**BROWN UNIVERSITY**

**PARENT PERMISSION**

[Use the *Parent Permission* *Template* with the *Child Assent Template (7-12)* and/or *Child Assent Template (13-17).* Areas shaded gray should be completed as appropriate for your study. Remove the gray shaded instructions and brackets in your final version.]

[Study Title]

[Version #, Date]

**KEY INFORMATION**:

Your child is invited to take part in a Brown University [and <List the name(s) of any other engaged institutions or organizations>] research study. Their participation is voluntary.

* PURPOSE: The study is about … [state the purpose(s) of the research.]
* PROCEDURES: Your child will be asked to … [state the procedures to be followed.]
* TIME INVOLVED: The study will take [state the total minutes, hours, days, etc.] of your child’s time.
* COMPENSATION: Your child [will/will not] receive [state the total compensation] for their time.
* RISKS: [State the reasonably foreseeable risks to the child from participation.]
* BENEFITS: [State the direct benefits to the child that may reasonably be expected from the research, if any.]
* ALTERNATIVES TO PARTICIPATION: [*This bullet is only needed for studies involving an intervention*: Describe the standard of care and/or other reasonable, known alternative procedures available to the child instead of the research study. Stating, “Your child does not have to participate” is not an acceptable answer.]

1. **[Researcher(s)](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Researchers)**

[List names and contact information of principal investigator, contact person(s) for parents and/or child participants, advisor(s) for student research only.]

1. **Study Sponsor(s)**

This study is supported by … [List names of any external or private organization, institution, or individual providing funding for the study. If not externally funded, list Brown University and your department.]

1. **[What is this study about?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_is_this_study_about)**

The purpose of the study is … [Provide a brief explanation of the activity.]

Your child is being asked to be in this study because they are … [State the age of the child participants to be involved and any relevant eligibility criteria.]

1. **[What will my child be asked to do?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_will_I_be_asked_to_do)**

[Describe the tasks/procedures involved in the study using separate paragraphs for each task/procedure.

Describe any questionnaires, surveys, and interviews with examples of the most personal and sensitive questions child participants will be asked. State that child participants may refuse to answer or skip any question asked of them.

If there are multiple procedures/visits, a study flow chart, table or other visuals may be helpful.

If applicable, include the use of any medical, academic, or other records.

*If applicable*: State whether clinically-relevant results, including individual research results, will be returned to parents and/or the child, and if so, under what conditions.

*If applicable:* State whether the research will or will not include whole genome sequencing.]

[*If applicable:* With your permission and with your child’s assent <insert procedure that will be recorded/photographed> will be <choose applicable recording type: audio recorded, video recorded, photographed>. This <insert recording type> is optional. You can indicate your preference below whether you give the researcher permission to <insert recording type> below. You can also ask that the <insert recording type> be stopped at any time.

OR

<Insert procedure that will be recorded/photographed> will be <choose applicable recording type: audio recorded, video recorded, photographed>. This <insert recording type> is not optional. If you do not wish for your child to be <insert recording type>, they will not be able to enroll in the study.

[*If applicable:* Describe any reimbursement for parent or child participant expenses due to study enrollment (i.e. transportation, childcare, meals).]

Your child’s participation in this study may last up to \_\_\_\_\_ [hours, minutes].

1. **[Will my child be paid?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Will_I_be_paid)**

[Add any compensation per procedure and list the possible total amount. If creating a table of procedures, add any compensation to the table.

If you will use electronic gift cards as compensation, include that gift cards will be emailed to the parent’s email address if the child participant is under 13 or if their 13+ year old child does not have their own email address.]

1. **[What are the risks?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_risks)**

[All studies have risk (physical, psychological, social, legal, or financial, etc.). Do not state that there are no risks or that risks “should be” minimal. State the reasonably foreseeable risks to the child from participation. Describe any side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. Assess each risk’s likelihood and seriousness.

*If applicable:* Include a statement that the study’s research activities may involve risks that are currently unforeseeable.

Risks that are obvious to the study population due to the subject matter or their condition do not need to be included (i.e., stating that children who have frequent blood draws as part of their clinical care may experience some pain or bruising from having their blood drawn for the research study, or children may potentially become bored or restless while answering long questionnaires).

Describe the procedures for protecting against or minimizing any potential risks. State whom parents should contact in the event their child possibly experiencing a study-related injury, illness, or distress.

State that the procedures can be stopped at any time and whether this will impact whether the child can continue in the study.]

1. **[What are the benefits?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_benefits)**

[[](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_are_the_benefits)*If appropriate, include*]: Your child may not directly benefit from being in this research study.

[Provide a description, if there are direct benefits to the participant. Compensation and/or reimbursement are not study benefits and should not be mentioned in this section.]

1. **[How will my child’s information be protected?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "How_will_my_information_be_protected)**

[State whether data will be identifiable (identifiers collected), coded (identifiers collected, and linked to data by code or pseudonym) or anonymous (no identifiers collected).

Describe the physical, administrative, and technical safeguards used to protect the identities of research participants and research data. This should include a discussion of the privacy protections (referring to space/location) of the consent process and study procedures, and the confidentiality (referring to information) of research data.

For example, conducting a procedure in private, locking file cabinets and the office, or a computer not connected to the Internet are physical safeguards; random number coding of research data, or password protection of computers and electronic files are administrative safeguards; encryption of research data is a technical safeguard.

In this study we will be <audio, video, and/or photo> recording <list whatever task applies>. We will use <state method of recording – e.g., notebook, computer files, digital record, smartphone>. We will keep this information confidential. We will store it for <state duration of storage>. At the end of that we will destroy the recordings [if applicable].

