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| Parent Consent and Permission Form Template Version 1.12, 6/9/2023**GENERAL INSTRUCTIONS** – delete this box from the submitted consent formThis template is for research involving children when their parents are ALSO subjects. Do not use this template for research involving adults only (use “Adult Consent Form Template”) or if parents are NOT also subjects (use “Parent Permission Form Template”). This template is written on the assumption that any medical interventions involve the child only – consult the IRB (medirb@bu.edu or 617-358-5372) if your study involves medical intervention to parents or a HIPAA authorization for parent health information. Use this template as follows: * Red text represents instructions to you – to be deleted from the final version. For example, when a section starts with “[Include if…],” you should read the red bracketed phrase, and either delete the whole section if not applicable to your study, or delete just the red bracketed phrase and retain the section if applicable to your study.
* Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version. The language should be understandable at an 8th grade reading level.
* Green text represents text that should be changed to black if any of the participating children are cognitively capable of refusing assent and deleted otherwise.
* Black text represents text that should ordinarily be incorporated as-is, if applicable

If your study involves any of the following, see the specific instruction box at the end of this template:* Genetic testing and/or collecting genetic information
* Communication of pertinent and/or incidental findings to subjects and/or their physicians
* Repositories or other retention of samples or data
* ICH-GCP

There are five signature pages at the end of this template; use the one that is applicable and delete the remaining four. Please note that you must enter the project title and PI name in black in the header on the second page. The submitted version should have no red or blue text (including instruction boxes like this one) |

**RESEARCH CONSENT FORM**

**Basic Information**

Title of Project: Title

IRB Number: the “H number” of your submission

[Include if there is one or more external sponsor; otherwise, delete paragraph] Sponsor: External sponsor(s).

Principal Investigator: PI name

 PI/study email

 PI/ study mailing address

[Include A or B]

[A. Include if the study is no more than minimal risk; otherwise, delete paragraph] Study Phone Number: phone number

[B. Include if the study is greater than minimal risk; otherwise, delete paragraph] Study-Related Phone Numbers: Regular business hours: phone number 24 hours: 24-hour number

**Overview**

We are asking you to agree for you and your child to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you and your child should expect if you agree for you and your child to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to agree for you and your child to join the study. We are doing the research to a one-sentence summary in lay language of the purpose of the study. We are asking you and your child to be in this study because a one-sentence summary in lay language of why the subject is eligible for the study. If you agree, you and your child will a one-sentence overview in lay language of what will happen in the study. You and your child will be in the study for xx days, weeks, months if you and your child decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are a one-sentence overview in lay language of the risks that are most relevant to the potential subject’s decision about whether or not to join the study. You will find more information about risks later in this form.

[Include and complete if there is a potential direct benefit to subjects; otherwise, omit entire paragraph] You and your child might benefit from being in the study because a one-sentence overview in lay language of the benefits that are most relevant to the potential subject’s decision about whether or not to join the study. You will find more information about benefits later in this form.

[Include and complete if there is a potential direct benefit to subjects and there are appropriate alternative procedures or courses of treatment that might be advantageous to the subject; otherwise, omit entire paragraph] If you decide not to be in the study, some other things that might help your and your child’s condition are a one-sentence overview in lay language of the alternatives. You will find more information about alternatives later in this form.

[Include if the PI or any study investigator could also be the subject’s healthcare provider; otherwise, delete paragraph] Your child’s doctor may also be an investigator in this research study. Being an investigator means your child’s doctor is interested in both your child and the study. The goal of your child’s doctor as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is different from their role as your child’s doctor, where their goal is to treat you child as a patient. You may want to get another opinion about you and your child being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree for you and your child to be in this study even though it is offered by your child’s doctor.

**Purpose**

A brief explanation of the background and purpose of the study, stating in lay language why the study is needed and what the study is designed to discover or establish. Do NOT copy from a grant application or other scientific description.

**What Will Happen in This Research Study**

A concise description of study procedures in enough detail to give a clear picture of what the parent and the child will experience during the study. Explain the overall design of the study, and describe procedures to be followed (including pregnancy testing if applicable), the location and length of time for the procedures, the frequency of procedures, and, as appropriate, such study details as how subjects will be assigned to study groups, the method, dose, and frequency of medication administration, and specific tasks subjects will be expected to complete on their own. Any procedures which are experimental must be identified as such and differentiated from standard treatments. Technical language unfamiliar to the parent population should not be used. Subheadings may be inserted to make this section more readable.

