**June 2015 (doc)**

**COMBINED PARENTAL INFORMED CONSENT/AUTHORIZATION TEMPLATE**

***Use when ALL study participants are under 18 years of age and parent(s)/guardian(s) consent is required***

**Instructions for developing parental informed consent/privacy authorization document)**

Call the JHM IRB office (410-955-3008) if you have any questions

**Drafting the Parental Consent Form**

**Shaded Instruction Boxes:**

Many sections of this document include brief instructions to provide a general overview of information required in the section. **Please delete all shaded instruction boxes before submitting your consent form to the JHM IRB for review.** To delete, select a shaded box and click the cut button on the Word toolbar.

**Section Headings:**

* 14 point font [Times New Roman is preferred font]
* Section headings marked *Insert if applicable* may be omitted if they do not apply to your study. If Sections are omitted, the paragraphs should be renumbered.

**Text:**

* 12 point font [Times New Roman is preferred font]
* Suggestions/hints for the text to be written under each heading are included and instructions are shaded blue*.*
* **Please delete all shaded instruction boxes before submitting this form.** To delete these shaded boxes, click the “cut” icon in the toolbar at the top of the document.

**Header:**

* To insert the date of the consent form, the Principal Investigator’s name and the application number (for new studies the application number may not be available to you and can be left blank) into the Header, *go to the Toolbar, select View, select “Header and Footer.” After inserting your information, select Close.*

**Tips on Pagination:**

* Once the text of the consent document is complete, format the page numbers. In Microsoft Word, start by clicking on File on the toolbar. Then, click on Print Preview. If, in Print Preview, the numbers do not reset appropriately, return to the document. *Make sure you are not in a “track and change” mode. Go to the toolbar, select View, select “Header and Footer”, and then select the footer option. Highlight the page number, right click to select “Update Field.”*

**Protocol Description:**

* The portions of the consent form that are specific to the study must conform to the protocol.
* Individuals taking part in the study should be referred to as participants, not patients.
* The use of the second person (e.g., “You will receive…”) is generally required;
* The use of the first person (e.g., “I understand that…”) is generally not allowed.
* Guidelines for avoiding common errors in consent forms are on page 3.

**Required Paragraphs**:

* The HIPAA Privacy Authorization developed by the General Counsel must be included in all consent forms.
* The required institutional boilerplate language is provided under “**What other things should you know about this research study?**”

**Reading Level and Spell Checking**:

* Your completed version of the informed consent document should be spell checked and proofread before being submitted.
* Investigators are expected to write consent forms in simple language. The preferred reading level is 8th grade.
* Please use the Spelling and Grammar feature of Microsoft Word or Word Perfect to check the reading level of the text of the document that you write (instructions for Microsoft Word are on pages 5 and 6 of this document)
* The standard required institutional boilerplate language under “**How will your child’s privacy be protected?”** and “**What other things should you know about this research study?”** does not have to be checked

**Contact Information for PI or Other Study Team Members**:

* Make sure that the address, telephone and fax information inserted into the consent form are current and accurate.

**Signature Lines**:

* The signature page of the informed consent document must include applicable signature lines for your study.
* Include time and date of signature
* **Delete signature lines that are not required for your study**.

**Approved Consent Forms:** Only the approved consent form with the JHM IRB approval on the signature page or the JHM IRB Logo (for eIRB protocols) may be used to consent participants for research studies.

Questions or suggestions regarding the template should be sent to the JHM IRB office e-mail address (jhmirb@jhmi.edu).

**for research that includes creation of cell lines or pluripotent cells**

Follow instructions below and/or go to the human pluripotent stem cell research informed consent template on the jhm irb website for information required in the consent form.

**Section 2: Why is this research being done?**

* *If cell lines will be created, include the following:*

Your child’s tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your child’s cells in the future without asking for more samples from your child.

* *If iPS cells will be created, include the following:*

We may use the cells taken from your child’s [specify source of cells, e.g. skin] to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including [specify type of cells, e.g. cardiac, muscle, etc.] cells. Your child’s cells might be used in research involving genetic alteration of the cells.

* *If cells will be used in animal models include the following sentence:*

Your child’s cells will *(if known)*/might *(if unknown)* be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

***What you should know about the cell lines that will be derived in the course of this study?***

* The cell lines created will be similar or identical to your child genetically.
* The cell lines may be kept indefinitely.
* There is the possibility that your child’s cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
* The cell lines may be shared with researchers both inside and outside of Johns Hopkins, including our commercial partners.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

**Section 3: What will happen if you allow your child to join this study?**

*Describe how the human biological materials will or might involve: (i) the introduction of the cells into humans; (ii) the introduction of the cells into the central nervous system of non-human primates; (iii) the introduction of the cells into non-human animals and there is a significant possibility of the cells giving rise to gametes; or (iv) the creation of gametes or embryos.*

**Common Consent Form Errors**

*Describe (i) whether the donated material will be coded or de-identified prior to research use; (ii) if the donors’ identities are retained (even if coded), whether donors can elect to be contacted to receive information through studies of the cell lines, (iii) that restricted and/or directed donation (e.g., to individuals or groups) are/is not permitted.*

