**GUIDE:**

* *Utilize the Local Protocol Addendum Template (HRP-508) for crafting a document exclusively containing site-specific details relevant to the BetondBound location.*
* *For sections irrelevant to your study, remove the guiding text and indicate "NA," or completely eliminate the section.*
* *In the protocol segment of the eIRB+ application, submit both the sponsor's protocol document and the site-specific protocol addendum.*
* *During the creation of your Local Protocol Addendum, ensure all italicized guidance, including this message, is removed, leaving no instructional content in the document's final draft.*

TITLE OF THE STUDY: *(State the complete title of the study.)*

LEAD RESEARCHER:

*Name*

*Department endorsing or financing the study*

*Contact Number*

*Email*

DATE OF VERSION: *(Mention the date of this specific version for the site.)*

FEDERAL FINANCIAL SUPPORT:

*(If this investigation is financed by federal sources, fill out the subsequent table for each distinct source of funding. Omit this portion if there is no federal financial backing for the study. Note: The details here must align with those on the funding section of your eIRB+ submission.)*

| Funding Body: |   |
| --- | --- |
|  Sponsored Research ID#:  |   |
|  Is Human Subject Research specified in the grant's scope?(Yes / No / Unknown) |  |
|   | Organization Name:  | Evaluation of Research Involving Humans \*\*\*(examples: Non-Exempt Human Subject Research, Exempt Human Subject Research, Not Human Subject Research, etc.) |
|  Primary Funding Recipient\* |   |   |
|  Secondary Funding Beneficiaries\*\* |   |   |
|   |   |   |
|   |   |   |

*The main awardee is always involved in Human Research and must ensure IRB supervision whenever one or more of the sub-award entities carry out non-exempt Human Research. Numerous federal entities mandate that if multiple domestic locations participate in non-exempt Human Research, every location must adhere to the evaluation conducted by a “Single IRB.” Should this be relevant to your project, you are required to secure a Single IRB Support Letter and an estimate of the IRB fees from the IRB Office of BeyondBound before its IRB will consider your project for review. To commence this procedure, submit a request for a Single IRB Consultation.*

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

*\*\*\*The application for federal funding should detail plans regarding the involvement of award recipients in Human Research. Reflecting on the funding proposal, evaluate the activities at each location and revise the table accordingly if there are any changes in the planned activities or if another IRB assesses the activities and arrives at a different conclusion.*

**Eligibility Criteria:** (*Detail any criteria for inclusion or exclusion that will be unique to your local site in contrast to the protocol provided by the sponsor. As an instance, if the protocol from the sponsor permits the inclusion of minors but your site will not enroll minors, specify that distinction here.*)

**PROTOCOL ACTIVITIES:** (*Outline any activities that will vary at your location from what is outlined in the sponsor’s protocol. For example, if your site will opt out of participating in a sub-study concerning biomarkers. Additionally, use this section to detail all standard care procedures, including imaging, along with the frequency and/or quantity of these standard care procedures*.)

**Termination of Participation:** (*Outline the procedures to be implemented locally, should they diverge from those of the sponsor’s protocol, in the event of a participant's withdrawal from the study*.)

**Protection for Vulnerable Groups:** (*In cases where the study involves individuals susceptible to coercion or undue influence, describe any extra, site-specific precautions taken to safeguard their rights and well-being*.)

*Ensure all relevant checklists are reviewed to provide comprehensive information for assessment.*

* *HRP-412 CHECKLIST: Pregnant Women*
* *HRP-413 CHECKLIST: Newborns*
* *HRP-414 CHECKLIST: Newborns with Indeterminate Survival Prospects*
* *HRP-415 CHECKLIST: Incarcerated Individuals*
* *HRP-416 CHECKLIST: Minors (defined as individuals who have not reached the legal age of consent for medical treatments or procedures involved in the research)*
* *HRP-417 CHECKLIST: Adults with Compromised Decision-making Ability*

**Dissemination of Findings to Participants:** *(Outline whether and the manner in which the findings of the study or specific results pertaining to participants [such as outcomes from investigational diagnostic assessments, genetic evaluations, or incidental discoveries] will be communicated to the participants or to others (for instance, the primary healthcare providers of the participants).*