[Include if subjects will be audio- or video-recorded at any point in the research; otherwise, omit sentence] We will make an audio OR a video recording of specify what will be recorded.

[Include if the approximate total number of subjects in the entire study would be relevant to the decision about whether or not to participate; for example, if the number of participants is small so that unknown risks are less likely to be identified and/or deductive identification of their participation is more likely; otherwise, delete sentence] You and your child will be one of approximately number subjects who will be asked to be in the study.

**Risks and Discomforts**

A description of all reasonably foreseeable risks and discomforts, their likelihood of occurrence (when appropriate), and the steps you will take to minimize these risks. Include psychological, social, legal, and financial as well as physical risks. If applicable, identify any situations where the subject should seek immediate medical care.

[Include if the study is greater than minimal risk; otherwise, delete sentence] There may be unknown risks or discomforts involved.

[Include if there are any consequences of a decision to withdraw from the study or any necessary procedures for withdrawing; otherwise, delete paragraph] If you or your child decides that your child should stop being in the study, we ask that you or your child lets us know. If your child stops early, list risks of withdrawing. You and your child are free to stop at any time, but if you tell us, we can do some things to help keep your child safe. These things include list procedures for orderly withdrawal.

[Include and edit if biologically female children in the study should not become pregnant because of risks to the fetus (not applicable if all biologically female children will be below the age of menarche); otherwise, delete paragraph] If your child gets pregnant while in this study, it could be bad for the fetus/baby. All children who can get pregnant must use birth control if they have sex while in this study. [Include or modify time frame if applicable; otherwise, delete] They should also keep using birth control for three months after the study ends. Only some birth control methods work well enough to be safe for children while in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. Children who can get pregnant should not be in this study if they have sex and cannot use one of these birth control methods.

[Include if the study involves wearable devices that are commercially available and have established instructions for use and safety information available; otherwise delete paragraph] The most common risks of the name of wearable device(s) in this study include list the most common risks. We will provide you and your child with the instructions for use and safety information for the/each device and discuss the risks listed in the safety information with you and your child before asking your child to use the device(s).

There is a risk to the confidentiality of your and your child’s health information. We take special efforts to protect your and your child’s health information, but there is a small chance of a data breach. The ways we will protect your and your child’s privacy and confidentiality are described in a separate section later in this form.

**Potential Benefits**

[Include A or B]

[A. Include if there is a potential direct benefit to subjects; otherwise, delete paragraph] The benefits of being in this study may be: list potential benefits. However, you and your child may not receive any benefit. The primary goal of this research is to collect information about the scientific questions asked in this study. You and your child being in the study may help the investigators learn list what investigators will learn.

[B. Include if there is no potential direct benefit to subjects; otherwise, delete paragraph] You and your child will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. You and your child being in this study may help the investigators learn list what investigators will learn.

[Include **Alternatives** if the study is expected to have a direct benefit and there are appropriate alternative procedures or courses of treatment that might be advantageous to the subject; otherwise, delete **entire** Alternatives section] **Alternatives**

The following alternative procedures or treatments are available if you choose not to have your child be in this study: list alternatives, including other methods to get potential direct benefits or palliative care if appropriate.

**Costs**

[Include A, B or C]

[A. Include and edit this entire paragraph if the study uses any BMC clinical services (include the first sentence if the study uses a drug or device); otherwise, delete paragraph] The study drug/device will be provided by the Sponsor. There are no OR some additional costs to you and your child for being in the study. [Include if there are additional costs; otherwise, delete] The additional costs are (describe). Items and services done only for study purposes will be provided at no cost to you or your child. They won’t be billed to your child’s health insurance either. You or your child’s health insurance will be billed for all costs that are part of your child’s normal medical care. These costs include co-payments and deductibles. You can ask any questions now about insurance coverage for this study or about the research activities paid for by the sponsor. You can also ask the investigator later, using the number on the first page of this form.

[B. Include if the study does not use BMC clinical services and subjects may incur any costs; otherwise, delete sentence] If you and your child are in this study, you will have to pay for list costs

[C. Include if the study does not use BMC clinical services and subjects will not incur any costs; otherwise, delete sentence] There are no costs to you or your child for your child being in this research study.

