**Parental Consent with Child Agreement**

**Note:** This consent form is utilized when seeking the parent's authorization for their child's involvement and the child's willingness to participate in the study. The child is the focus of the research, not the parent. If the child is under the age of 12, an alternative, developmentally appropriate agreement form/process must be added. Please refer to the Guidance on Children as Research Participants, Parental Permission, and Child Agreement for more detailed information. If both the child and the parent are subjects of the research, use the form titled "Parent Consent and Child Agreement."

Eliminate any text highlighted in “red” before submitting the final version for IRB assessment.

**Title of Research Study:** [Enter the title of the research study]

**Principal Investigator:** [Enter the name of the principal investigator]

**Student Investigator:** [If relevant, include the name of the student researcher, especially if the project is conducted by a graduate or undergraduate student as part of a degree or certificate program]

**Supported By:** [Document all forms of financial and non-financial assistance for this study [For example, amenities and infrastructure]. If there is no external funding, please specify your academic school or department] The funding for this research is provided by \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Conflict of Interest Disclosure:**

[This section should be filled if there exists any conflict of interest. If not, please omit this section.] This disclosure aims to inform you and allow you to assess whether this relationship impacts your decision to allow your child to engage in this research study: [detail the nature of the conflict of interest and outline measures implemented to mitigate its impact.]

[This part should be included if the researcher is also your child's treating physician. If not applicable, please delete.] The physician overseeing your child's medical care is also leading this research study, which presents a dual interest in both your child's health and the success of this research. You are entitled to discuss the specifics of this study with an independent individual who is not associated with the research team, prior to making a decision on your child's participation.

**Collaborating Institutions:** [Include this section if there are any institutions collaborating on this research project – if not relevant, please omit.]

**Key Information about this research study:**

This section provides a brief overview of the study to assist you in deciding whether you and your child should participate. More comprehensive details are provided further in this document.

* The aim of this study is to \_\_\_\_\_ [Explain the primary goal of the study in clear, straightforward language].
* In this study, you and your child will be required to \_\_\_\_\_\_\_\_\_ [offer a concise description of the activities involved. For example: "Your child will be requested to fill out a questionnaire and participate in a follow-up interview."].
* The expected duration of your and your child's participation in this study is \_\_\_\_\_\_\_\_ [specify the time frame, such as "10 minutes; hours; days; months; weeks; years; until a certain event occurs"].
* The principal potential risk involved in participating is \_\_\_\_\_\_\_ [Identify the main risks associated with the study. Avoid stating "there are no risks." If risks are primarily related to breaches of privacy or confidentiality, mention this explicitly and describe how these risks are being mitigated].
* The primary benefit from participation in this study is \_\_\_\_\_\_\_.

**Reason for Your Child's Involvement in This Research Study:**

Your child has been invited to participate in this research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Please specify the reasons and ensure that they align with the inclusion and exclusion criteria outlined in the research protocol, which detail who is eligible and who is not eligible to take part in this research.]

**Number of Participants in This Study:**

It is anticipated that [Indicate number] children will participate in this research study. If the research is being conducted across multiple locations, instead include: It is anticipated that \_\_\_\_\_ children will be participating in this research study through BeyondBound, which is part of a larger group of \_\_\_\_\_ children participating across all involved institutions.

**Information You Need Before Participating in a Research Study:**

* A representative will provide you and your child with a detailed explanation of the research study. [Omit if not relevant.]
* The decision to participate is entirely yours and your child’s.
* Your child is free to decline participation.
* Your child may initially agree to participate but can withdraw at any time.
* Your child's choice will be respected without any negative consequences.
* You and your child have the right to ask any questions before making a decision.
* Your child is not obligated to respond to any question they prefer not to answer. [Include this statement for studies involving questionnaires, interviews, and/or focus group discussions.]

**If you agree to allow your child to participate in this study, here’s what will be involved:**

We will provide you and your child with a clear explanation of what the research entails, using straightforward language and simple terms. We will outline the research activities and procedures in the order they will occur, along with the frequency of these actions. If the study involves multiple steps or visits, we may provide a chart or table along with the descriptions of protocols and tests for studies that call for 1 or 2 phases or visits.

You will be informed about:

* The total number and duration of the study visits, along with what each visit entails.
* The nature of interactions your child will have with researchers or other individuals during the study.
* The schedule and location of the research activities.
* The types of questions that will be posed to your child.
* The distinction between standard or customary practices (such as regular classroom activities or standard clinical care) and what procedures are specifically for research purposes.
* Whether audio recording, video recording, or photography will be part of the research activities, and if these are mandatory for participation or optional.
* Additionally, if the study involves grouping participants into different treatment or control groups (randomization): Your child’s assignment to a specific group will be random, akin to the toss of a coin. The assignment is not controlled by either you, your child, or the research team. Your child will have an [equal/one in three/etc.] chance of being placed in any of the study groups.

