The IRB Office at BeyondBound is mandated to conduct reviews of Human Research in instances where any entities under an IRB service agreement are actively involved. Before commencing any human research endeavors, investigators must submit their proposals for evaluation. BeyondBound, alongside its partner organizations and those entities receiving IRB services will thereafter be collectively known as the "Institution(s)." The requirement for an IRB evaluation applies exclusively to activities classified as “research” that involve “human subjects,” according to definitions provided in the DHHS, FDA, or other relevant regulations (refer to Sections 1/2 for further details).

Investigators have the autonomy to assess if their work constitutes research involving human participants. Should you find it challenging to ascertain if your endeavors align with the regulatory criteria for "research" involving "human subjects," or if you require the Institutional Review Board (IRB) to review your project for an official verdict, along with documentation confirming that your study does not involve human subjects research, please fill out this form completely and submit it as an alternative to a comprehensive protocol within a new study application through the BeyondBound IRB website.

Should you conclude during your assessment of this form that your proposed activity qualifies as Human Research, please initiate a new study application through the BeyondBound IRB website. You are required to draft and upload a protocol, and if applicable, an informed consent form, utilizing the latest templates provided by the IRB for protocols and consents.

Consult the Appendix located at the conclusion of this document, which contains examples of activities typically not regarded as Human Research yet still necessitate IRB review.

**NOTE:** The Institutional Review Board (IRB) is only able to make such determinations before the commencement of the activity. Determinations regarding the nature of the activity as Human Research will not be made by the IRB after the activity has started. To facilitate these determinations, the IRB Office employs the "WORKSHEET: Human Research Determination" (HRP-310). It is recommended that you refer to this worksheet as a reference prior to submitting your application.

If the Institution(s) (for example, BeyondBound) receives a primary federal award (such as from the NIH, NSF, DoE, DoD) and external entities are involved in conducting human subject research, then the human research determination form is not suitable. This is because the Institution(s) itself is engaged in human subjects’ research. In scenarios where the Institution(s) is the main recipient of the award and the grant proposal identifies the project as involving human subject research, the project will be classified as human research. In such cases, this determination form should be accompanied by a human research application and related study documents.

| **SECTION 1:**  Utilize the details provided in subsections A and B to ascertain whether your project qualifies as research involving human subjects according to the definitions set forth in the federal guidelines for the federal entities that have implemented the Updated Common Rule. PLEASE NOTE: In instances where research is not subject to regulation by another federal supervisory body, BeyondBound's IRB employs the Updated Common Rule as its standard for evaluating research activities. |
| --- |
| **PART A: DETERMINATION OF “RESEARCH”** |
| **CFR 46.102(d):** **Research** - constitutes a systematic inquiry, encompassing the development, examination, and assessment of research, aimed at fostering or augmenting knowledge that can be generalized.  This **systematic** inquiry entails a deliberate plan, methodology, or strategy for investigating a particular subject, addressing a certain query, verifying a specific supposition, or formulating a theoretical framework. Such an approach involves the gathering of data or biological specimens and the execution of quantitative or qualitative analyses.  Activities **intended to foster or enhance generalizable knowledge** refer to those endeavors aimed at deriving broad conclusions, influencing policy, or extending findings beyond the particular group, organization, or institution involved (that is, to contribute significantly to the discovery or enlargement of universally relevant truths, facts, and information). |
| Is the proposed activity based on a **systematic** methodology?  ☐YES\* ☐ NO  Is the objective of the proposed activity to foster or **contribute to knowledge that can be generalized**?  ☐YES\* ☐NO  \*If the answer is **YES** to **both** questions 1 & 2, then the activity is classified as **research.** |
| **PART B: DETERMINATION OF “HUMAN SUBJECT”** |
| **CFR 46.102(f):** ***Human subject*** - refers to any living person whom a researcher (be it faculty, student, or staff) engaged in a study collects information from, by either: **(1)** gathering data through an ***intervention*** or ***interaction*** with the person; or ***(2) acquiring identifiable personal information.***  **An intervention** encompasses physical procedures used to collect information (for example, blood draws) as well as changes made to the subject's environment or to the subject directly for the purposes of the study.  **Interaction** involves any form of communication or personal contact between the researcher and the participant.  **Personal information** pertains to details about behavior that takes place in settings where an individual expects privacy and that no observations or recordings are being made, and data that an individual has shared for specific reasons with the expectation that it remains confidential (for example, health records). Such personal information must be able to be linked back to the individual.  **Identifiable** means the researcher can potentially determine the subject's identity or associate the information with the individual. The study might include utilizing coded data or specimens.  **Coded** refers to instances where identifiable details about a person, like their name or social security number, are replaced with a code, such as a number, symbol, or combination thereof, with a key available to match the code back to the individual's identifiable details. Under the Common Rule, coded data are treated as identifiable. |
| ***Use the definitions above to answer the following questions.*** |
| 1. Does the project include collecting data about living persons via interventions or interactions with those individuals?  ☐YES\* ☐NO  If the response to question #1 is YES, the project involves human subjects.  If the answer to #1 is NO, does the project collect protected health information (PHI) regarding deceased individuals?  ☐YES ☐NO ☐N/A  \*If YES, the criteria below must be met:   1. The access or sharing of information is exclusively for the research concerning the PHI of deceased individuals; and 2. The PHI is essential for the research endeavors. 3. Upon request from the overseeing entity, the Principal Investigator must furnish proof of the individual(s)'s death.   2. Does the project entail collecting identifiable and private information about living persons?  ☐YES\* ☐NO  \*If YES to question #2, the project involves human subjects.  3. Is the project concerned with the utilization of coded private data or specimens?  ☐YES\* ☐NO  4. If YES to question #3, the researchers are not in a position to easily identify the individuals associated with the coded private data or specimens because:  a. There exists an agreement between the key holder and the researcher that prohibits the disclosure of the key to the researcher under any circumstances until after the individuals have passed away. A document of this agreement (an informal email communication suffices) is to be provided.  OR  ☐YES ☐NO\*  b. The researcher possesses confirmation of established policies and procedures from a repository or data management entity that prevents the sharing of the key with researchers under all circumstances until after the death of the individuals involved. Submission of these policy and procedure documents is required.  ☐YES ☐NO\*  c. Additional legal stipulations prevent the disclosure of the key to researchers until after the individuals have passed away. Submission of evidence pertaining to these legal stipulations is necessary.  ☐YES ☐NO\*  \*If the answer is YES to question #3, but NO to options 4a, 4b, or 4c, the activity includes human subjects. In this case, please prepare and submit a research protocol through eIRB+.  \*If the response is YES to question #3, and also YES to any of the options 4a, 4b, or 4c, then the activity does not involve human subjects. Ensure this completed document is preserved in your research records. |