* Do not use “treatment” or “therapy” to describe an investigational drug, device or procedure. For investigational drugs use words like, “study drug” or “study product.” For an investigational device, use words like “study device” or “study product.” For an investigational procedure, use “study procedure” or “research procedure.”
* For investigational drugs or devices, state they are investigational and describe that term (e.g., the word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies. Be consistent in using “investigational” throughout the consent form. **Do not describe investigational drugs, devices or procedures as “new.”** The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition.
* Do not use the term "treatment” or “therapy”" if one of the study arms will use a placebo. Clarify for the participant by using “study drug or placebo,” or “study product,” or “study substance.” Do not refer to a placebo as medicine or medication.
* Use "study doctor" (more understandable to a lay person) instead of “principal investigator."
* Use "research study," instead of "trial."
* Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study.
* Do not use the word “invite” (for example, “You are invited to participate in a research study.”) Instead use, “You are being asked to participate in a research study because (insert condition here).”
* When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat."
* Do not use e.g. or etc., use instead, "for example," "so forth."
* Spell out acronyms when first used.
* Do not use all capital letters (CAPS) or bold items unnecessarily.
* Use initial lines or check boxes for optional portions of the study (e.g., asking permission to store samples for future research).
* For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out to what study group your child is assigned.”

**Assessing Flesch-Kincaid Readability**

**Using Microsoft Word 2013**

1. Open the Microsoft Word document for which you would like to assess readability.
2. Select “FILE” in the upper-left hand corner. Then, choose “Options”. A box opens. Click on “Proofing” on the left hand side of this box. Make sure that check box, titled “Show readability statistics” is selected under “When correcting spelling and grammar in Word” header.
3. Highlight/Select the text which you would like to assess. For consent form purposes, assess the study-related text leaving out any University boilerplate and HIPAA language.
4. Unless you know that your Microsoft Word is set for English (U.S.), then you should select “Review” on the top ”Ribbon”. Then, click on “Language” in the “Language and select “Set Proofing Language”.” group
5. A dialog box will appear. Use the list provided in this box to assure that the appropriate language is highlighted. Usually, this is “English (U.S.)”. Occasionally, studies are targeting a population using another language, or another type of English, such as U.K., Singapore, etc.
6. Once you have selected a language, make sure that the option within this box that reads, “Do not check spelling or grammar” is unchecked.
7. Next, click the “Ok” button at the bottom of this dialog box.
8. Now, select “Spelling and Grammar” icon visible in the “Proofing” group.
9. Microsoft Word will start guiding you through the Spelling and Grammar function. Use this chance to correct spelling/grammar errors that Word may have identified. (Use discretion. This function is not fool proof!)
10. Once Spelling and Grammar are complete, a dialog box will appear asking if you would like to continue checking the remainder of the document. Click “No.”
11. Once you click “No”, a box containing the readability statistics for the selected text will open.
12. The Flesch-Kincaid Grade Level is the last number listed under the Readability section in the dialog box.
13. Click “Ok” to exit Readability Statistics and to continue using this Word document.

**Review of Required and Additional Elements**

This checklist is provided to help you in the preparation of the consent form**.**

**Do not submit this checklist with the consent form.**

**Verify that the informed consent document contains each of the eight required elements (45 CFR 46.116)**

| **Yes** | **No** | **Item #** | **ITEMS** |
| --- | --- | --- | --- |
|  |  |  | 8 REQUIRED ELEMENTS |
|  |  | **1a** | a statement that the study involves research, and |
|  |  | **1b** | an explanation of the purposes of the research, and |
|  |  | **1c** | the expected duration of the participant ‘s participation, and |
|  |  | **1d** | a description of the procedures to be followed, and |
|  |  | **1e** | identification of any procedures which are experimental; |
|  |  | **2** | a description of any reasonably foreseeable risks or discomforts to the participant; |
|  |  | **3** | a description of any benefits to the participant or to others which may reasonably be  expected from the research |
|  |  | **4** | a disclosure of appropriate alternative procedures or courses of treatment, if any,  that might be advantageous to the participant; |
|  |  | **5a** | a statement describing the extent, if any, to which confidentiality of records  identifying the participant will be maintained; and |
|  |  | **5b** | if the research is subject to FDA regulation, a statement that notes the possibility that FDA may inspect the records |
|  |  | **6a** | for research involving more than minimal risk, an explanation as to whether any  compensation is available if injury occurs, and |
|  |  | **6b** | an explanation as to whether any medical treatments are available if injury occurs and, |
|  |  | **6c** | if so, what they consist of, or where further information may be obtained; |
|  |  | **7a** | an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and |
|  |  | **7b** | whom to contact in the event of a research-related injury to the participant; |
|  |  | **8a** | a statement that participation is voluntary, and |
|  |  | **8b** | a statement that refusal to participate will involve no penalty or loss of benefits to  which the participant is otherwise entitled, and |
|  |  | **8c** | a statement that the participant may discontinue participation at any time without  penalty or loss of benefits to which the participant is otherwise entitled. |

**When appropriate, which of the following additional elements of information are provided in the consent form?**

| **Yes** | **NA** | **Item #** | **ITEMS** |
| --- | --- | --- | --- |
|  |  |  | 7 ADDITIONAL ELEMENTS |
|  |  | 1a | a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and |
|  |  | 1b | if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable; |
|  |  | 2 | anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent; |
|  |  | 3 | any additional costs to the participant that may result from participation in the research; |
|  |  | 4 | If this is a clinical trial, a statement that the research will be entered into the clinical trials.gov website; |
|  |  | 5a | the consequences of a participant’s decision to withdraw from the research; and |
|  |  | 5b | procedures for orderly termination of participation by the participant; |
|  |  | 6 | a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant |
|  |  | 7 | The approximate number of participants involved in the study. |