**Payment**

[Include A or B; include C if applicable]

[A. Include if subjects will be given any payment or reimbursement; otherwise, delete paragraph] You will receive description of amount, method, and timing, including how payment will be prorated if the subject withdraws and whether the child will receive any payment or reimbursement. [Include if payments are > $400 for BMC study and > $600 for BU study and thus requires collection of SSNs/ITINs; otherwise, delete sentence] You must give us your Social Security Number or Individual Taxpayer Identification Number to receive this payment.

[B. Include if subjects will not receive any payment or reimbursement; otherwise, delete paragraph] You and your child will not be paid for being in this study.

[C. Include if the research could lead to commercial products; otherwise, delete paragraph] The research may lead to the development of drugs, tests, or procedures that might have commercial value. You or your child will not get any money if products are developed from the research.

**Confidentiality**

[Include the following paragraph and delete the remainder of the Confidentiality section if study does not record ANY information that would identify subjects; otherwise, delete paragraph] We will not record your or your child’s name or any information that shows your or your child’s identity. Neither you nor your child will sign this form. Further explanation of measures to preserve anonymity, if appropriate.

We must use information that shows your and your child’s identity to do this research. Information already collected about you and your child will remain in the study record even if you and your child later withdraw.

We will store your and your child’s information in ways we think are secure. [Include next sentence if biospecimens are collected; otherwise, delete only next sentence] We will store biological samples taken from your child’s body (such as urine, blood, or tissue) describe storage methods. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

[Include if study involves use of third-party software apps/programs/vendors that have access to subject data [sponsors are NOT third-parties]; otherwise delete] This study proposes to share data with name of third party. Data that is not stored at Boston Medical Center or Boston University is outside of our control. Your or your child’s information could get out or be used by name of third-party for other purposes that are not related to the study.  Please carefully read and think about the Terms of Service and Privacy Policies before agreeing to give them any of your or your child’s information. [Include if sharing with third-party is mandatory to be in study; otherwise delete] If you do not want to share your or your child’s data with name of third-party, that is completely acceptable, but you and your child cannot be in the study. [Include if sharing with third-party is optional; otherwise delete] You do not have to agree to share your and your child’s data with name of third-party to be in the study.

[Include if study proposes to give subjects the option of unsecure email or text communication; otherwise delete] This study gives you and your child the option of communicating using describe which unsecure methods and why, such as unsecure email and/or text for appointment reminders and satisfaction surveys. This is because some people like the option of communicating by email and/or text message. It is important for you and your child to understand that regular email and text are convenient but are generally not secure. As a result, information about you or your child could be intercepted by someone not involved with the study. We will give you and your child the option of using add secure and unsecure options such as secure email (Data Motion or BMC secure email), non-secure email, and/or non-secure text.

[Include if study has a Certificate of Confidentiality (edit if the CoC is from an agency other than NIH); otherwise, delete paragraph] This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. [Include if study is NIH funded (check [list of NIH institutes](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) if in doubt); otherwise, delete sentence] All studies funded by the National Institutes of Health that involve identifiable information [if no biospecimens are collected, delete blue phrases] or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you or your child to anyone that is not involved in the research except as we describe below. Even if someone tries to get your or your child’s information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you or your child from sharing your or your child’s own research information. [Include if study information will be placed in medical records; otherwise, delete remainder of paragraph] We will record information from this study in your child’s medical record, such as information related to your child’s medical care. Please ask us if you have any questions about what information will be included in your child’s medical records. You should know that once information has been put into your child’s medical records, it is not covered by the CoC. However, information in your child’s medical records is protected in other ways.

If you agree for you and your child to be in the study and sign this form, we will share information and biological samples that may show your and your child’s identity with the following groups of people:

* People who do the research or help oversee the research, including safety monitoring.
* People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
* [Include if study information will be placed in medical records; otherwise, delete bullet] People who see your child’s medical records. [Include if study does NOT have a Certificate of Confidentiality; otherwise, delete sentence] Please ask us if you have any questions about what information will be included in your child’s medical records.
* [Include and edit if identifiable study information or samples will be released to anyone not included in the above bullets (for example, investigators not included in the research team for this study); otherwise, delete bullet] People who will get information and biological samples from us describe who will get the information and why. These people are expected to protect your and your child’s information and biological samples in the same way we protect it.
* Any people who you give us separate permission to share your or your child’s information.