| **SECTION 2:**  **Answer the questions below to determine if the proposed activity is human subjects research as defined by the FDA.** |
| --- |
| **PART A: DETERMINATION OF “HUMAN SUBJECT”** |
| **21 CFR 50.3(g):** Human subject refers to a person who participates in a research study, whether by receiving the test article or serving as a control. This encompasses both individuals in good health and patients. |
| **Use the definition above to answer the following questions.** |
| 1. Is the project involving human subjects as delineated by FDA guidelines?  a. Will an individual be receiving any test article (for instance, a drug, biological product, or medical device) or act as a control?  ☐YES\* ☐NO  b. Will a test article be utilized on an individual's specimen+ (according to 21 CFR 812.3(p)) (for example, In Vitro Diagnostic (IVD)++ device, drug, biological product)?  ☐YES\* ☐NO  **Note:** FDA regulations (21 CFR Parts 50 and 56) are applicable to all clinical investigations overseen by the FDA as well as other clinical studies that contribute to applications for research or marketing approvals. Consequently, all investigations of investigational IVDs intended to support submissions to the FDA fall under the purview of 21 CFR Parts 50 and 56, even if they do not meet most criteria of 21 CFR Part 812. Refer to the FDA's Guidance on In Vitro Diagnostic Device Studies - FAQs for additional details.  +Specimen – this term includes the use of residual specimens that cannot be linked to specific individuals (e.g., portions of human specimens collected for regular clinical care or testing that would have been otherwise disposed of).  ++In vitro diagnostic products (IVD) encompass those reagents, instruments, and systems designed for use in diagnosing diseases or other conditions, including assessing health status, with the aim to cure, alleviate, treat, or prevent disease or its consequences. |

Should the answer be **YES** to any of the preceding, **STOP at this point**.



If your project involves research with human subjects, it necessitates approval from the Institutional Review Board (IRB) prior to commencement. Please prepare a comprehensive protocol and submit a Human Research Application via eIRB+.