**Location Details:** *(Detail the specific venues where your research team will carry out the study. This should include:*

* *the locations where research activities will be executed.*
* *an explanation of the structure and role of any community advisory board involved.*
* *For studies taking place outside of the organization and its affiliates, provide information on:*
	+ *Any local regulations or cultural practices that could influence the research for studies conducted beyond the institution.*
	+ *The framework for scientific and ethical review applicable outside the institution.)*

**Resource Availability:** *(Elaborate on the additional resources at your disposal for executing the research, for instance:*

* *Outline the qualifications (for example, education, experience, supervision) required of you and your team to fulfill their respective roles. Where relevant, describe their familiarity with the local study environments, culture, and societal norms. Offer sufficient detail to assure the IRB of your team’s capability to undertake the proposed research. It is not necessary to list the names of individual team members in this protocol.*
* *Validate the practicality of enrolling the needed number of appropriate participants within the designated recruitment timeframe. For instance, quantify the potential participants available for recruitment. What proportion of these potential participants must you enlist?*
* *Detail the availability of medical or psychological support services for participants, should they require it due to any expected outcomes of the human research.*
* *Describe the methodology to guarantee that all individuals contributing to the study are thoroughly briefed about the protocol, the research operations, and their responsibilities and roles.)*

**Pre-Research Approvals:** *(Outline any permissions or endorsements that will be secured before initiating the study, such as approval from educational institutions, external sites, funding bodies, laboratories, radiation safety, or biosafety committees.)*

**Local Participant Recruitment Strategies:** *(This section should outline recruitment approaches that are under the jurisdiction of the local site, excluding centralized recruitment efforts managed by the sponsor. Your recruitment strategy should employ techniques specifically aimed at effectively reaching and enrolling potential participants from diverse racial and ethnic backgrounds or underrepresented populations in relation to the study. The objective is to ensure the recruitment strategy is comprehensive and reflective of the eligible demographic within the research locale, while also considering the study's implications on all such groups.*

* *Specify the timing, location, and methods for recruiting potential participants.*
* *Identify the source from which participants will be drawn.*
* *Detail the strategies to be used for identifying potential participants.*
* *Explain the materials that will be utilized in the recruitment process. Attach the relevant documents to the application. For advertising materials, include the final versions of print ads. For advertisements intended for local broadcasting, attach the final audio/video recordings. The wording for advertisements can be submitted ahead of recording to avoid the need for re-recording due to unsuitable content, ensuring that the IRB reviews the final audio/video content.)*
* *Outline any participant compensation details, including the amount and schedule of payments.*

**Local Participant Numbers:** *(State the local target number for participant enrollment. Make a clear distinction between the expected number of participants to be enrolled and screened, and the number needed to complete the study protocols (i.e., the count of participants excluding those who do not pass the screening process.)*

*Data, Sample Storage, and Privacy: (Describe the local protocols for ensuring confidentiality.*

* *Detail the local storage solutions for data or samples.*
* *Mention the duration for which the data or samples will be kept locally.*
* *Identify individuals who will have access to the data or samples within the local context.*
* *Specify who will be accountable for the local reception or dispatch of the data or samples.*
* *Explain the procedures for the local transportation of data and specimens.)*

**Privacy Protection Measures:** *(Detail the actions that will be implemented to safeguard the privacy interests of participants. "Privacy interest" pertains to an individual's right to control their interactions and the sharing of personal information.*

* *Explain the measures that will be employed to ensure participants are comfortable with the research context, focusing on the nature of the questions posed and the procedures undertaken. The aim is to mitigate any sense of intrusion that may arise from queries, examinations, and methodologies.*
* *Describe the conditions under which the research team will be allowed to access participant information.)*

***Data and Sample Storage:*** *(Should the sponsor's guidelines necessitate the archiving of data or samples for future analysis, such storage and subsequent use will be dictated by the sponsor. If there is an intention to locally store additional data or samples for future examination, specify the storage location, retention period, accessibility protocols, and the entities authorized to access these materials.*

* *List the data that will accompany each locally stored sample.*
* *Outline the protocol for the release of locally stored data or samples, including the request process, necessary approvals, eligible requestors, and the information to be provided alongside the samples.)*