[Include and edit if study gathers information that requires mandatory reporting (this applies to studies where the information is or may be collected and to studies conducted by mandated reporters); otherwise, delete paragraph] You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.

[Include and edit if study gathers information on self-harm; otherwise, delete paragraph] If your child is in immediate danger of hurting themself at any time in the study, the study team will try to work with you and your child on a plan to keep your child safe. Because study staff will be trying to protect your child, it is possible that your child’s information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your or your child’s identity. There still may be a small chance that someone could figure out that the information is about you or your child. Such sharing includes:

* Publishing results in a medical book or journal.
* Adding results to a Federal government database.
* Using research data in future studies, done by us or by other scientists.
* [Include if biospecimens are collected; otherwise, delete bullet] Using biological samples in future studies, done by us or by other scientists.

[Include and edit if the study involves focus groups; otherwise, delete paragraph] We will ask everyone in the focus group not to talk about the discussions outside the group. However, we can’t promise that everyone will keep what you or your child says confidential.

[Include without editing if the study is a clinical trial that is sponsored by NIH or includes a drug, biologic or device (note – observational studies that monitor drug treatment but do not involve interventions are not clinical trials); otherwise, delete paragraph] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include **Use and Sharing of Your Child’s Health Information** if HIPAA authorization is required; otherwise, delete **entire** Use and Sharing of Your and Your Your Child’s Health Information section. Change blue “your and your child’s health information” to black if you are collecting health information about the parent, or delete “your and...” if not] **Use and Sharing of Your and Your Child’s Health Information**

The research team has to use and share your and your child’s health information to do this study, including information that may identify you or your child. By agreeing to allow you and your child to be in this study and signing this form, you are giving us your permission where needed to use and share your and your child’s health information as described in this form.

Health information that might be used or shared during this research includes:

* Information that is in your and your child’s hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
* Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
* [Include this closed bullet and all applicable open bullet(s) if the study involves any of the following types of information; otherwise, delete this closed bullet and all open bullets] The health information specifically includes:
* Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
* Domestic violence counseling
* Social work communications
* Rape victim counseling
* HIV/AIDS information
* Sexually transmitted disease information
* Communicable disease information
* [IMPORTANT NOTE: Please consult with BMC or BU counsel about the need for specific written consent if the study intends to further disclose alcohol or drug use information] Alcohol or drug use disorder treatment records about list specific data to be used and shared
* Genetic testing

The reasons that your and your child’s health information might be used or shared with others are:

* To do the research described here.
* To make sure we do the research according to certain standards set by ethics, law, and quality groups.
* To comply with laws and regulations. This includes safety-related information. [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete sentence] As we explained above, we also have to share any information from your and your child about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
* [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] To protect you and your child. As we explained above, if you and/or your child is in immediate danger of hurting themself, it is possible that your and your child’s information will be shared with others as part of a plan for safety.

The people and groups that may use or share your and your child’s health information are:

* Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
* Other people within Boston Medical Center and Boston University who may need to access your and your child’s health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
	+ People or groups that the researchers use to help conduct the study or to provide oversight for the study
	+ The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
	+ Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
	+ [Include if applicable; otherwise delete bullet] The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
	+ [Include if applicable; otherwise delete bullet] Government agencies in other countries that are involved in the research
	+ [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete bullet] Public health and safety authorities who receive our reports about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
	+ [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] Other care providers and public safety authorities who may be involved in helping to protect you and your child if you and/or your child expresses thoughts about hurting themself.
	+ [Include if applicable; otherwise delete bullet] list other group(s) that will have access to the subject’s health information

We ask anyone who gets your and your child’s health information from us to protect the privacy of your and your child’s information. However, we cannot control how they may use or share your and your child’s health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your and your child’s health information:

* The time period is not known, because research is an ongoing process. We cannot give you an exact date when we will either destroy or stop using or sharing your and your child’s health information.

Your privacy rights are:

* You have the right not to sign this form that allows us to use and share your and your child’s health information for research. If you do not sign this form, you and your child cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits for you or your child.
* You have the right to withdraw your permission to use or share your and your child’s health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you and your child cannot continue to be in the study.
* When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your and your child’s treatment or payment decisions. If you ask for research information that is not in your and your child’s medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your and your child’s health information. You may also contact the HIPAA Privacy Officer at [choose applicable privacy contact] Boston Medical Center at DG-privacyofficer@bmc.org / Boston University at HIPAA@BU.EDU.