IF **NO,** kindly fill out the following form with detailed information regarding the activity and its funding.

| **SECTION 3: ACTIVITY INFORMATION FORM** |
| --- |
| 1. Explain the objective of the proposed activity. (Clarify the rationale and motivation for your actions, and the reasons behind them) |
| 2. Offer a detailed account of the methods to be employed. |
| 3. Detail the demographic or the nature of the data/specimens under investigation. |
| 4. Were the data/specimens initially gathered exclusively for research objectives?  ☐YES\* ☐NO ☐N/A  \*If the answer to question **#4 is YES**, the Institutional Review Board (IRB) might require submission of the IRB Approval Letter and the Consent Form from the original investigation. The IRB will examine these documents to ensure that the utilization of the data/specimens is in alignment with what was agreed upon by participants in the informed consent document. |
| 5. Clarify the origin of the data/specimens (i.e., specify from where the data/specimens were sourced).  **☐Not Applicable – The activity does not utilize data/specimens.**  **☐Utilization of a Research Biorepository/Registry [Supply the IRB Project STU number or the name of the external Repository/Registry]**  **AND/OR** |
| 6. Describe the method by which the data/specimens will be delivered to the researcher (for instance, the researcher will request de-identified data from the EDW; the researcher will receive a pre-existing, de-identified dataset, etc.). Specify the party responsible for de-identifying the data and/or specimens, along with the process through which the data and/or specimens will be de-identified.  OR **☐N/A** |
| 7. Detail every data point, variable, or piece of information that will be gathered or examined for this initiative.  OR **☐N/A**  Notes:  • Access is restricted to the elements specified in this section. Any changes or additions must be communicated to the IRB.  • Ensure that the details you have shared here do not contain private identifiable information (i.e., the 18 PHI Identifiers). |
| 8. Kindly articulate in your own terms the reasons you consider this study does NOT constitute Human Research. (Refer to the relevant categories listed in the Appendix provided, as applicable). |
| **FUNDING** |
| Will the project receive Federal funding (for example, from NIH, NSF, DoE, DoD) awarded directly to the Institution(s) (that is, BeyondBound or its affiliated entities is the primary recipient)?  **☐YES\* ☐NO**  \*If the answer to **#1 is YES**, please attach the relevant InfoEd Number on the Funding Information section within the eIRB+ platform. If BeyondBound does not receive the funds, list the original funder (e.g., NHLBI), the primary award recipient, and any sub-award recipients in the protocol document you submit in the eIRB+ system.  NOTE: If the Institution (such as BeyondBound) is the primary beneficiary of a federal grant (like NIH, NSF, DoE, DoD), and one or more external organizations will partake in human subject research, then the human research determination form is NOT suitable because the Institution(s) are also participating in human subject’s research. In this case, you must fill out a Human Research Application.  2. Is this project identified as human subject research in the grant, contract, or cooperative agreement application?  **☐YES ☐NO**  NOTE: If the Institution(s) (for instance, BeyondBound or its affiliated institutions) is the main recipient of the award and the application specifies the project as human subject research, it must be accompanied by a human research protocol and related study documents. This will be regarded as human research. |

**APPENDIX:**

The activities listed below are usually not classified as Human Research according to the criteria in Sections 1 and 2. If your project exclusively involves one of the examples listed, it is likely not considered Human Research and does not necessitate IRB review. It's important to note that the intention to publish does not influence the classification of an activity as Human Research.

**1.1 Quality Assurance/Improvement and Program Evaluation Projects:**

This pertains solely to activities focused on quality assurance/improvement or program evaluation, aimed specifically at assessing, ensuring, or enhancing performance within a department, classroom, or hospital environment.

Refer to the IRB Guidelines on Quality Improvement and Program Evaluation Projects for further insights on how these activities differ from research activities and for more comprehensive considerations.

**1.2 Case Report or Case Series:**

A case report involves the documentation and presentation of a single instance to showcase a notable experience, observation, treatment, presentation, relationship, or outcome. A case series aggregates a small number of case reports, typically 2-5 instances. This often stems from a retrospective analysis of patient records but may also include a prospective intervention or the prospective gathering of specimens or data not included in standard services or care. Conducting tests on a patient's biospecimen (for example, special staining, immunohistochemistry, molecular analyses) usually falls outside the scope of a case report. A key aspect is the absence of any "research" intention prior to the patient(s)'s involvement.

**1.3 Course-Related Activity:** *The initiative is confined to one or more activities associated with a course, specifically aimed at educational or instructional objectives, where data collection from and regarding students occurs as part of standard classroom exercises or tasks and does not fulfill the criteria of Human Research as described in Section 1.0.*

Classroom assignments designed to systematically gather information with the aim of contributing to or enhancing generalizable knowledge are recognized as “research” under federal guidelines. Such assignments are subject to Institutional Review Board (IRB) governance and necessitate an IRB application, approval, and supervision. Educators intending to implement these types of assignments are required to seek review and authorization from the relevant IRB before commencing.

Assignments may fall under IRB oversight if there is a change in how the faculty or students intend to utilize the data. Should the faculty or students decide to use data derived from classroom assignments for research and publication purposes, the faculty member is obligated to submit these plans to the IRB and secure approval prior to initiating these activities.