**Instructional Template**

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

# **PARENT INFORMED CONSENT AND PRIVACY**

# **AUTHORIZATION FORM**

**Protocol Title**:

Application No.:

**Sponsor:** *Delete line if not applicable*

**Principal Investigator**: *Include name, address, phone and fax information*

1. **What you should know about this study:**

* You are being asked to allow your child to join a research study. This consent form explains the research study and your child’s part in the study. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
* Joining this study is voluntary. If you allow your child to join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide not to allow your child to continue the study.
* During the study, we will tell you if we learn any new information that might affect whether you wish to continue to allow your child to participate.
* If we think your child’s participation in this study may affect your child’s clinical care, information about your child’s study participation will be included in your child’s medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information.  You can ask the research team to send this information to any of your child’s doctors.
* When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children’s Hospital.

*Include this bullet if biospecimens will be collected in the study:*

* Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

*Include these bullets if this study will be in clinicaltrials.gov:*

* 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.
* If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

*Include this for a blinded study or a study where medical information will not be available to participants until the study is completed:*

* During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while your child is in the study, medical information needed for your child’s treatment can be made available to your study physician and other physicians who treat your child. When the study is completed, all the information in your child’s medical record will be available to you.

1. **Why is this research being done?**

* *Start with an introductory sentence describing the primary purpose of the research as stated in the protocol:*

This research is being done to....

* *State what the study is designed to discover or establish. If this is a treatment study, describe the nature of the experimental design and how it differs from standard clinical care (including, for example: projected differences in morbidity and mortality rates, consequent medication differences that might affect participants, what factors the PI considered in choosing the experimental design, etc.) Identify any procedures that are experimental.*
* *If cell lines may be created from tissue samples or iPS cells are used in this research, include the information on page 3 of this template.*
* *If you are using a drug or device that is investigational and is not approved by the Food and Drug Administration, state that the drug, combination of drugs, device, etc. are investigational and include the following:*

The use of “X” (study drug or device name) in this research study is investigational. The word “investigational” means that “X” is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of “X” in this study.

* *If you are using an FDA approved drug or device, but not for an FDA-approved purpose, include the following:*

“X” (drug or device name) is approved by the Food and Drug Administration (FDA) for the treatment of \_\_\_ (include disease name). It is not approved for use in \_\_\_ (disease name). The FDA is allowing the use of \_”X” in this research study.

* *If the FDA may approve the study drug while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved.*
* *Describe the basic eligibility criteria, but DO NOT state that the participant has been selected for the study:*

Children with \_\_\_\_\_\_ may join.

***How many children will be in this study?***

* *Include the approximate number of participants expected to take part. If this is a multicenter study, include the total number of participants at all sites, and the approximate number who will take part at Johns Hopkins.*

1. **What will happen if you allow your child to join this study?**

* *Start with the statement:*

If you agree to allow your child to be in this study, we will ask you to allow your child to do the following things:

* *Describe the procedures chronologically using lay language, short sentences, and short paragraphs.*
* *Blood draw measurements should be provided in teaspoons/tablespoons, ounces, etc.*
* *Use subheadings and bulleted items.*
* *Distinguish which procedures are part of the study and which are standard clinical treatments.*
* *Clarify any change in participant’s care as s/he shifts from standard clinical care to the study intervention.*
* *Define and explain all medical and scientific terms in ordinary language. For example, volumes should be described in terms of teaspoons or tablespoons.*
* *Specify the assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of procedures, etc.*

* *For research involving randomization, specify the randomization procedure. For two groups use “like flipping a coin.” If your research includes more than two groups use “like drawing numbers from a hat.”*
* *For research involving the use of placebo, clearly define the term placebo. Use language like “A placebo is an inactive substance that looks like the study drug, but contains no active drug.”*
* *If results are given to parents of participants or their physicians, include here.*
* *If your study will include asking permission to allow future contact or to allow optional procedures (e.g., additional blood draws), the yes/no options must include the full signature of the parent(s). If you include yes/no options, you must track the yes and no responses.*
* *If your research will include genetic testing, insert the following:*

The Genetic Information Nondiscrimination Act (GINA) may help protect you and your child from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

* may not ask for genetic information from this research and
* may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as: life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you or your child were to become known to people outside of this study.

*If this research will include a request to store biospecimens for future research, include the following:*

**Request to collect and store biospecimens for future research**

As part of this research study, we would like to ask you to let us store your child’s biospecimens and health information for future research. This research could include other diseases.

*If there is the possibility but not certainty that the future research will involve gene sequencing or the creation of cell lines, include the appropriate statement(s) below. If it is known that the study* ***will*** *include gene sequencing or the creation of cell lines, language provided on page 3 of this instructional template must be included in the consent form.*

The research may involve research tools such as gene sequencing or the creation of cell lines.

* Gene sequencing of your DNA provides researchers with the code to your child’s genetic material.
* Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your child’s complete DNA.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your child’s biospecimens can be found in this consent document under the heading “*What happens to Data and Biospecimens that are collected in the study*.”

