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| **GENERAL INSTRUCTIONS** – delete this box from the submitted consent formThis template is for research involving children only. Do not use this template for research involving adults; instead use “Adult Consent Form Template” if only adults are subjects. 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) |

Use this header:

**Texas A&M University**

**Kingsville**

**IRB Informed Consent Form, IRB # \_\_\_\_\_\_\_\_\_\_**

(Once received by the IRB, the proposal will be issued an identifying number.)

**CONSENT FOR RESEARCH PARTICIPATION**

Title of Project: Title

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

Principal Investigator:

|  |  |
| --- | --- |
| PI Name: | Type here |
| PI contact phone: | Type here |
| PI contact email: | Type here |

Co-Investigator(s): Delete section if no Co-PI, copy/paste if more than one

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| --- | --- |
| Co-PI Name: | Type here |
| PI contact phone: | Type here |
| PI contact email: | Type here |

Student-Investigator: Delete section if no SI, copy/paste if more than one

|  |  |
| --- | --- |
| SI Name: | Type here |
| SI contact phone: | Type here |
| SI contact email: | Type here |

**Overview**

We are asking you to allow 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 to allow your child to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

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| **Key Information for You to Consider** |
| * **Voluntary Consent**. Your child is being asked to volunteer for a research study. It is your decision whether or not to allow your child to join the study. Even if you agree to allow your child to participate, your child may still decline to be in the study. There will be no penalty or loss of benefits to which you are otherwise entitled if you or your child choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
* **Duration.** It is expected that your child’s participation will last [expected duration].
* **Procedures and Activities.** Your child will be asked to [briefly highlight the key research activities/procedures].
* **Risks.** Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
* **Benefits**. Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
* **Alternatives.** As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, “Participation is voluntary, and the only alternative is to not participate.”].
 |

**Potential Conflict of Interest:**

 [Include if the PI or any study investigator could also be the subject’s healthcare provider; otherwise, delete paragraph] Your healthcare provider may also be an investigator in this research study. Being an investigator means your healthcare provider is interested in both your child and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another healthcare provider who is not an investigator can give you a second opinion about being your child participating in the study. You do not have to agree to be in this study even though it is offered by your healthcare provider.

**Why is this research being done?**

A brief explanation of the purpose of the study, stating in lay language 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 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.

The ways we will protect your and your child’s privacy and confidentiality are described in a separate section later in this form.

[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 only if the study is more than minimum risk] Do you grant permission for us to make an audio and/or a video recording of your child? **If this is an exempt study you still need to state the participants they will either be audio or video recorded but they do not need to check the boxes or initial. You will want to remove the check boxes and initials.**

 YES NO Initial \_\_\_\_\_\_\_

 [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] 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. Do NOT include the risk of loss of confidentiality to avoid duplicating information in the **Confidentiality** section.

[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 female children in the study should not become pregnant because of risks to the fetus (not applicable if all female children will be below the age of menarche); otherwise, delete paragraph] If your child is female and gets pregnant while in this study, it could be bad for the fetus/baby. Your daughter must use birth control if she has sex with men while in this study. [Include or modify time frame if applicable; otherwise, delete] She should also keep using birth control for three months after the study ends. Only some birth control methods work well enough to be safe while your daughter is 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. Your daughter should not be in this study if she has sex with men and cannot use one of these birth control methods.

**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, your child may not receive any benefit. 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] Your child will receive no direct benefit from being in this study. 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; 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 TAMUK 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 TAMUK clinical services and subjects may incur any costs; otherwise, delete sentence] If your child is in this study, you will have to pay for list costs

[C. Include if the study does not use TAMUK 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

[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 A or B]

[A. 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 child’s name or any information that shows their identity. You will not be signing this form. Further explanation of measures to preserve anonymity, if appropriate.

[B. Include the following paragraph and the remainder of the Confidentiality section if study does record ANY information that would identify subjects; otherwise, delete paragraph]

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

We will store your child’s information in ways we think are secure. [Include next sentence if biospecimens are collected; otherwise, delete 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. However, we cannot guarantee complete confidentiality.