[*For all studies with anonymous data*: State if study data will be kept indefinitely by the research team, shared with a data repository, shared with other researchers/institutions, or used in presentations/publications.]

* *If anonymous data will be shared with a data repository for future research*:
  + Refer to the HRPP “[Sharing with Data Repositories](https://www.brown.edu/research/guidance-and-faqs-sharing-information-data-repositories)” for guidance
  + Complete the “[Data Repository Parent](https://www.brown.edu/research/forms-and-templates) Permission”

[*For all studies* *with identifiable and/or coded data in which links between child participant identities and data will be collected*: State if study data will be shared with a data repository, shared with other researchers/institutions, or used in presentations/publications.]

* *Include*: Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your child’s records may be examined. The reviewers will protect your child’s confidentiality.
* *If applicable*: List the state, federal, regulatory, or funding agencies that will have access to identifiable data.
* *If the study is subject to the NIH Policy for Data Management and Sharing, you may be required to ask participants to share their data with a data repository for future research*:
  + Refer to the Office of Research Integrity’s “[NIH Policy for Data Management and Sharing](https://www.brown.edu/research/conducting-research-brown/nih-policy-data-management-and-sharing)” for guidance
  + Refer to the HRPP “[Sharing with Data Repositories](https://www.brown.edu/research/guidance-and-faqs-sharing-information-data-repositories)” for guidance
  + Complete the “NIH [Data Repository Parent](https://www.brown.edu/research/forms-and-templates) Permission”
* *If you will remove identifiers from identifiable and/or coded data:* Describe arrangements for destroying identifiable data after the identifiers are no longer needed.
* Once anonymized, state that the data may be used by you for future research and/or shared with other investigators for the other investigators’ future research.

OR

* Once anonymized, state that the data will not be used by you for future research and/or shared with other investigators for the other investigators’ future research.]

*If collecting biospecimens:* State if the biospecimens may be used for commercial profit and if the child will share in that profit.

*If you will apply for a Certificate of Confidentiality or if the study is NIH-funded, a* Certificate of Confidentiality *is automatically applied to the research*: Refer to the HRPP “[Certificates of Confidentiality (CoCs)](https://www.brown.edu/research/certificates-confidentiality-cocs)” for further guidance.

*If the study meets the definition of a* [*clinical trial*](https://www.brown.edu/research/clinical-trials)*:* Refer to the HRPP“[Additional Parent Permission Language](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#Consents)” for further guidance.

1. **[Are there any alternatives to this study?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Are_there_alternatives)**

[*Only include this section for intervention studies (behavioral, educational, social, medical, etc)*: Include a description of alternative procedures or standard of care that are available if the child participant chooses not to be in the study.]

1. **[What if my child wants to stop? What if I no longer want my child to participate?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "What_if_I_want_to_stop)**

Your child does not have to be in this study if you do not want them to, or your child decides they do not want to participate. Even if you or your child decide your child can enroll in this study, you or your child can change your mind and stop at any time by contacting the research team (see below: “Who can my child or I talk to if we have questions about this study?”).

If your child refuses to participate in or leaves the study, your child’s current or future relationship with Brown University [or any other name of organization, Dr., if applicable] or [academic standing, job status, reputation, etc., if applicable] will not be affected.

1. **Can my child’s participation end without our permission?**

[Include the anticipated circumstances under which you may end the child participant’s enrollment without the child’s assent or the parent’s permission.]

1. **[Who can my child or I talk to if we have questions about this study?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Study_questions)**

If you have any questions about your child’s participation in this study, you can call [(name) at (phone #) or email [XXX@brown.edu](mailto:XXX@brown.edu).

[*If conducting student research,* ***add****:* You can also contact my advisor (name) at (phone # or email).

[*If conducting international student research,* ***add****:* You can also contact my local contact (name) at (phone # or email).]

1. **[Who can I talk to if I have questions about my child’s rights as a participant?](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "HRPP_questions)**

If you have questions about your child’s rights as a research participant, you can contact Brown University’s Human Research Protection Program at 401-863-3050 or email them at [IRB@brown.edu](mailto:IRB@brown.edu).

1. **[Permission to Participate](C:\\Users\\iirizarr\\Documents\\Additional consent document language, 10-02-17 HC.docx" \l "Consent_to_participate)**

Your signature below shows that you have read and understood the information in this document, you are the child’s parent or legal guardian, and that you give permission for your child to volunteer as a research participant for this research study.

You acknowledge that even if you have granted permission for your child to enroll in this research study, if your child declines enrollment, resists participation, or chooses to withdraw, their decision prevails.

You will be offered a copy of this form.

Parent/Legal Guardian’s Signature and Date / PRINTED NAME

Parent/Legal Guardian’s Signature and Date / PRINTED NAME

[Include a second signature line for parent/legal guardian, when conducting:

* Research involving greater than minimal risk and no prospect of direct benefit to children, but likely to yield generalizable knowledge about the disorder or condition of the children [45 CFR 46.406]
* Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children [45 CFR 46.407]

Federal regulations require adequate provisions must be made to solicit permission of both parents/ guardians, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. ([45 CFR 46.408](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46/subpart-D/section-46.408))]

Child’s Name

[If applicable and these activities are optional:]

Indicate Yes or No [any blank responses must be interpreted as permission NOT given]:

I give permission for my child to be audio recorded during this study:  Yes  No

I give permission for my child to be video recorded during this study:  Yes  No

I give permission for my child to be photographed during this study:  Yes  No