Will you allow us to store the biospecimens we collect for this study for use in future research*?*

**Yes € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Parent

**No € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Parent

* *If appropriate, state that the study will involve long-term follow-up.*

**How long will your child be in the study?**

* *Insert the expected duration (days, weeks or months) of the child’s participation.*

Your child will be in this study for \_\_\_\_

1. **What are the risks or discomforts of the study?**

* *Identify each intervention with a subheading and then describe any reasonable risks, discomforts, inconveniences, and how these will be managed. Each medication used must be listed. Within subheadings, consider the use of bulleted items.*
* *In a treatment study, describe the risks associated with joining the study as compared with the risks associated with continuing standard clinical care.*
* *If this is a placebo-controlled study, include the risk that the participant’s disease/condition may not be treated and that the participant’s condition may worsen.*
* *If the study includes a washout period, describe the possible risks of discontinuing medications.*
* *List risks in order of relative probability (e.g., “likely,” “less likely” or “unlikely,” and “rare but serious”). Always include risk of death in studies that involve serious underlying disease.*
* *All drugs that are mandated (i.e., no substitutions permitted) by the protocol, even those that are standard of care, must be included in the procedures section, and the risks that are listed on their package inserts should be described in this section.*
* *In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information.*
* *If the research involves interviews or questionnaires, include the following:*

Your child may get tired or bored when we are asking her/him questions. Your child may find it tiring or boring if s/he is asked to complete questionnaires. Your child does not have to answer any question s/he does not want to answer.

*If the research involves genetic material, include the following:*

Genetic information is unique to your child and your family, even without your child’s name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your child’s DNA from being able to discover it belongs to your child. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your child’s genetic information will never be linked to you.

* *If the research involves investigational drugs or devices, or the risk profile of any research procedures are not well known, end with the statement:*

There may be side effects and discomforts that are not yet known.

1. **Are there risks related to pregnancy?**

* *Insert this heading and section if applicable (if study includes children/adolescents capable of having or fathering children).*
* *Describe foreseeable risks to a fetus.*
* *Describe any required pregnancy testing and actions that may be taken if the child participant or a child participant‘s partner becomes pregnant. This should also include the requirement of adequate birth control measures for females capable of having children and for males (when appropriate to a study).*
* *Include information for adolescent participants that results of pregnancy testing will be given to them and to their parents. Use written assent form with this information. Advise adolescents that if they do not wish to be tested for pregnancy, they should decline to participate in the study.*
* *If the risk profile of the research procedures on an embryo or fetus are not well known, end with the statement:*

This research may hurt an embryo or fetus in ways we do not currently know.

1. **Are there benefits to your child from being in the study?**

* *State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state:*

There is no direct benefit to your child from being in this study.

* *Describe the generalizable or societal benefits and use a sentence such as:*

If your child takes part in this study, your child may help others in the future.

**Do NOT include financial rewards for participation in the study. Any payment to participants should be included in the “Will you or your child be paid if you allow your child to join this study” section. Results of tests given to participants and free medical care are not considered benefits. If results will be provided this should be explained in “What will happen if you allow your child to join this study?**

1. **What are your options if you do not want your child to be in the study?**

* *Describe any alternatives that should be considered before deciding whether or not to allow the child to be in the study. If applicable, explain why these procedures are being withheld. If there are no alternatives, state that an alternative is to not take part in the study.*
* *In a treatment study, describe the option of continuing with standard clinical care and whether clinical care could include the study intervention proposed.*
* *If the prospective participants are suffering from a terminal illness, and there are no alternative treatments available, you should say so, but you might include some palliative care language.*
* *If the prospective participants have a chronic, progressive disorder for which no treatment has been demonstrated to be safe and effective, say that as well.*
* *Avoid suggesting that participation in the research is the only way to obtain medical care and attention.*
* *If other treatments are available to the participant, include the following*:

If you decide not to allow your child to join this study, other options are available. You do not have to allow your child to join this study to get treatment. Othertreatmentsinclude*(describe treatments)*

* *End with the statement:*

You do not have to allow your child to join this study. If your child does not take part in the study, your child’s care at Johns Hopkins will not be affected

1. **Will it cost you anything to allow your child to be in this study?**

* ***Healthy Volunteer Studies:*** *If billing will not be required, then state: “No” as the answer to this question and do not include the text below.*
* ***Studies enrolling only*** *at international sites: Do not include the text below. Provide whatever cost information is applicable to your study.*

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

* The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
* The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

1. **Will you or your child be paid if you allow your child to join this study?**

* *State whether the parents and/or child will be paid or offered other types of rewards (e.g., coupons, gift certificates). If not, state* No.
* *List rates of payment or other financial rewards or reimbursement (transportation, babysitting, etc.)*.
* *List method and timing of payment, and provisions for partial payment if a participant leaves early.*
* *If parents or child participant will be paid, include the following statement:*

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

1. **Can your child leave the study early?**

* *If appropriate to the study, add some or all of the following statements:*
* You can agree to allow your child to be in the study now and change your mind later.
* If you wish to end your child’s participation, please tell us right away.
* Leaving this study early will not stop your child from getting regular medical care*.*
* If your child leaves the study early, Johns Hopkins may use or give out your child’s health information that it already has, if the information is needed for this study or any follow-up activities***.***
* *If gradual withdrawal will be required for safety considerations, explain this and any unique procedure(s) required for timely and safe withdrawal.*