Please remember, this explanation is tailored to help both you and your child understand what participation involves, ensuring it is a fully informed decision.

**Will Participating in This Study Benefit Me or My Child?**

We cannot guarantee any direct benefits to you, your child, or others by participating in this research. However, potential advantages might include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Detail the prospective benefits for the participant first, then mention any potential advantages for others. Note that financial compensation for participation is not considered a benefit – such compensations and reimbursements will be discussed in a later section titled “Will I receive any payment or rewards for participating in this study?”].

**Could Participation in This Study Pose Any Risks to Me or My Child?**

It is important to consider and understand the possible foreseeable risks involved. These might include:

* Physical discomforts or hazards
* Psychological distress
* Breaches of personal privacy and confidentiality
* Legal implications
* Social or interpersonal repercussions
* Financial implications
* Risks to particular groups or communities

[Include this paragraph in the consent for ALL studies that will collect data that are potentially identifiable:] Please note that a universal risk in research is the potential breach of confidentiality, meaning that confidential information could be inadvertently disclosed to those outside the study. We are committed to implementing rigorous measures to significantly reduce this risk, which will be elaborated upon further in this document.

**What If I Choose Not to Have My Child Participate or Decide to Withdraw Later?**

Participation in this research is entirely voluntary. You have the freedom to decide whether or not you wish your child to be a part of this study. Should you prefer not to involve your child in the study or decide to withdraw them at any time, such a decision will not impact your child's association [this includes academic performance, class status, and/or access to healthcare services] with BeyondBound [and any associated entities if applicable to your study].

Your child has the right to discontinue participation at any stage without any negative repercussions.

Regarding the handling of data if you decide to withdraw:

If you decide to remove your child from the study, or if your child opts to exit, you will be consulted on whether the data already gathered can be retained and used by the researchers.

OR

If you opt to withdraw your child from the study, or if your child chooses to leave, any information collected up to that point will be eliminated.

**How Will Researchers Ensure the Confidentiality of My Child's Information?**

The research team is committed to maintaining the confidentiality and security of your child's information through various measures. For instance, data encryption will be employed to protect the information during transmission and storage. Identifiable information will be stored separately from other research data to minimize risks. In cases involving interviews or focus groups, only de-identified transcripts will be kept to further ensure privacy.

For comprehensive details on proper data security practices in research, please refer to BeyondBound's guidelines available at: https://beyondbound.org/.

Should this study receive funding from the NIH or plan to apply for a Certificate of Confidentiality, specific provisions and limitations associated with the Certificate of Confidentiality will be clearly outlined, as mandated. Please refer to the Supplemental Consent Language Document for precise wording regarding the Certificate of Confidentiality's protections.

If the study involves the use of focus groups for data collection, be aware that while all participants will be asked to respect privacy, absolute confidentiality during such settings cannot be guaranteed. Additional details regarding privacy limitations in focus groups can be found in the Supplemental Consent Language Document.

**Who Will Access the Information Collected in This Research Study?**

Measures will be implemented to restrict the usage and sharing of your child’s personal data, including records related to the research study, to individuals who require this information for review purposes. We cannot ensure absolute confidentiality.

Your child’s information may be accessed or used by individuals beyond the research team for various reasons during or after the completion of this study. Such instances include:

* Officials from the governmental bodies, sponsors of the study, auditors, and the Institutional Review Board might need to review your information to ensure the research is conducted properly and safely.
* Researchers collaborating from other institutions who participate in this research. [insert this item ONLY if relevant to your study]
* For health and safety concerns, the research personnel might disclose information to relevant authorities, such as if there is a risk of harm to yourself or others, or for reasons related to public health. [insert this item ONLY if pertinent to your study]

Regarding the reporting of child abuse or neglect, as mandated by Nevada law and BeyondBound policies:

If current or ongoing child abuse or neglect comes to light during the study, we might be required or allowed by law or policy to report this information to the appropriate authorities.

OR

Although we will not inquire directly about abuse, if your child discloses instances of child abuse or neglect, we may be obligated or permitted by law or policy to report such disclosures to the authorities.

If the study could result in the disclosure of information under Federal laws concerning sexual harassment and violence, specific provisions regarding Title IX reporting responsibilities will be included in the consent form, as outlined in the Supplemental Consent Language Document.

[Applicable if your study includes assessments or tests] Most assessments conducted in research settings are designed solely for research purposes and do not have direct personal significance.

If, however, any findings from the research are relevant to your child’s health or development, the researchers will [will/will not] reach out to inform you of these results, depending on the nature of the findings and the conditions set forth by the study.

