| **Determining the suitability of this document for your needs:** Should your sole research activity involve the examination of data or samples, and there is no intention to collect biological specimens exclusively For research objectives, then this document serves as the correct protocol template. This includes scenarios such as reviewing medical records, intending to evaluate data or biological samples previously gathered in past research efforts, or data accessible from student academic records, public sector databases, and so on.  Should your research encompass methods beyond the analysis of data or samples (for example, conducting surveys, performing interviews, or collecting biological specimens), this protocol template should not be utilized. Instead, refer to the suitable protocol template available on the IRB website at <https://beyondbound.org/>  If your initiative does not constitute research involving human participants, or if there is uncertainty about whether it qualifies as research on human subjects, you should complete and submit the Human Research Determination Form (HRP-503) rather than this document. This form is designated solely for projects that are identified as research involving human subjects (further information on when the analysis of data or samples necessitates IRB examination can be found further down on this page).  Is the information or the specimens identifiable? If they are de-identified, this protocol template should not be applied.  In cases where your project exclusively focuses on the analysis of de-identified information and/or specimens, without being integrated into broader human subject’s research, IRB scrutiny is not mandatory for the examination of such de-identified materials. Should a formal decision from the IRB be required, confirming that the analysis of de-identified data or specimens does not fall under research involving human subjects, you should submit the Human Research Determination Form (HRP-503) via the eIRB+ system.  Typically, data or specimens are deemed identifiable if they can be associated with specific individuals by the investigator, either directly or indirectly through coding systems, or if the attributes of the data acquired are such that a person with reasonable knowledge could identify the subjects. It's important to remember that a dataset may be devoid of direct identifiers (for example, names, addresses, or student identification numbers), yet it might still be possible to identify someone through the aggregation of other details (such as age, gender, ethnicity, or workplace). For more insights on when data and specimens are considered de-identified, refer to the Guidance on Research Using Coded Data and Specimens by the HHS Office of Human Research Protections. If there is any uncertainty regarding the status of your data or specimens as de-identified for IRB purposes, it is advisable to reach out to the IRB for clarification.  What should be done if the data provider demands an IRB exemption or approval? |
| --- |

| The protocol template starts beneath the red line – kindly fill in all the requested details below and submit your finished protocol through the eIRB+ platform under the "Basic Information" segment of the electronic application form, specifically at Question 8, where you are prompted to "Attach the protocol." Ensure that every member of the research team has completed the most recent training on human subjects – additional details regarding training on the protection of human subjects can be found at: [BB website link]. |
| --- |

1. **PROTOCOL TITLE: (include full study title)**
2. **VERSION DATE: (MM/DD/YYYY)**
3. **BeyondBound or affiliate RESEARCH TEAM**

**PRINCIPAL INVESTIGATOR:**

Name

P.I. Department sponsoring/supporting the study

Telephone Number

Email Address

**STUDENT INVESTIGATOR** [if applicable]:

Name

Department

1. **FEDERAL FUNDING:**

(If this research is financed through federal funds, please fill out the matrix below. For each distinct funding source, include extra matrices as necessary. This section should be omitted if the study does not receive federal funding. Note: The details provided here must align with the information entered on the funding page 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 award recipient is invariably involved in Human Research and is required to have IRB oversight whenever any sub-award recipients undertake non-exempt Human Research. Numerous federal agencies mandate that if multiple domestic sites are involved in non-exempt Human Research, all such sites must depend on the evaluation of one "Single IRB." Should this be relevant to your research, it is necessary to secure a Single IRB Letter of Support and an IRB Fee Quote from the BB IRB Office before the BB IRB can proceed with reviewing your study. To commence this procedure, please submit a Single IRB Consultation Request.

\*\*Incorporate the activities conducted by all sites not affiliated with BB in the section dedicated to multi-site/collaborative research within the protocol below.

\*\*\*The application for federal funding must detail the involvement of award recipients in Human Research. Relying on the information from the funding application, evaluate the tasks at each location and revise the table accordingly if there are changes to the planned activities or if another IRB evaluates the activities and reaches an alternative conclusion.

