heightened risk.*

* *Countries currently under embargo include Cuba, Iran, North Korea, Syria, and specific regions within Ukraine (Crimea, Donetsk region, Luhansk region, Sevastopol region). Please note that the list of embargoed countries is subject to change.*
* *Countries identified for military-end use include Belarus, Burma, Cambodia, China, Russia, and Venezuela. This list may also vary over time.*

*Researchers planning to conduct research outside the United States should consider seeking advice from the export control team, regardless of the country involved. For guidance related to international travel, please visit the ECIC International Travel guidance page.*