 [End of Use and Sharing section]

[Include **Compensation for Injury** if the study is greater than minimal risk; otherwise delete **entire** Compensation for Injury section] **Compensation for Injury**

Insert language approved by sponsor and BMC Clinical Trial Office or BU Office of Sponsored Programs if available; otherwise use and edit the following:

If you think that your child has been injured by being in this study, please let the Principal Investigator know right away. Use the phone number on the first page of this form. If you have a health emergency, get care first. Your child can get treatment for the injury at Boston Medical Center, the BU School of Dental Medicine, or at any healthcare facility you choose. Tell the doctors that your child is in this study.

There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your child’s insurance will be billed for the medical care your child receives for a research injury. You are not giving up any of your legal rights by signing this form.

[Include **Re-Contact** if you might re-contact the subjects after their participation in the study is over (delete any categories that are not applicable to your study); otherwise, delete **entire** Re-Contact section] **Re-Contact**

We would like to ask your permission to contact you and your child again in the future. This contact would be after your participation in the study has ended. Please initial your choice below:

 \_\_\_\_Yes \_\_\_\_No You may contact me and my child again to ask for additional information related to this study

 \_\_\_\_Yes \_\_\_\_No You may contact me and my child again to ask for additional biological samples related to this study

 \_\_\_\_Yes \_\_\_\_No You may contact me and my child again to let us know about a different research study

 \_\_\_\_Yes \_\_\_\_No You may contact me and my child again to list reason – or delete line

**Subject’s Rights**

By consenting for you and your child to be in this study, you do not waive any of your or your child’s legal rights. Consenting means that you have been given information about this study and that you agree to participate and to have your child participate in the study. You will be given a copy of this form to keep.

If you or your child do not agree for you and your child to be in this study or if at any time you or your child withdraws from this study, you or your child will not suffer any penalty or lose any benefits to which you or your child are entitled. Your and your child’s participation is completely up to you and your child. Your decision and your child’s decision will not affect your or your child’s ability to get health care or payment for your or your child’s health care. It will not affect your or your child’s enrollment in any health plan or benefits you or your child can get. [Include if subjects will be given any payment or reimbursement; otherwise, delete sentence] You will only be paid for the study activities that you complete before withdrawing.

[Include if the study involves more than one visit AND is greater than minimal risk; otherwise, delete sentence] During this study, we may find out something that might make you or your child not want to stay or have your child stay in the study. If this happens, we will tell you and your child as soon as possible. You should also tell us if you or your child ever have concerns about being in the study.

[Include if the study has the potential for direct benefit or if the subjects are being paid; otherwise, delete sentence] We may decide to have you or your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if staying in the study may be bad for you or your child, or if the study is stopped.

**Questions**

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact name at phone number. Also call if you need to report an injury to your child during this research. [Include if the study is greater than minimal risk; otherwise, delete sentence] Contact name at phone number if there is no answer at that phone number or if you are calling after normal business hours.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your or your child’s rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

[Include and edit if this is an international study also overseen by a local Ethics Board; otherwise, delete sentence] You may also contact information for the local Ethics Board

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| **SPECIAL DIRECTIONS** – delete this box from submitted consent formYou are ready to select and edit the signature page, unless your study involves any of the following, in which case, copy the required language to the indicated sections. Delete this entire text box from the submitted version. 1. Genetic testing and/or collecting genetic information
	* In **What Will Happen in This Research Study**, describe:
	* If the research will or might include whole genome sequencing of biospecimens, include language such as the following:

We will perform a whole examination of your/your child’s DNA or genome. Usually researchers study just a few areas of your/your child’s genetic code that are linked to a disease or condition. In whole genome studies, all or most of your/your child’s genes are examined and used by researchers to study links to a disease or condition.* + Plans for future use of genetic samples and genetic data
	+ The plans for return of pertinent and incidental findings (see 2. below), or a statement that no findings will be returned to parents/subjects
	+ In **Risks**, describe the psychological and socioeconomic risks related to generating personal genetic information (including risks to genetic relatives)
	+ If individually identifiable results will be returned to parents/subjects, include the following language in **Risks** (edited as appropriate depending on whose genetic information is returned):

There is a potential risk that your/your child’s genetic information could be used to your or your child’s disadvantage. For example, if genetic research findings suggest a serious health problem, that could be used to make it harder for you/your child to get or keep a job or insurance. Both Massachusetts state laws and federal laws, particularly the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you/your child based on your/your child’s genetic information. These laws will generally protect you/your child in the following ways: * + 1. Health insurance companies and group health plans may not request your/your child’s genetic information that we get from this research.
		2. Health insurance companies and group health plans may not use your/your child’s genetic information when making decisions regarding your/your child’s eligibility or premiums.
		3. Massachusetts employers with 6 or more employees (or 15 or more employees in other states, under GINA) may not use your/your child’s genetic information that we get from this research when making a decision to hire, promote, or fire you/your child or when setting the terms of your/your child’s employment.