**5. OBJECTIVE OF THE STUDY:**

* Outline the issue or condition under investigation – what are the key research questions or hypotheses? In what ways is the study designed to extend its findings beyond the immediate circumstances in which the data or specimens were obtained?
* Identify the final goal and target audience(s) for the findings of the research.

**6. CRITERIA FOR INCLUSION/EXCLUSION**

Detail the specific characteristics of the population that will guide the selection of data or specimens for analysis in this study (for instance, diagnosis of particular medical conditions/diseases, defined age groups, gender, data sourced from prisoners, pregnant women, etc.). Indicate the age spectrum of the individuals from whom the data or specimens were gathered, and clarify if any of the data or specimens originated from individuals below the age of 18.

**7. INVOLVED PROCEDURES**

Type of study: Specify whether the study is 1) retrospective; 2) prospective; or 3) a combination of both retrospective and prospective. NOTE: If the plan involves collecting biospecimens in the future exclusively for research (for example, via biopsies), this template is not applicable.

☐ Retrospective Analysis (the data and/or specimens are already available at the point of submitting this study for initial review by the IRB) Timeframe for the data/specimens under review:

☐ Prospective Analysis (the data and/or specimens are not available at the moment of submission to the IRB for initial review – this template may be used for specimens gathered for purposes other than research, such as clinical treatment or diagnosis)

☐ Combined Retrospective and Prospective Analysis Timeframe for the data/specimens under review:

**8. DETAILS OF THE DATA/SPECIMENS FOR ANALYSIS**

* Identify the datasets/specimens you intend to analyze, including the source of the data/specimens and the original collector. Enumerate the specific data elements to be analyzed, or alternatively, you may choose to append a detailed list of these data elements to this protocol as an appendix. Note: To de-identify information in accordance with the HIPAA Privacy Rule, a covered entity must eliminate all 18 identifiers that could be used to recognize the individual or the individual's family, employers, or members of the household – for more information on the identifiers that must be removed for de-identification under HIPAA, visit [info@beyondbound.org](mailto:info@beyondbound.org)
* Clarify whether the data/specimens were obtained from a prior research project, collected through a governmental initiative or as a routine part of an organization’s operations, or gathered for different reasons. If the data/specimens were initially amassed as part of a study reviewed by the BB IRB, mention the BB IRB study number(s) allocated to the former study. If accessing specimens from a biobank/biorepository, indicate the specific biobank/biorepository supplying the specimens.
* Include web links to descriptions of the datasets if such information is accessible. Should the analysis involve numerous datasets, detail each one separately, including the custodian of each dataset. If you have prior access to the data/specimens not related to this study (for instance, as part of your professional duties), provide an explanation for this access.
* Detail if utilizing the data/specimens necessitates any specific permissions, restrictions, and/or agreements (such as a data use agreement (DUA), data transfer agreement (DTA), or material transfer agreement (MTA)). If there exists a DUA, DTA, MTA, or any other kind of agreement, submit this agreement in the Supporting Documents section of the eIRB+ application.
* IMPORTANT: Data suppliers frequently mandate that researchers agree to terms of data exchange or similar contracts that detail data protection protocols and related confidentiality commitments. In every instance, lead researchers must assess their capacity to adhere to these data protection standards. Should you require support in fulfilling data security obligations? It is not permissible for researchers to execute a Data Use Agreement (DUA), Data Transfer Agreement (DTA), or Material Transfer Agreement (MTA) in the name of the University.
* Do the data/specimens come with any associated identifiers? If affirmative, kindly enumerate the specific types of identifiers present (for instance, names, telephone numbers, home addresses, social security numbers, etc.). If convenient, you may choose to provide a detailed list of these identifiers as an additional appendix to this document.
* In cases where the data/specimens currently possess identifiers but are scheduled to have these removed before the initiation of your analysis: who is responsible for or will take on the responsibility of de-identifying the data/specimens? Will this individual participate in the study in any capacity?
* Is there a linkage between the data/specimens and individuals via a unique code? If so, is there anyone in the research team granted access to the key that connects these codes to individual identities? Should the research team have access to this key, where will the key that associates’ codes to specific identifiers be safeguarded?