1. **Why might we take your child out of the study early?**

* *Insert this heading and section if applicable.*
* *If appropriate to the study, add some or all of the following statements:*

Your child may be taken out of the study if:

* Staying in the study would be harmful.
* Your child needs treatment not allowed in the study.
* You or your child fails to follow instructions.
* Your child becomes pregnant.
* The study is cancelled.
* There may be other reasons to take your child out of the study that we do not know at this time.
* If your child is taken out of the study early, Johns Hopkins may use or give out your child’s health information that it already has if the information is needed for this study or any follow-up activities***.***

1. **How will your child’s privacy be protected?**

* *If the sponsor would like to add further information in this section, you may do so and the JHM IRB will decide if the language is acceptable.*
* *If this consent form will be used at an international site, the appropriate privacy language can be found on the JHMIRB website in the HIPAA Authorization Form for International Research (HIPAA Form 1.1)*

We have rules to protect information about your child. Federal and state laws and the federal medical Privacy Rule also protect your child’s privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about your child. This includes things learned from the procedures described in this consent form. They may also collect other information including your child’s name, address, date of birth, and information from your child’s medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your child’s identity and that your child is in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your child’s information. We make this information available to your child’s doctors for your child’s safety.

People outside of Johns Hopkins may need to see or receive your child’s information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If your child is in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your child’s participation.  You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your child’s information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your child’s information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your child’s information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your child’s information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your child’s information has no time limit. You may revoke (cancel) your permission to use and disclose your child’s information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your child’s information, your child’s part in this study will end and no further information about your child will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

1. **Will the study require any of your other health care providers to share your child’s health information with the researchers of this study?**

* *Insert this heading and section if applicable*.

As a part of this study, the researchers may ask to see your child’s health care records from her/his other health care providers.

* Optional: You will be asked to give us a list of other health care providers that your child uses.

1. **What if there is a Certificate of Confidentiality for this study?**

* *Insert this heading and section if applicable*.

*Insert appropriate agency* has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you or your child. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you or your child as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you or your child if, for example, your child needs medical help.

We may also disclose identifiable information about you or your child as described in Section 12 of this form or in other cases. For example, the government may see you or yourchild’s information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

* If they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
* If certain diseases are present; and
* If the team learns that you or your child plans to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your child’s participation in the research, then we may not use the Certificate to withhold this information.

**This Certificate does not mean the government approves or disapproves of this research project.**

1. **What does a conflict of interest mean to the participants in this study?**

* *Insert this heading and wording if applicable*.

A researcher has a financial or other interest in this study.

*For studies that also have an institutional conflict, replace the first sentence with:* A researcher and Johns Hopkins have a financial or other interest in this study

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins’ policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to *name and telephone number of non-financially interested designee*. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

1. **What treatment costs will be paid if your child is injured in this study?**

* *Insert this heading and choose the appropriate Section for your consent form:*
* ***Insert the following 3 paragraphs for all studies except commercially sponsored studies with an IND/IDE held by the commercial sponsor:***

Johns Hopkins does not have a program to pay you if your child is hurt or has other bad results from being in the study. However, medical care at Johns Hopkins is open to your child as it is to all sick or injured people.

* *For studies sponsored by the federal government, replace the first sentence with:* **Johns Hopkins and the federal government do not have programs to pay you if your child is hurt or has other bad results from being in the study.**

The costs for any treatment or hospital care your child receives as a result of a study-related injury that is not covered by a health insurer will be billed to you.

By signing this form you and your child will not give up any rights you have to seek compensation for injury.

* ***For commercially sponsored studies with an IND/IDE held by the commercial sponsor, insert the following language:***

Johns Hopkins does not have a program to pay you if your child is hurt or has other bad results from being in the study. However, medical care at Johns Hopkins is open to your child as it is to all sick or injured people.

The study sponsor, *insert study sponsor name*, has agreed to pay the usual and standard costs of treatment or hospital care your child receives as a direct result of a study-related injury at are not covered by a health insurer (provided the costs are not the result of care required to treat your child’s underlying disease or condition).

Any costs that are not covered by the study sponsor or a health insurer will be billed to you.

By signing this form you and your child will not give up any rights you have to seek compensation for injury.

The following section is required on ALL consent forms in this format.

1. **What other things should you know about this research study?**
   1. **What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

* Doctors
* Nurses
* Ethicists
* Non-scientists
* and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your child’s rights as a participant or if you think you or your child have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

*If this study is being done in the Johns Hopkins Clinical Research Network (Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Peninsula Regional Medical Center, and/or Reading Health System) or if it may include participants at the Kennedy Krieger Institute, include the following:*

If your child is a participant at Anne Arundel Health System Research Institute, you may contact the AAMC IRB office at 443-481-1320.

If your child is a participant at Greater Baltimore Medical Center, you may contact James Mersey, M.D. (Chairman of the GBMC IRB) at 410 828 7417.

If your child is a participant at Inova Health System, you may contact the Inova Human Research Protection Program (IRB) at 703-776-3167.

If your child is a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

If your child is a participant at Peninsula Regional Medical Center, you may contact Timothy Feist, Vice President Performance Improvement/Patient Safety Officer at 410-548-7118.