**Compensation for Study-related Harm:** *(For research posing more than minimal risk to participants, describe the compensation measures for injuries related to the study. Include relevant contractual terms pertaining to compensation for such injuries.)*

**Financial Implications for Participants:** *(Identify any expenses for which participants might be liable due to their involvement in the study, such as transportation, parking, or childcare costs.)*

**Informed Consent Process:** *(Confirm whether consent will be obtained and, if so, detail the following aspects:*

* *The location where the consent procedure will be conducted.*
* *Any period of reflection offered between briefing potential participants and obtaining their agreement.*
* *Measures to ensure continuous consent throughout the study.*
* *The responsibilities of individuals named in the application regarding the consent process.*
* *The duration allocated for the consent discussion.*
* *Strategies to reduce the risk of coercion or undue pressure.*
* *Initiatives to confirm participants' comprehension of the study.*
* *\*Consult the Standard Operating Procedures for the Informed Consent Process in Research (HRP-090) for guidance.)*

*(Justify any instances where the standard consent requirements might not be met.)*

**Accommodating Non-English Speaking Participants:** *(In instances where enrollees do not speak English, detail the methodology to ensure that both oral and written communications provided to these participants are in their preferred language. Specify the languages that will be employed by those obtaining consent and by those delivering any pertinent future information.)*

**Modifications to the Consent Process:** *(If obtaining consent is not feasible, required information will not be disclosed, or the study entails deception, consult the CHECKLIST: Waiver or Alteration of Consent Process (HRP-410) to affirm that adequate details are available for the IRB to make informed decisions.)*

*(For studies involving an exemption from the consent process in planned emergency research, examine the CHECKLIST: Waiver of Consent for Emergency Research (HRP-419) to ensure comprehensive information is provided for IRB decisions.)*

**Minors as Participants:** *(Outline the criteria for assessing whether a potential participant is legally a minor in the context of the study, according to the laws of the jurisdiction where the research will be conducted. For example, individuals below the age of 18 years.)*

*(For studies within Nevada, refer to “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to understand the definition of “children” within the state.)*

*(For research outside Nevada, describe how the legal age for consent to research treatments or procedures is determined under the laws of the research location. Consulting with legal counsel or a legal authority to review your protocol, along with the definition of “children” as per “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013),” is one approach to acquiring this information.)*

*(Parental Permission Acquisition:*

*Permission will be sought from both parents unless a situation arises where one parent is deceased, untraceable, not competent, or cannot be reasonably accessed, or in cases where only one parent holds legal responsibility for the child’s care and custody.*

*Or*

 *Permission may be obtained from one parent, even if the other parent is alive, locatable, competent, reasonably accessible, and shares legal responsibility for the child’s care and custody.*

 *(Permission may also be sought from individuals other than parents, where applicable. The eligibility of these individuals to grant permission will be determined based on their legal authority to make general medical decisions for the child).*

*(Assent will be sought from all, some, or none of the children involved, depending on their capacity to understand the research. If assent is required from certain children, the criteria for these children will be clearly defined).*

 *(When the assent of children is obtained, it will be documented directly within the consent form. While the IRB does not usually mandate separate assent forms or require children to sign assent documents, these options are provided within the template consent document for those who choose to use them).*

**Determining Consent Capability in Adults with Impaired Decision-Making:** *(The process to determine an adult’s ability to consent involves evaluating their understanding and decision-making capacity. Documentation of assent for individuals with impaired decision-making capacity will be incorporated directly into the consent document. Separate assent documents or signatures from these adults are not routinely required but are available options in the template consent document).*

**Consent for Adults Unable to Consent Themselves:** *(Permission will be sought from individuals in a prioritized order, including durable power of attorney for healthcare, court-appointed guardians for healthcare decisions, spouses, and adult children.*

* *For research conducted within Nevada, “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” should be reviewed to identify those recognized as “legally authorized representatives.”*
* *For studies outside Nevada, it is necessary to define who are considered legally authorized representatives under the relevant jurisdiction's laws. Consulting legal counsel or an authority to review the protocol and the definition of “legally authorized representative” as per “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” is advised to ascertain this information.*