**How Might the Information Collected in This Study Be Utilized in the Future?**

The data we gather about your child during this study will be retained for recordkeeping purposes [and may be used in subsequent research endeavors]. Should the study data include identifiable information: Your child’s name and other identifying details will be securely stored and kept separate from the rest of the research data.

For studies that extend over a period (longitudinal studies): We [plan to/may] reach out to you in the future as part of this ongoing research effort.

Data that do not identify your child may be shared within the scientific community, with academic journals where study findings are published, and with databases or repositories that support research activities. [If participant identifiers will be collected:] Prior to sharing the study data, we will either remove or encrypt any personal information that could directly identify your child. However, we cannot completely assure the anonymity of your child’s personal data.

If there is a possibility of maintaining or disseminating identifiable data for future research that is not yet specified, a distinct IRB application must be filed, including an appropriate protocol, consent form, and supporting documentation. If the Principal Investigator (PI) intends to offer the possibility for your child to be approached regarding future studies by this PI, this will be mentioned towards the end, and your agreement will be sought at that time. Your contact details will be used exclusively for informing you about future research possibilities by this PI and will not be shared with other researchers. Consent for this will be requested at the end of this document. Participation in this current study does not require agreement to future use of your identifiable data for other research.

[Omit if no identifiable data will be shared] The findings from this study may be disclosed in scholarly articles and presentations, but they will not include any identifiable information about you unless you specifically consent to the disclosure of such information.

**Will My Child Receive Any Compensation for Participating in This Study?**

If you consent to your child's participation in this study, they will be compensated with [specify type e.g., cash, gift card, check] in the amount of [specify total amount] for their involvement. [Specify if the compensation is to be received by the parent instead.] This compensation will be provided even if your child does not complete the study.

Please note the following details if applicable to your study:

* If compensation is to be adjusted on a prorated basis (for example, if a participant exits the study early or does not complete all aspects of the study).
* If there is an additional bonus payment or if any part of the compensation depends on the participant's decisions, actions, or the performance of a group.
* If the study involves a raffle or lottery, details including the prize amount, total number of payments, odds of winning (if applicable), estimated timing of the draw, and the method of notification for winners should be clearly explained.
* If participants will be reimbursed for travel, parking, or other expenses incurred as a result of taking part in the study.

If there will be no compensation or reimbursement for participating in this research, please be informed: There is no financial compensation or reimbursement provided for your child's participation in this study.

**Here is additional information that may be beneficial for you and your child:**

[This section should be included if your child will be participating in an educational study requiring surveys or interviews:] Please note, under the Protection of Pupils Rights Act 20 U.S.C. Section 1232(c)(1)(A), you are entitled to review the survey questions or educational materials that will be presented to your child. If you wish to review these materials, please contact [insert the name of the Principal Investigator and their contact details] to request a copy.

[If HIPAA protected information is being collected, ensure to apply the appropriate HIPAA Authorization terms as specified in the Social and Behavioral consent template or HRP=1721].

**Whom can you contact for more information?**

Should you or your child have any inquiries, issues, or grievances, please feel free to reach out to the Principal Investigator [insert Name and contact details] and [insert the name of another investigator, such as a student, if applicable]. [For studies conducted internationally, add the U.S. country dialing code for the contact numbers of the study team, along with the details of any local collaborators.]

This study has undergone and received approval from an Institutional Review Board (IRB) – a committee established to safeguard the rights and welfare of research study participants. Should you have any of the following concerns:

* If the research team has not addressed your questions, concerns, or complaints to your satisfaction.
* If you are unable to get in touch with the research team.
* If you wish to speak with someone other than the research team.
* If you have questions about your rights as a participant in this research.
* If you desire to obtain further information or offer feedback regarding this study.

You are encouraged to contact the IRB at (646) 217-0403 or via email at [info@beyondbound.org](mailto:info@beyondbound.org).

**Optional Elements:**

[Only include the following information if there are optional components to the research; otherwise, please remove.] The components listed below are optional aspects of the research, signifying that your consent for these specific activities is not required for your child’s main participation in the research study. You can express your approval for your child to engage in these optional activities by initialing beside each one listed below. Following your decision, your child will also have the chance to express their willingness or unwillingness to participate in these same optional elements:

**Parent:**

| **I Agree** | **I Disagree** | **Statement** |
| --- | --- | --- |
|  |  | The researcher may [specify: audio record, video record, or both] my child to facilitate data analysis. These recordings will be accessible only to the research team and will not be shared beyond this group. (If recording is mandatory for participation, this option should be omitted.) |
|  |  | The researcher may [specify: audio record, video record, or both] my child for inclusion in academic presentations or publications. This might involve displaying my child's image or playing their voice, which could lead to their identification despite efforts to prevent this. I am aware of and accept the potential risks of such exposure. |
|  |  | The researcher may reach out to me in the future to inquire about my interest in having my child participate in subsequent studies conducted by the principal investigator of this current study. |