Be aware that neither Massachusetts law nor GINA protects you/your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance, and long-term care insurance companies may legally ask whether you/your child has had genetic testing and deny coverage for refusal to answer this question.* + If data will be sent to an NIH database such as dbGaP, add the following language to **Confidentiality** (edited as appropriate depending on whose genetic data will be sent):

Samples that are collected from you/your child in this study will be analyzed to find out information about your/your child’s genetics. Your/your child’s genetics and health information, without your/your child’s name or other data that could easily identify you or your child, will be put in a database run by the National Institutes of Health (NIH). [Include if the study involves whole genome sequencing; otherwise, delete sentence] This may include your/your child’s whole genome information. Other researchers can ask the NIH to get your/your child’s information from the database. You should know that it is possible that your/your child’s genetics information might be used to identify your child, you, or other family members, though we believe it is not too likely that this will happen. Once your/your child’s information is given to the NIH database, you can ask to have NIH stop sharing it, but NIH can’t take back information that was already shared. 1. Communication of pertinent and/or incidental findings to subjects and/or their physicians
	* In **What Will Happen in This Research Study**, describe:
	* The anticipated findings that will be communicated and/or the criteria that will be used to determine which findings will be communicated if there may be unanticipated findings
	* To whom and by whom the findings will be communicated, when, and how
	* The reliability and limitations of the information provided by any findings that are not standard measurements
	* If applicable, any further diagnosis or other actions may be required based on the findings, including their risks and costs to the subject (and to their relatives if applicable)
	* Whether or not subjects and/or their parents can request not to have some or all of the findings returned to themselves or to their physicians, and if so, the categories of findings they can choose and the considerations relevant to making those choices
	* If applicable, the resources such as counseling available to subjects and/or their parents to help with receiving and interpreting findings

As applicable, edit and add the following when pertinent findings may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:The research measurements we make are not necessarily the same as tests done by your doctor. We are collecting information on many people to answer our research questions. Not everyone doing the research tests is a doctor or a nurse. You or your child’s doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your child’s doctor decides that follow-up tests and treatments are necessary, then you or your child’s insurance will be billed for the costs.As applicable, edit and add the following when incidental findings from imaging may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:The imaging test you will have in this study is for research purposes only. However, we might see something that could be important to your child’s health. If we do, we will ask you if you want us to explain what we noticed. If you would like, we will also tell your child’s doctor. You or your child’s doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your child’s doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs. As applicable, edit and add the following when no findings will be returned to subjects or their physicians:The tests we are doing in this study are for research purposes only. We will not tell you or your child the results because explain the reason, such as it is not known if the results mean anything.1. Repositories or other retention of samples or data
	* In **What Will Happen in This Research Study**, describe:
* How samples or data will be obtained
* What types of research will use the samples or data
* Whether genetic information will be included
* Plans for release of samples or data from the repository, including:
* What types of researchers may request release (from BMC or BU, external universities, industry, government, etc.)
* Who will review requests for release to ensure the research is consistent with the aims of the repository
* What sample or data handling procedures will the researchers be required to agree to
* For release of samples, what information will accompany the samples (demographics, diagnosis, etc.)
* If the study has the potential for direct benefit to the subject, a statement that agreeing to the retention of samples or data is optional and that the subject can agree to participate in the main study but not agree to having their samples retained
	+ In **Confidentiality**:
	+ Add: The repository has standard operating procedures to protect your and your child’s confidentiality. A description of how specimens and/or data are stored and shared.
	+ Add the following bullet to the bulleted list of people who will receive identifiable samples/data:
* People who will get your and your child’s data and biological samples as we described in the section **What Will Happen in This Research Study**. These people are expected to protect your and your child’s information and biological samples in the same way we protect it.
1. ICH-GCP (note that the IRB does NOT perform an ICH-GCP compliant review; if this is an issue, contact the IRB at 617-358-5372 or medirb@bu.edu): If your study protocol says that the consent form complies with ICH-GCP:
	* In the **What Will Happen in This Research Study** section, the number of subjects is REQUIRED, not optional. Also include the subject’s responsibilities and the probability of random assignment, if applicable
	* In the **Alternatives** section, include any clear advantages or disadvantages of the alternatives.
	* In the **Confidentiality** section, include statements that the subject’s Primary Care Provider will be informed of their participation in the research, unless specifically requested not to do so by the subject and that the monitor(s), auditor(s), IRB, and regulatory authorities will be granted direct access to the subject’s original medical records for verification of research procedures and/or data.
	* In the **Subject’s Rights** section, the following statements are REQUIRED, not optional: During this study, we may find out something that might make you or your child not want to have your child stay in the study. If this happens, we will tell you and your child as soon as possible. AND We may decide to have your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if staying in the study may be bad for your child, or if the study is stopped.
	* In the **Signature** page, a witness signature and date is REQUIRED if limited- or non-readers are enrolled.
 |