If your child is a participant at Reading Health System, you may contact Sharon House, R.N., IRB Manager at 484-628-5083.

If your child is a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

* 1. **What do you do if you have questions about the study?**

Call the principal investigator, Dr. \_\_\_\_\_\_\_ at insert telephone number. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

*If this study may include participants at another site, include the following:*

If your child is taking part at All Children’s Hospital, call Dr*.\_\_\_\_\_\_\_\_\_\_\_\_*at *insert telephone*

*number.*

If you are taking part at Howard County General Hospital, call Dr. \_\_\_\_\_\_\_\_\_\_\_ at *insert telephone number*.

If your child is taking part at Sibley Memorial Hospital, call Dr.\_\_\_\_\_\_\_\_\_\_at *insert telephone number*.

If your child is taking part at Suburban Hospital, call Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Anne Arundel Health System Research Institute, call Dr. \_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Greater Baltimore Medical Center, call Dr. \_\_\_\_ at *insert telephone number.*

If your child is taking part at Inova Health System, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Kennedy Krieger Institute, call Dr.\_\_\_\_\_\_\_\_\_ at *insert telephone number.*

If your child is taking part at Peninsula Regional Medical Center, call Dr. \_\_\_\_\_\_\_\_\_ at *insert telephone number.*

If your child is taking part at Reading Health System, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Kennedy Krieger Institute, call Dr.\_\_\_\_\_\_\_\_\_ at *insert telephone number.*

* 1. **What should you do if your child injured or ill as a result of being in this study?**

If you think your child is injured or ill because of this study, call *Principal Investigator* *(If the Principal Investigator is not a medical doctor, include designated physician)* at *insert telephone number* during regular office hours.

*A 24 hour number must be included if the research is more than minimal risk to ensure that the child participant has access to a physician for an urgent medical problem*.

**If your child has an urgent medical problem** related to taking part in this study, call *designated physician* at *insert telephone number* during regular office hours and at *insert phone or pager number available 24 hours* after hours and on weekends.

*If you insert a pager number, include the following instructions:* **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

*If this study may include participants at Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Kennedy Krieger Institute, Peninsula Regional Medical Center and/or Reading Health System, include the following:*

If your child is taking part at All Children’s Hospital and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Howard County General Hospital and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Sibley Memorial Hospital and you have a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Suburban Hospital and you have a medical problem related to taking part in this study, call Dr.\_\_\_\_\_\_\_\_\_\_ at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Anne Arundel Health System Research Institute and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Greater Baltimore Medical Center and your child has a medical problem related to taking part in this study, call Dr.\_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Inova Health System and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Peninsula Regional Medical Center and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Reading Health System and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Kennedy Krieger Institute and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

* 1. **What happens to Data and Biospecimens that are collected in the study?**

*If your study does not include biospecimens, you may delete that word from the heading and text*

Johns Hopkins and our research partners work to understand and cure diseases.  The biospecimens and/or data you provide are important to this effort.

If you allow your child to join this study, you should understand that you/your child will not own your child’s biospecimens or data, and should researchers use them to create a new product or idea, you/your child will not benefit financially.

*If consent for biospecimens is part of this informed consent, include the following:*

With appropriate protections for privacy, Johns Hopkins may share your child’s biospecimens and information with our research sponsors and partners.

1. **Assent Statement**

* Insert this statement except when (a) the child is incapable of understanding the explanation; or, (b) the study intervention offers the prospect of direct benefit to the child that is only available through research.

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

1. What is Genomic Data Sharing

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your child’s health and your child’s individual genes.

This information will be sent to a National Institutes of Health (NIH) designated data repository that includes all kinds of genomic data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that:

* may increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity)
* may affect the progress of a certain disease or condition
* may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We will remove direct identifiers (such as your child’s name) and instead code your child’s information before sending it to the repository***.*** NIH will never get this code or the identifiers we have removed.

The repository is a controlled-access repository. Controlled-access data is only available to researchers and companies who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not know what types of health-related research will be done with the data that are sent to the repository.

**What are the risks to your privacy?**

There may be risks to your and your child’s privacy and the privacy of your relatives from storing your child’s information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your or your child’s identity could become re-connected with your child’s genetic and health information.

If your child’s genetic information were re-identified, personal information about your child, your child’s health and your child’s risk of disease could become known to others. This could present unknown risks. Current federal law will help protect your child from genetic discrimination in health insurance and employment.

**Are there benefits to sharing your genetic information?**

There is no direct benefit to your child from placing your child’s genetic information in the repository. Allowing researchers to study your child’s genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

1. **What does your signature on this consent form mean?**

Your signature on this form means that:

* you understand the information given to you in this form
* you accept the provisions in the form
* you agree to allow your child to join the study
* You and your child will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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

Signature of Parent (Print Name) Date/Time

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

Signature of Person Obtaining Consent (Print Name) Date/Time

*If a physician is required to take part in the consent process and will conduct the entire consent process, then the physician should sign above as the person obtaining consent. If the physician will only discuss the risks, benefits and alternatives, the physician must complete the second signature page and the non-physician consent designee discussing the remainder of the consent should sign above.*