**Child Participant:**

| **I Agree** | **I Disagree** | **Statement** |
| --- | --- | --- |
|  |  | The researcher may [specify: audio or video] record me to support data analysis efforts. These recordings will be kept confidential and not shared with individuals beyond the core research team. (Indicate whether audio or video recording will be used. Remove this option if recording is obligatory for participation.) |
|  |  | The researcher may [indicate: audio or video] record me for inclusion in academic presentations or publications, where visual or auditory representation could enhance understanding of the research among other professionals. There is a possibility that I could be recognized in these recordings, despite attempts to minimize such risks. I acknowledge and understand the potential risks of being identified. |
|  |  | The researcher may reach out to my parent or guardian in the future to determine my interest in taking part in additional studies conducted by the study's principal investigator. |

**Parent Consent and Permission for Participation of Children Aged 12 or Older**

Your signature confirms your agreement to participate and grants permission for the specified child to engage in this study.

Place Signature of the Child/Student here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Enter the Date here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place Printed Name of the Child/ Student here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Parent [ ] or Individual Legally Authorized [ ] Date

Consenting to Participate and Granting Permission for the Child to Participate

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent [ ] or Individual Legally Authorized [ ] Date

Consenting to Participate and Granting Permission for the Child to Participate

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent, Permission Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

Note: Investigators must verify that individuals who are not the child's parents have the legal authority to consent to the child's participation in the research. If there are any doubts or questions regarding this matter, please consult with legal counsel.

Electronic Consent and Permission (analogous to written signed consent but acquired remotely via an electronic platform):

To secure proper signed consent and permission, it is necessary to collect a verified electronic signature. The electronic form should include fields for the participant to type their name and the current date, ensuring that consent and permission are both informed and legally binding.

**Verbal Parental Consent and Child Agreement:**

There may be situations where obtaining a written signature from the participant on the consent document is not practical. For instance, when permission, agreement, and data gathering are conducted via telephone or online platforms like Skype, securing a physical signature from the parent or child on the Parental Consent and Child Agreement document may be challenging and could make the process of obtaining consent and agreement unfeasible. In other instances, such as studies involving illegal or socially sensitive subjects, having a parent or child’s signature on the consent and assent forms might increase the risk to the participants. Additionally, in certain international contexts, it may not align with the cultural practices of specific groups or communities to sign consent forms. In your study protocol, you must provide a rationale for not planning to obtain written consent from neither the parent nor the child.

If you are not planning to collect signed consent and agreement forms or electronic signatures, you must meet the criteria for a waiver of documentation of informed consent. This entails providing a sufficient justification within the protocol that meets the federal waiver requirements (refer to Checklist for Research Involving Children).

Should there be no signed consent form from the parent or child, remove the signature section from above and use this document as an informational sheet for the study. When initiating contact with the parent and child for data collection, it's important to go over the key elements of the consent and agreement information orally with both parties to ensure they understand and agree to participate in the study before any data collection begins. If there is a plan to audio-record the verbal consent and agreement of the parent and/or child, this must be clearly stated and explained in the protocol document.

| **Question** | **Response** |
| --- | --- |
| [Parent/Guardian] Do you consent for your child to participate in this study? | Record the parent’s response: Yes No |
| [Child/Student] Are you willing to participate in this study? | Record the parent participant’s response: Yes No |

Participant Name or Study ID Number (If the participant's name is not being recorded on the consent and assent document to reduce risk, please record the study ID number instead):

[Parent] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Child] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
Printed Name of Person Obtaining Consent Date

**Online Consent with Agreement**

**(consent and agreement obtained without physical or electronic signature):**

If you are not obtaining a signed consent with agreement form, either physically or electronically, it is essential to fulfill the criteria for a documentation waiver of informed consent. This requires your study's protocol to thoroughly justify not meeting the standard signature requirements, in line with the federal waiver guidelines (refer to Checklist for Research Involving Children).

For obtaining parent consent and child agreement through an online format, eliminate the standard signature section provided above. Instead, adopt the following consent and agreement wording:

If you desire a copy of this Parent Consent with Child Agreement document for your records, you have the option to print it directly from the screen. Should printing not be feasible for you and you wish to have a copy for your records, please reach out to the Principal Investigator using the contact details provided above.

The parent must grant permission, and the child must provide their agreement. Both the parent and child are required to select “I agree” for the child to be eligible to participate.

| **Question** | **I Agree** | **I Disagree** |
| --- | --- | --- |
| [Parent/Guardian] Are you willing to participate in this study? |  |  |
| [Child/Student] Are you willing to participate in this study? |  |  |

If you choose not to participate in this study, please select “I Disagree” or click on the 'X' at the corner of your browser to close the window.