**9. DATA AND SPECIMEN HANDLING PROCEDURES**

* Detail the methodologies for accessing, transmitting, and storing the data or specimens. Include any limitations set by the data provider regarding data access and storage locations.

NOTE: Should there be plans to utilize clinical data obtained from NMHC EMR or other clinical systems for research purposes, adherence to the University and Hospital's Permissible Use Policy is mandatory.

* Upon completion of your analysis, outline the procedures for handling the data or specimens. If there is an intention to destroy the data or specimens at the end of the study, provide a description of the destruction method.
* Indicate whether there are intentions to retain any of the data or specimens for an extended period or to deposit them into a databank, biobank, or registry. If so, specify the purposes for long-term storage and the locations where these will be maintained.
* Offer additional details pertinent to the measures you will implement to maintain the confidentiality of the data or specimens.

**10. EVALUATION OF POTENTIAL RISKS**

Explore the potential risks, including both the likelihood and severity of these risks, that might arise from a confidentiality breach. This discussion should encompass social, economic, legal, reputational, or other forms of harm that could impact individuals or a collective/group.

**11. SOCIETAL BENEFITS OF THE PROJECT**

Discuss the potential advantages this project could offer to society at large.

**12. INFORMED CONSENT AND CONSENT WAIVER PROCEDURES**

* Where relevant, detail whether consent was secured from participants in the original study or program from which the data/specimens were derived. It's important to note that not all data collection efforts necessitate consent (for instance, certain types of governmental or private sector data).
* Should you seek a waiver for informed consent for this research, provide justification that your request satisfies the criteria listed below:
* The study poses no more than minimal risk to participants;
* The waiver or modification will not negatively impact the rights and well-being of the subjects from whom you are collecting data;
* The study could not feasibly be conducted without the consent waiver;
* If the research involves the analysis of identifiable private information, it could not feasibly be conducted without using the information in an identifiable manner;
* Whenever suitable, individuals will be offered further details regarding their involvement in the research (though this is often not required for projects analyzing secondary data).
  + IMPORTANT information concerning student education records protected by the FERPA law: According to FERPA regulations and law, the standard procedure requires obtaining consent from a parent or the student (at the university level, consent must be from the student) to access personally identifiable information within student education records. The Institutional Review Board (IRB) is not in a position to waive consent for research purposes that necessitate access to personally identifiable information in student educational records, except in situations where the data under consideration is classified as “directory information” or the research project qualifies for an exemption from FERPA’s consent prerequisites.

**13. HIPAA AUTHORIZATION AND REQUEST FOR WAIVER**

* If the data are considered protected health information (PHI) under HIPAA and were collected prior to this research endeavor, the Institutional Review Board (IRB), acting as the HIPAA Privacy Board, will evaluate the possibility of waiving the HIPAA Authorization requirement.

Should you seek a waiver for HIPAA authorization for this study, please provide a rationale demonstrating your request fulfills the criteria outlined below:

* The proposed use or disclosure of protected health information poses no more than minimal risk to the privacy of individuals. This assessment is based on the inclusion of the following measures:

1. A comprehensive plan to safeguard identifiers against improper use and disclosure.
2. A robust plan for the destruction of identifiers as soon as possible in alignment with the research's execution, unless retaining the identifiers is justified by health or research needs, or retention is mandated by law.
3. Sufficient written guarantees that the protected health information will not be repurposed or shared with any third party, except as legally required, for authorized research oversight, or for additional research where the use or disclosure of protected health information is allowed under the HIPAA Privacy Rule.

* The research could not feasibly be conducted without the waiver or modification; and
* The research could not feasibly be conducted without the access to and utilization of the protected health information.