*Participant Assent Process:*

* *Assent Requirement: Assent will be required from:*
	+ *All participants, some participants, or none, depending on specific criteria set forth for the study.*
	+ *If assent is required from some participants, those required to give assent and those exempt will be clearly identified.*
	+ *If assent will not be obtained from some or all participants, a rationale for this decision will be provided.*
* *Documentation of Assent: The process for documenting assent will be defined. While the IRB permits assent documentation directly within the consent document and does not typically necessitate separate assent forms or participant signatures, these options are integrated into the consent document template for use as needed.*
* *Obtaining Consent from Previously Incapable Participants: The procedure for securing consent from participants who were initially unable to consent on their own will be delineated.*

**Documentation of Consent in Writing:**

* *The method and process by which participant consent will be recorded in writing will be described, adhering to IRB requirements and preferences for documentation.*

**Management of Study Interventions/Investigational Agents:**

* *Storage, Handling, and Administration: Detailed plans for the storage, handling, and administration of investigational drugs or devices will be outlined, ensuring their exclusive use on subjects by authorized investigators.*
* *SOP Reference: If the control of drugs or devices follows an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs), this SOP will be referenced herein.*
* *Investigational Drugs Protocols: For investigational drug research at NMH, the IDS Pharmacy will be utilized for storage, dispensing, and control, applicable to both inpatient and outpatient scenarios. Additional details can be found on the IDS Pharmacy website or via contact at their dedicated email.*
* *IND/IDE/Abbreviated IDE Information: For investigational drugs (with an IND) or devices (with an IDE or an abbreviated IDE claim for non-significant risk devices), the following will be included:*
	+ *Identification of the IND/IDE/Abbreviated IDE holder.*
	+ *Explanation of the procedures adhered to for complying with sponsor requirements regarding FDA-regulated research.*

| ***Applicable to:*** |
| --- |
| ***Compliance with FDA Regulations***  |  ***IND******Research*** |  ***IDE*** ***Research*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

MULTI-SITE OR COLLABORATIVE RESEARCH:

Multi-site and collaborative research involves the participation of researchers from BeyondBound and other institutions, or individual investigators from outside, in conducting the study. Please provide the details requested below:

* Identify the institutions or individuals participating in this research.
* Describe the roles and activities of these institutions or individuals in the research.
* Determine whether each participating institution or individual will conduct their own IRB review of their activities, or if a single IRB will act as the IRB of Record.

If there is any uncertainty about how to proceed with IRB review and oversight for your multi-site or collaborative study, confirm your agreement with the statements below:

* Research activities at external locations will not commence until either local IRB reviews are initiated or reliance agreements are fully in place.
* Necessary approvals or permissions from external sites will be secured by their respective research teams, adhering to their local guidelines.
* Upon availability, IRB approval notifications from external sites, evidence that IRB review is not required at those sites, or fully implemented reliance agreements will be submitted alongside protocol amendments.
* Any deviations from the approved study protocol or relevant regulations will be reported following local procedures.

If a single IRB is to oversee all involved parties or institutions in the research, identified as reliance, please outline a comprehensive reliance strategy:

* Is reliance required by federal regulations or a sponsor's stipulations?
* For federally sponsored research, who is the primary recipient of the funding?
* Which institution or individual is suggested to act as the IRB of Record for all involved entities?
* What form of reliance agreement will be adopted?
* Specify the timeline for integrating institutions or individuals. When BeyondBound is suggested as the IRB of Record, our preference is to initially review the site and the study's broad objectives before incorporating other participants through modifications supported by fully signed reliance agreements. Incorporating them during the initial review might postpone the initial approval.
* Describe how changes to the study's procedures will be communicated and approved by all participating entities before implementation, and how these participants will be informed of any issues, interim results, or the conclusion of the study? Refer to WORKSHEET: Communication and Responsibilities (HRP-830).
* Detail the measures in place to ensure participant data protection. All parties must adhere to data security protocols, including secure data transmission, as mandated by relevant local, state, and federal laws.

Reliance agreements are official contracts among institutions allowing one IRB, institution, or investigator to depend on another's IRB for human research review. BeyondBound's IRB will not act as the IRB of record for another entity without a mutual agreement. For more details, visit our website: https://beyondbound.org/

If your project is a non-exempt, federally funded, human study conducted at multiple sites, you might need to establish a Single IRB through reliance agreements. When BeyondBound acts as the Single IRB, certain fees may apply.