**1.4 Journalistic or Documentary Activities (including Oral History)**: This type of activity is confined to conducting research or carrying out interviews (whether they are structured or unstructured) centered around particular occurrences (whether they are contemporary or historical), perspectives, etc. These research activities or interviews can be communicated or made public through various channels (for instance, newspapers, documentary films, or online publications).

**Oral History:**

The Office for Human Research Protections (OHRP) has clarified that oral history interview activities are typically not aimed at contributing to knowledge that can be generalized, and therefore, they do not qualify as research under the Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d). As a result, they do not require examination or approval by an institutional review board (IRB).

However, this does not imply that the application of oral history techniques invariably obviates the need for an IRB review. The applicability of this OHRP policy to a particular project is contingent on the researcher's objective. Employing oral history methods as part of a systematic study aiming at deriving generalizable insights about living individuals would be categorized as “human subjects research” according to federal regulations.

**1.5 Study Involving Public or Anonymous Private Information on Living Individuals**: This task involves examining information about living people (1) where the researcher has obtained the data from open, accessible datasets, or (2) where personal data have been shared with the researcher devoid of any accompanying identifiers that would allow the researcher to determine the identity of the subjects.

**1.6 Study Involving Health Information of Deceased Individuals:** This activity focuses solely on the analysis of data (whether identifiable or not) pertaining to individuals who have passed away.

*NOTE: It's important to recognize that, according to the Department of Health and Human Services (DHHS), deceased individuals do not qualify as Human Subjects. However, under FDA regulations, they might be considered Human Subjects. For further understanding, please refer to the definitions provided earlier. Additionally, be aware that HIPAA and possibly other state or local regulations might still be applicable to this research. It's advised to seek further direction from the organization from which you obtained or accessed the information for this study.*

**1.7 Preliminary Activities (for exploratory and developmental purposes**):

Preliminary activities refer to small-scale efforts aimed at formulating and refining the research plan or specific elements of the research plan (for example, the design, methodology, or instrument(s)) before executing a more comprehensive study.

Development of Instruments/Questionnaires is confined to interactions with individuals to gather feedback on the types of questions that could or should be incorporated to create an instrument or questionnaire. The emphasis is on crafting and designing a tool for data collection rather than on the individuals providing input on the questions being formulated. This remains the case even when feedback is deliberately solicited from a particular group of individuals most impacted by the subject matter of the instrument, survey, or questionnaire. The process of developing the instrument/questionnaire encompasses various aspects of testing the reliability and validity of the tool. However, once the activity progresses to assessing discriminant, concurrent, or predictive validity, it may necessitate reevaluation as human subject research.

**Note:** If you or your team requests additional information from participants that is not directly related to the development of the instrument/questionnaire, such as demographic details intended to be analyzed in a research study, the project may require submission for IRB review.

It's important to recognize that some preliminary activities do not fall under the definition of research because they do not constitute part of a systematic investigation. Examples include:

* Visiting a potential site to assess the feasibility of conducting research there.
* Testing the clarity of consent forms with acquaintances to ensure comprehensibility.
* Distributing your newly developed survey to a handful of experts within the field for feedback on the suitability of questions for the intended topic and/or study demographic.
* Soliciting advice from colleagues and peers regarding the research design.
* Engaging with a community advisory board (such as a tribal committee/council) for input on the proposed research focus and/or the most appropriate methods for conducting the study.

1.8 Institutional Engagement:

According to the Office for Human Research Protections (OHRP), an institution is deemed engaged in a specific non-exempt human research project if its employees or agents, in the context of the research project, carry out any of the following: (1) acquire data about the research subjects through intervention or interaction with them; (2) obtain identifiable private information about the research subjects; or (3) gather informed consent from the human subjects for the research.

Additionally, an institution is considered engaged in non-exempt human research if it is the recipient of "an award through a grant, contract, or cooperative agreement directly from the Department of Health and Human Services (HHS) for the non-exempt human subjects research (i.e., awardee institutions), even if all activities involving human subjects are conducted by employees or agents of another institution." Consequently, Beyond Bounds Institutional Review Board (IRB) must either act as the Single IRB for all sites involved in non-exempt human research or delegate IRB review authority to an external IRB. For further details, please reach out to [info@beyondbound.org](mailto:info@beyondbound.org) or call at (646) 217-0403.

Scenarios where the Institution is not considered engaged encompass situations where the Institution’s employees:

* Engage in communication with potential subjects regarding the availability of research opportunities.
* Provide potential subjects with written information about the research, which might include a copy of the informed consent document and other materials approved by the IRB, without the aim of obtaining the subjects’ consent.
* Supply potential subjects with contact information for the investigators.
* For a comprehensive compilation of examples, please consult the Engagement Worksheet HRP-31.