[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 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 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 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 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, and the National Institutes of 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 child’s information and biological samples in the same way we protect it.
* Any people who you give us separate permission to share 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 information about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.

[Include 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 child’s identity. There still may be a small chance that someone could figure out that the information is about your child. Such sharing includes:

* Publishing results in a professional 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 their 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 Child’s Health Information section] **Use and Sharing of Your Child’s Health Information**

The research team has to use and share your child’s health information to do this study, including information that may identify you or your child. By agreeing to allow your child to be in this study and signing this form, you are giving us your permission where needed to use and share 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 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 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 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 your child. As we explained above, if your child is in immediate danger of hurting themself, it is possible that 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 child’s health information are:

* Researchers involved in this research study from The Texas A&M University-Kingsville, and/or other organizations
	+ 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 your child if 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 child’s health information from us to protect the privacy of your child’s information. However, we cannot control how they may use or share your child’s health information. We cannot promise that they will keep it completely private.

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

* Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

* You have the right not to sign this form that allows us to use and share your child’s health information for research. If you do not sign this form, your child cannot be in the research. This is because we need to use health information to do 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 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, your child cannot continue to be in the study.

[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**

If you think that your child has been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. 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 insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

**Re-Contact**

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

We would like to ask your permission to contact you and your child again in the future. This contact would be after 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 giving permission for your child to be in this study, you do not waive any of your or your child’s legal rights. Giving permission means that you have been given information about this study and that you agree 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 your child to be in this study or if at any time 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 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 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 does not want to have your child stay in the study. If this happens, we will tell you and your child as soon as possible.

[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 your child stop being in the study even if you and your child want to stay. Some reasons this could happen are if we feel that staying in the study may be bad for 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 contact email (IRB chairperson email). You will be talking to **(**IRB Chairperson name), the University chair of the IRB at Texas A&M University-Kingsville. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your 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.

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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 child’s DNA or genome. Usually, researchers study just a few areas of your child’s genetic code that are linked to a disease or condition. In whole genome studies, all or most of 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**:

There is a potential risk that 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 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 your child based on your child’s genetic information. These laws will generally protect your child in the following ways: * + 1. Health insurance companies and group health plans may not request your child’s genetic information that we get from this research.
		2. Health insurance companies and group health plans may not use your child’s genetic information when making decisions regarding 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 child’s genetic information that we get from this research when making a decision to hire, promote, or fire your child or when setting the terms of your child’s employment.

Be aware that neither Massachusetts law nor GINA protects 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 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 and edit the following language to **Confidentiality**:

Samples that are collected from your child in this study will be analyzed to find out information about your child’s genetics. Your child’s genetics and health information, without 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 child’s whole genome information. Other researchers can ask the NIH to get your child’s information from the database. You should know that it is possible that 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 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 the findings
* 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
* 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 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 ask 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 the 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 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 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 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 written signatures (waiver of documentation of consent)
2. Signature of one parent
3. Signature of two parents
4. Signature of one parent – limited- or non-readers excluded
5. Signature of two parents – limited- or non-readers excluded

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.Parents and/or subjects physically unable to write: a parent and/or 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 parent and/or subject must be an adult and may not be the person conducting the consent discussion. The person signing the form on behalf of the parent and/or 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. 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 allow your child to 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 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 have their child participate. I consider that the above-named child (check one):

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

🞏 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 have their child participate.

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

Signature of person conducting consent discussion Date

[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 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

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**If you have questions or concerns, those questions or concerns should be directed to the University IRB at****tamuk.irb@tamuk.edu****or (361)593-3344**

|  |
| --- |
| **2. 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 allow your child to 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 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 have their child participate. I consider that the above-named child (check one):

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

🞏 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 have their child participate.

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

Signature of person conducting consent discussion Date

[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

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|  |
| --- |
| **3. 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 allow your child to 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 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 have their child participate. I consider that the above-named child (check one):

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

🞏 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 have their child participate.

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

Signature of person conducting consent discussion Date

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|  |
| --- |
| **4. 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 allow your child to 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 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.

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

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

Signature of person conducting consent discussion Date

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