**Add any of the following that are applicable for this study and delete any that do not apply**

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For CHILD PARTICIPANT**

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

Description of LAR’s authority under state or applicable local law to act as surrogate health care Date/Time

decision-maker for child research participant (for example, Legal Guardian; Court-ordered representative)

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

Signature of Parent #2 (Print Name) Date/Time

(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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

Signature of Witness to Consent Procedures (Print Name) Date/Time

(optional unless IRB or Sponsor required)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

**NOTE**: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**

*If your study requires physician/mid-level provider consent, complete and include this page*

**DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT**

**My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Parent (Print Name) Date/Time

**Add any of the following that are applicable for this study and delete any that do not apply**

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For CHILD PARTICIPANT**

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

Description of LAR’s authority under state or applicable local law to act as surrogate health care Date/Time decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)

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

Signature of Parent #2 (Print Name) Date/Time

(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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

Signature of Witness to Consent Procedures (Print Name) Date/Time

(optional unless IRB or Sponsor required)

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

# **REMOVE ALL SHADED INSTRUCTIONS BEFORE PRINTING**

# **PARENT INFORMED CONSENT AND PRIVACY**

# **AUTHORIZATION FORM**

**Protocol Title**:

Application No.:

**Sponsor:** *Delete line if not applicable*

**Principal Investigator**: *Include name, address, phone and fax information*

1. **What you should know about this study:**

* You are being asked to allow your child to join a research study. This consent form explains the research study and your child’s part in the study. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
* Joining this study is voluntary. If you allow your child to join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide not to allow your child to continue the study.
* During the study, we will tell you if we learn any new information that might affect whether you wish to continue to allow your child to participate.
* If we think your child’s participation in this study may affect your child’s clinical care, information about your child’s study participation will be included in your child’s medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information.  You can ask the research team to send this information to any of your child’s doctors.
* When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children’s Hospital.

*Include this bullet if biospecimens will be collected in the study:*

* Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person

*Include these bullets if this study will be in clinicaltrials.gov:*

* 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.
* If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

*Include this for a blinded study or a study where medical information will not be available to participants until the study is completed:*

* During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while your child is in the study, medical information needed for your child’s treatment can be made available to your study physician and other physicians who treat your child. When the study is completed, all the information in your child’s medical record will be available to you.

1. **Why is this research being done?**

This research is being done to....

Children with \_\_\_\_\_\_ may join.

**How many children will be in this study?**

1. **What will happen if you allow your child to join this study?**

If you agree to allow your child to be in this study, we will ask you to allow your child to do the following things:

**How long will your child be in the study?**

Your child will be in this study for

1. **What are the risks or discomforts of the study?**
2. **Are there risks related to pregnancy?**

*Delete this heading if not applicable.*

1. **Are there benefits to your child from being in the study?**
2. **What are your options if you do not want your child to be in the study?**

You do not have to allow your child to join this study.

If your child does not take part in the study, your child’s care at Johns Hopkins will not be affected.

1. **Will it cost you anything to allow your child to be in this study?**

1. **Will you or your child be paid if you allow your child to join this study?**

1. **Can your child leave the study early?**

1. **Why might we take your child out of the study early?**

*Delete this heading if not applicable.*

1. **How will your child’s privacy be protected?**

We have rules to protect information about your child. Federal and state laws and the federal medical Privacy Rule also protect your child’s privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about your child. This includes things learned from the procedures described in this consent form. They may also collect other information including your child’s name, address, date of birth, and information from your child’s medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your child’s identity and that your child is in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your child’s information. We make this information available to your child’s doctors for your child’s safety.

People outside of Johns Hopkins may need to see or receive your child’s information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If your child is in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your child’s participation.  You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your child’s information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your child’s information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your child’s information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your child’s information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your child’s information has no time limit. You may revoke (cancel) your permission to use and disclose your child’s information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your child’s information, your child’s part in this study will end and no further information about your child will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

1. **Will the study require any of your other health care providers to share your child’s health information with the researchers of this study?**

*Delete this heading and section if you will not be obtaining medical records. If you will be requesting health care records for this study, insert the required language from the instructional template.*

1. **What if there is a Certificate of Confidentiality for this study?**

*Delete this heading and section if there is no Certificate of Confidentiality. If there is a Certificate of Confidentiality for this study, insert the required language from the instructional template.*

1. **What does a conflict of interest mean to the participants in this study?**

*Delete this heading if not applicable. If there is a conflict of interest for this study, insert the required language from the instructional template.*

1. **What treatment costs will be paid if your child is injured in this study?**
2. **What other things should you know about this research study?**
   1. **What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

* Doctors
* Nurses
* Ethicists
* Non-scientists
* and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your child’s rights as a participant or if you think you or your child have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

*If this study is being done in the Johns Hopkins Clinical Research Network (Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Peninsula Regional Medical Center, and/or Reading Health System) or if it may include participants at the Kennedy Krieger Institute, include the following:*

If your child is a participant at Anne Arundel Health System Research Institute, you may contact the AAMC IRB office at 443-481-1320.

If your child is a participant at Greater Baltimore Medical Center, you may contact James Mersey, M.D. (Chairman of the GBMC IRB) at 410 828 7417.

If your child is a participant at Inova Health System, you may contact the Inova Human Research Protection Program (IRB) at 703-776-3167.

If your child is a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

If your child is a participant at Peninsula Regional Medical Center, you may contact Timothy Feist, Vice President Performance Improvement/Patient Safety Officer at 410-548-7118.