|  |
| --- |
| **SIGNATURE PAGES** – delete this box from submitted consent formFive signature pages follow. Select and edit the one that is applicable to your study, and delete the other four pages. 1. No parent signatures (waiver of documentation of consent), or parent(s) signature is obtained but no signature of person conducting consent discussion
2. Signature of one parent and person conducting consent discussion
3. Signature of two parents and person conducting consent discussion
4. Signature of one parent – limited- or non-readers excluded and person conducting consent discussion
5. Signature of two parents – limited- or non-readers excluded and person conducting consent discussion

Note that parents who are limited- or non-readers **should be included** unless there are specific reasons to exclude them. For research that is greater than minimal risk, to assure comprehension if parents who are limited- or non-readers are included, either an impartial witness must be present during the consent process or some other method will be used and documented, as described in the INSPIR application.Subjects physically unable to write: a subject who is physically unable to provide a signature on a consent form may provide consent or assent by requesting another person to sign in their presence. The person signing the form on behalf of the subject must be an adult and may not be the person conducting the consent discussion. The person signing the form on behalf of the subject must provide a statement to this effect on the page with their signature, such as “[Name] is unable to sign and has directed me to sign in their presence – [printed name of person signing].” If the study is likely to enroll subjects physically unable to write, the investigator may include a pre-printed statement to the signature page to be used in such circumstances. |

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| --- |
| **1. NO PARENT SIGNATURE OR NO INVESTIGATOR SIGNATURE** – delete this box from submitted consent form |

[Include if parent signature is waived or parent signature is obtained electronically; otherwise, delete first two paragraphs below]

By agreeing for you and your child to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, that you permit the use and sharing of information that may identify you or your child as described, [include if health information is obtained and HIPAA authorization is not waived; otherwise, delete blue phrase] , including your and your child’s health information, and that you voluntarily agree to participate and to allow your child to participate in this research study.

[Include if parent signature is obtained electronically and edit as-needed to reflect your proposed language for documenting electronic consent; otherwise, delete blue text below] Please type your name into the box below to indicate your consent to participate and to allow your child to participate in the study and click “Next” to continue.

[Include if written “wet ink” parent signature is obtained but investigator signature is not obtained; and if so ensure you deleted the two above paragraphs); otherwise, delete all text below]

**Child Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this permission form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate and to have your child participate in this research study
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your and your child’s health information.

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

Printed name of parent/legal guardian

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

Signature of parent/legal guardian Date

[Include if any children will read the permission form (this is recommended only for children aged 16 or 17); otherwise, delete paragraph and signature line] By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

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

Signature of child Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARENT

|  |
| --- |
| **2. SIGNATURE OF ONE PARENT** – delete this box from submitted consent form |

**Child Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this permission form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate and to have your child participate in this research study
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your and your child’s health information.

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

Printed name of parent/legal guardian

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

Signature of parent/legal guardian Date

[Include if any children will read the permission form (this is recommended only for children aged 16 or 17); otherwise, delete paragraph and signature line] By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

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

Signature of child Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include A, B, or C]

[A. Include if all children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named child and to the parent/legal guardian and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

[B. Include if some children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parent/legal guardian and answered all questions. I believe that the parent/legal guardian understands what is involved in the study and freely agrees to participate and to have their child participate. I consider that the above-named child (check one):

o is capable of understanding what is involved in the study and freely agrees to participate.

o is not capable of understanding what is involved in the study.