NOTE: On handling mental health and developmental disabilities information analysis: Under the Nevada Mental Health and Developmental Disabilities Confidentiality Act (NMHDDCA), researchers aiming to analyze mental health information or "all medical records" must obtain consent from both the research participant and a witness on the consent form. It's important to note that a waiver of HIPAA authorization cannot be issued for research projects intending to access records for information on mental health or developmental disabilities services. The NMHDDCA is applicable to records concerning mental health and developmental disability services maintained by a therapist or an organization offering such services. The definition of a therapist within this context is extensive and encompasses a range of professionals including psychiatrists, doctors, psychologists, social workers, nurses, mental health therapists, mental health counselors, among others who provide similar services. Records related to mental health or developmental disabilities services cover a variety of documents, including those pertaining to physical or mental assessments; diagnostics, treatments, or training; evaluations; medication details; aftercare, habilitation, and rehabilitation plans; and service provision notes (excluding references to receipt of mental health or developmental disabilities services mentioned in a patient's history, physical, or other care summaries).

**14. GUIDELINES FOR MULTI-SITE OR COLLABORATIVE RESEARCH:**

In scenarios involving multi-site or collaborative research, where researchers from BeyondBound alongside those from other institutions or independent external investigators engage in the research process, the following details are required:

* Identify the institutions or individuals participating in the research.
* Describe the roles or activities that these institutions or individuals will undertake within the research framework.
* Clarify whether each participating institution or individual will have their IRB review their respective activities, or if a singular IRB will function as the IRB of Record for all involved.

In instances where there is uncertainty regarding the approach to IRB review and oversight for your multi-site or collaborative research, ensure adherence to the following guidelines:

* No research activities will be initiated at external locations until the local IRB has conducted a review or until reliance agreements are officially in place.
* Any necessary approvals or permissions from external sites will be obtained by the respective external research teams, following their local procedures.
* Documentation such as IRB approval letters from external sites, evidence indicating that IRB review at external sites is not required, or signed reliance agreements will be submitted as soon as they are available, along with any updates to the protocol.
* Any deviations from the study protocol or violations of relevant regulations will be reported following the established local policies.

If a single IRB will act as the IRB of Record for all entities involved in the research, often referred to as a reliance agreement, a comprehensive reliance plan is essential. Please provide the following information in your reliance plan:

* Determine whether reliance is necessitated by federal guidelines or a sponsor's stipulations.
* If the research receives federal funding, identify the primary recipient of the award.
* Nominate the proposed IRB of Record that will oversee all participating sites.
* Specify the form of reliance agreement that will be employed.

Outline the timeline for onboarding institutions or individuals. When BB is nominated as the proposed IRB of Record, it is preferred to initially review the BB site and the overall scope of the study, subsequently incorporating other sites or individuals through modifications under fully executed reliance agreements. Incorporating external parties during the initial review may result in delays in receiving initial approval.

* Describe the process for communicating changes in study procedures to all participating sites or individuals, ensuring these changes are approved before implementation. Detail how updates, including notifications of any issues, interim findings, or the study's conclusion, will be shared. Refer to the WORKSHEET: Communication and Responsibilities (HRP-830) for guidance.
* Explain the measures that will be taken to ensure participant protection across all sites. This includes managing data security, such as the secure transfer of data, in accordance with relevant local information security policies, state laws, and federal regulations.

Reliance agreements are official contracts among institutions that allow one Institutional Review Board (IRB), institution, or individual to depend on the IRB of another for the oversight of human research. The BB IRB will not act as the IRB of record for another IRB, institution, or individual without a mutual agreement to this effect. For more detailed information, please refer to our website <https://beyondbound.org/> or call at tel:(646)2170403

For non-exempt, federally funded human research projects conducted at multiple sites, you may need to set up a Single IRB arrangement through reliance agreements. Should BB serve as the Single IRB, certain fees could apply. Additional details can be found on our website <https://beyondbound.org/> or call at tel:(646)2170403.