If your child is a participant at Reading Health System, you may contact Sharon House, R.N., IRB Manager at 484-628-5083.

If your child is a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

* 1. **What do you do if you have questions about the study?**

Call the principal investigator, Dr. \_\_\_\_\_\_\_ at insert telephone number. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

*If this study may include participants at another site, include the following:*

If your child is taking part at All Children’s Hospital, call Dr*.\_\_\_\_\_\_\_\_\_\_\_\_*at *insert telephone*

*number.*

If you are taking part at Howard County General Hospital, call Dr. \_\_\_\_\_\_\_\_\_\_\_ at *insert telephone number*.

If your child is taking part at Sibley Memorial Hospital, call Dr.\_\_\_\_\_\_\_\_\_\_at *insert telephone number*.

If your child is taking part at Suburban Hospital, call Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Anne Arundel Health System Research Institute, call Dr. \_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Greater Baltimore Medical Center, call Dr. \_\_\_\_ at *insert telephone number.*

If your child is taking part at Inova Health System, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Kennedy Krieger Institute, call Dr.\_\_\_\_\_\_\_\_\_ at *insert telephone number.*

If your child is taking part at Peninsula Regional Medical Center, call Dr. \_\_\_\_\_\_\_\_\_ at *insert telephone number.*

If your child is taking part at Reading Health System, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.*

If your child is taking part at Kennedy Krieger Institute, call Dr.\_\_\_\_\_\_\_\_\_ at *insert telephone number.*

* 1. **What should you do if your child injured or ill as a result of being in this study?**

If you think your child is injured or ill because of this study, call *Principal Investigator* *(If the Principal Investigator is not a medical doctor, include designated physician)* at *insert telephone number* during regular office hours.

*A 24 hour number must be included if the research is more than minimal risk to ensure that the child participant has access to a physician for an urgent medical problem*.

**If your child has an urgent medical problem** related to taking part in this study, call *designated physician* at *insert telephone number* during regular office hours and at *insert phone or pager number available 24 hours* after hours and on weekends.

*If you insert a pager number, include the following instructions:* **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

*If this study may include participants at Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Kennedy Krieger Institute, Peninsula Regional Medical Center and/or Reading Health System, include the following:*

If your child is taking part at All Children’s Hospital and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Howard County General Hospital and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Sibley Memorial Hospital and you have a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Suburban Hospital and you have a medical problem related to taking part in this study, call Dr.\_\_\_\_\_\_\_\_\_\_ at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Anne Arundel Health System Research Institute and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Greater Baltimore Medical Center and your child has a medical problem related to taking part in this study, call Dr.\_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Inova Health System and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Peninsula Regional Medical Center and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Reading Health System and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

If your child is taking part at Kennedy Krieger Institute and your child has a medical problem related to taking part in this study, call Dr. \_\_\_\_\_\_\_\_\_\_at *insert telephone number.* If this doctor is not available, the operator will page the “on call physician.”

* 1. **What happens to Data and Biospecimens that are collected in the study?**

*If your study does not include biospecimens, you may delete that word from the heading and text*

Johns Hopkins and our research partners work to understand and cure diseases.  The biospecimens and/or data you provide are important to this effort.

If you allow your child to join this study, you should understand that you/your child will not own your child’s biospecimens or data, and should researchers use them to create a new product or idea, you/your child will not benefit financially.

*If consent for biospecimens is part of this informed consent, include the following:*

With appropriate protections for privacy, Johns Hopkins may share your child’s biospecimens and information with our research sponsors and partners.

1. **Assent Statement**

*Delete this heading if not applicable.*

1. **What is Genomic Data Sharing?**

*Delete this heading if not applicable.*

1. **What does your signature on this consent form mean?**

Your signature on this form means that:

* you understand the information given to you in this form
* you accept the provisions in the form
* you agree to allow your child to join the study

You and your child will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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

Signature of Parent (Print Name) Date/Time

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

Signature of Person Obtaining Consent (Print Name) Date/Time

*If a physician is required to take part in the consent process and will conduct the entire consent process, then the physician should sign above as the person obtaining consent. If the physician will only discuss the risks, benefits and alternatives, the physician must complete the second signature page and the non-physician consent designee discussing the remainder of the consent should sign above.*

**Add any of the following that are applicable for this study and delete any that do not apply**

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For CHILD PARTICIPANT**

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

Description of LAR’s authority under Maryland Law to act as surrogate health care Date/Time

decision-maker for child research participant (for example, Legal Guardian; Court-ordered representative)

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

Signature of Parent #2 (Print Name) Date/Time

(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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

Signature of Witness to Consent Procedures (Print Name) Date/Time

(optional unless IRB or Sponsor required)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

**NOTE**: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**

*If your study requires physician/mid-level provider consent, complete and include this page*

**DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT**

**My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Parent (Print Name) Date/Time

**Add any of the following that are applicable for this study and delete any that do not apply**

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For CHILD PARTICIPANT**

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

Description of LAR’s authority under state or applicable local law to act as surrogate health care Date/Time decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)

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

Signature of Parent #2 (Print Name) Date/Time

(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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

Signature of Witness to Consent Procedures (Print Name) Date/Time

(optional unless IRB or Sponsor required)

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**