[C. Include if no children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parent/legal guardian and answered all questions. I believe that the parent/legal guardian understands what is involved in the study and freely agrees to participate and to have their child participate.

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

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the parent/legal guardian*

This consent/permission form was read to and apparently understood by the parent/legal guardian in my presence.

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

Printed name of witness (a person not otherwise associated with the study)

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

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARENT

|  |
| --- |
| **3. SIGNATURE OF TWO PARENTS** – delete this box from submitted consent form |

**Child Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this permission form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate and to have your child participate in this research study
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your and your child’s health information.

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

Printed name of parent/legal guardian 1

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

Signature of parent/legal guardian 1 Date

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

Printed name of parent/legal guardian 2

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

Signature of parent/legal guardian 2 Date

If only one parent/guardian signature is obtained, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Include if any children will read the permission form (this is recommended only for children aged 16 or 17); otherwise, delete paragraph and signature line] By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

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

Signature of child Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include A, B, or C]

[A. Include if all children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named child and to the parents/legal guardians and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

[B. Include if some children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parents/legal guardians and answered all questions. I believe that they understand what is involved in the study and freely agree to participate and have their child participate. I consider that the above-named child (check one):

o is capable of understanding what is involved in the study and freely agrees to participate.

o is not capable of understanding what is involved in the study.

[C. Include if no children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parents/legal guardians and answered all questions. I believe that they understand what is involved in the study and freely agree to participate and to have their child participate.

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

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the parents/legal guardians*

This permission form was read to and apparently understood by the parents/legal guardians in my presence.

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

Printed name of witness (a person not otherwise associated with the study)

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

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARENTS

|  |
| --- |
| **4. SIGNATURE OF ONE PARENT – LIMITED- AND NON-READERS EXCLUDED** – delete this box from submitted consent form |

**Child Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this permission form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate and to have your child participate in this research study
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your and your child’s health information.

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

Printed name of parent/legal guardian

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

Signature of parent/legal guardian Date

[Include if any children will read the permission form (this is recommended only for children aged 16 or 17); otherwise, delete paragraph and signature line] By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

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

Signature of child Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include A, B, or C]

[A. Include if all children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named child and to the parent/legal guardian (who has read this permission form) and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

[B. Include if some children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parent/legal guardian (who has read this permission form) and answered all questions. I believe that the parent/legal guardian understands what is involved in the study and freely agrees to participate and to have their child participate. I consider that the above-named child (check one):

o is capable of understanding what is involved in the study and freely agrees to participate.

o is not capable of understanding what is involved in the study.

[C. Include if no children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parent/legal guardian (who has read this permission form) and answered all questions. I believe that the parent/legal guardian understands what is involved in the study and freely agrees to participate and to have their child participate.

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

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARENT

|  |
| --- |
| **5. SIGNATURE OF TWO PARENTS – LIMITED- AND NON-READERS EXCLUDED** – delete this box from submitted consent form |

**Child Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of subject

By signing this permission form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate and to have your child participate in this research study
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your and your child’s health information.

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

Printed name of parent/legal guardian 1

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

Signature of parent/legal guardian 1 Date

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

Printed name of parent/legal guardian 2

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

Signature of parent/legal guardian 2 Date

If only one parent/guardian signature is obtained, explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Include if any children will read the permission form (this is recommended only for children aged 16 or 17); otherwise, delete paragraph and signature line] By signing below, you are indicating that you have read this form, that your questions have been answered, and that you voluntarily agree to participate in this research study.

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

Signature of child Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Printed name of person conducting consent discussion

[Include A, B, or C]

[A. Include if all children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named child and to the parents/legal guardians (who have read this permission form) and answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

[B. Include if some children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parents/legal guardians (who have read this permission form) and answered all questions. I believe that they understand what is involved in the study and freely agree to participate and to have their child participate. I consider that the above-named child (check one):

o is capable of understanding what is involved in the study and freely agrees to participate.

o is not capable of understanding what is involved in the study.

[C. Include if no children are capable of assent; otherwise, delete paragraph] I have personally explained the research to the above-named parents/legal guardians (who have read this permission form) and answered all questions. I believe that they understand what is involved in the study and freely agree to participate and to have their child participate.

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

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARENTS