**Notice:** Instructions for filling out the consent form are written in **BLUE**. **DELETE all of the instructions before submitting your informed consent**. Delete this notice. **Do not delete the IRB stamp statement. *For research taking place at UMC, please include the subject research ID# at the top of the first page of the consent form and signature page of the HIPAA authorization.***

*[For research personnel use only]* Subject Research ID#: \_\_\_\_\_\_\_\_\_

***This parental consent form is not valid without a TTUHSC El Paso IRB stamp in the lower left corner of each page.***

**PARENTAL CONSENT FORM FOR CHILD’S RESEARCH PARTICIPATION**

This form provides important information about participating in research. If you are a parent or legal guardian of a child who may take part in this study, permission from one or both parents is required. The assent (agreement) of your child may also be required. If you have more than one child who will take part in this study this consent form will cover them as well, however, a separate HIPAA Authorization is needed for each child.

This research study is optional and participation is completely voluntary. Please read this form carefully. You and your child have the right to take your time in making decisions about your child’s participation in this research. You and your child may discuss the decision with family, friends and/or your child’s doctor. If you or your child has any questions about the research or any portion of this form, please ask us. If you decide your child can participate in this research you will be asked to sign this form.

**STUDY TITLE**: (This title must match in all documents)

**INVESTIGATOR(s)**:

**CONTACT TELEPHONE NUMBERS**:

(You may contact the investigator(s) at the number(s) listed above (Choose one of the following: at any time OR during normal business hours) if your child develops any of the conditions listed in Question #5 of this form or if your child has any unexpected complications.)

**INSTITUTION**: Texas Tech University Health Sciences Center El Paso (you may include other approved sites that will be involved in the study)

**KEY INFORMATION**

1. **What is my child being asked to do?**

We are asking your child to take part in a research study about [insert general description of the study].

This key information is being provided to you to help you decide whether or not your child should participate. Additional information is provided to you in the ‘**Detailed Information**’ section of the document.

1. **Does my child have to take part in this study?**

You can choose for your child to take part or you can choose for your child not to take part in this study.

You also can change your mind at any time. Whatever choice you and your child make, you will not lose access to your child’s medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered.

1. **What is this study about? How long will it last?**

This study is being done to answer the following question: [provide brief description].

Provide a very BRIEF description of what the study involves. (Include length of time, description of intervention) Example: Your child will need to come to the clinic 4 times to complete questionnaires and have one blood draw, over 4 month period. Each visit will last one hour. This will end your child’s study involvement.

1. **What are the key reasons I might choose for my child to take part in this study?**

Briefly state the most important reason(s) [potential benefit(s)] a parent may want to volunteer for their child to be in this study. For a complete description of the benefits, refer to the ‘**Detailed** **Information**’ section of the consent form.

1. **What are the key reasons I might choose for my child not to take part in this study?**

Briefly state the most important reason(s) [risk(s)] why a parent may not want to volunteer for their child to be in this study. For a complete description of the risks, refer to the ‘**Detailed** **Information’** section of the consent form.

There may be some risks that the study doctors do not yet know about.

If alternative treatments/procedures are key to the participant’s choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists. For a complete description of the alternative treatment/procedures, refer to the ‘**Detailed Information’** section of the consent form.

1. **What if I have questions?**

For questions about this study, contact the Investigator, NAME,at xxx-xxx-xxxx.

If you would like to speak to someone who is not involved in the study about your child’s rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352.

Or, you can file an EthicsPoint report online: <https://secure.ethicspoint.com/domain/media/en/gui/44534/index.html>.  Please choose the “Regulatory Compliance” option when making an online report.

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study doctor or nurse.

**Make a page break here – this ends the key information**

**DETAILED INFORMATION**

1. **What is the purpose of this study?**

Provide a brief, phase-specific description of why the study is being done.

Insert the names and types of investigational drugs/agents/interventions/biomarkers, where indicated.

Insert the number of study participants taking part in the study at this site and at all sites.

1. **What will happen during this study?** (From the research procedures question on the application) [If applicable, include a statement “clinically relevant results of this research will be communicated with you (describe when and under what conditions)].
2. **What will be done that is different from my child’s usual care?** (If all procedures are only for research purposes, please state this.)
3. **Are there any benefits to my child if s/he takes part in this study?** (This question is only necessary if additional benefits may be anticipated beyond what was listed earlier.)
4. **What are the risks and/or discomforts to my child if s/he joins this study?** (This question is only necessary if additional risks may be anticipated beyond what was listed earlier.)
5. **Will there be any added risks to my child from this study if s/he is a female/male?** (If there are added risks, describe them; if there are added risks because a subject is a male, answer that too [or instead]).
6. **What other choices does my child have if s/he does not take part in the research study?** (If the study does not involve treatment, say, “This study does not involve treatment. Your child does not have to take part in this study.”)

1. **What about confidentiality and the privacy of my child’s records?**

We will keep your child’s involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that your child is in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC El Paso Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your child’s participation in this research. A copy of this document may be placed in your child’s medical record.

(Delete if there is no outside sponsor)  The sponsor of the study, NAME, can also review the study records, but the sponsor is not allowed to remove or copy information that identifies your child by name, with one exception.  If your child receives Medicare benefits, the Sponsor, NAME is required by law to report payments made to your child for treatment, complications, and injuries that arise from this Study. Information that your child is taking part in the Study, medical treatments received, Medicare claims, and other personal information about your child such as his/her name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

Study results that are used in publications or presentations will not use your child’s name.

1. **Who is funding this study?**

(Choose the correct response below; delete the other response)

(For investigator-initiated studies) NAME OF DEPARTMENT is providing the space and supplies for this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.

**OR**

(For sponsored studies) NAME OF AGENCY/ORG/CO is funding this research study. This means that TTUHSC El Paso (or affiliate) is being paid by NAME OF SPONSOR to support the activities that are required to carry out the study. No one on the research staff will receive anything of value from NAME OF SPONSOR for carrying out this study.(If someone IS receiving something of value from the sponsor for carrying out the study, it should be disclosed here).

1. **Will it cost me or my child anything to take part in this research study?**

Any procedures that are considered standard of care are your or your insurance provider’s responsibility.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include: xx (List procedures covered by the study.)

Talk to your insurance provider and the study staff to make sure that you understand what your insurance pays for and what it does not pay for if your child takes part in this study. Also, find out if you need approval from your plan before your child can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

1. **Will my child receive anything for taking part in this research study?** (Here is where you can discuss payment. The following two paragraphs need to be included for all studies with compensation of more than $25):

Payment for participation in this research is considered taxable income. In order for your child to receive payment for this research, we will need to collect his/her name, address, and social security number. If you are not able to provide this information, 30% of the amount being paid for this research study will be automatically deducted and sent to the Internal Revenue Service (IRS).

If your child receives payments that total more than $600 in one calendar year, Texas Tech University Health Sciences Center El Paso is required to report this information to the IRS.  A Miscellaneous Income form (1099-MISC) will be sent to you and to the IRS.

(If payment is $25 or less and there is a possibility of enrolling non-resident aliens, please only include the following paragraph-delete previous two paragraphs):

If your child is a non-resident alien, payment for participation in this research is considered taxable income and 30% of the amount being paid for this research study will be automatically deducted and sent to the Internal Revenue Service (IRS). In order for your child to receive payment for this research, we will need to collect his/her name and address.

1. **Does anyone on the research staff have a personal financial interest in this study?**

(Choose the correct response; delete the other one).

No one on the research staff has a financial interest in this study.

OR

NAME OF INVESTIGATOR/ STAFF has nature of financial interest [e.g., paid consultant, owns stock in, etc.] in name of company. PERSON’s financial interest in this company has been reviewed by the TTUHSC El Paso Conflict of Interest in Research Committee to make sure that the research will be conducted objectively.

1. **What if my child is hurt by participating in this study?**

(Do not delete-This must remain as the first paragraph.)

Texas Tech University Health Sciences Center El Paso (and UMC EP or EPCH) does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you or your child in the event of such injury or illness unless specifically stated.

(Choose the correct response below; delete the other response)

The following two paragraphs are required for greater than minimal risk, industry-sponsored clinical trials:

If your child has a research related illness or injury, [THE STUDY SPONSOR] will provide payment for extra unanticipated tests, treatments, and hospitalizations unless such expenses were due to: (i) TTUHSC El Paso’s and Principal Investigator’s failure to strictly adhere to the terms of the Protocol; (ii) the negligence or misconduct of TTUHSC El Paso or its employees or agents; or (iii) a pre-existing medical condition or your child’s underlying disease. You or your medical or hospital insurance company is not responsible for any costs of extra treatment.

If you think your child has a research-related illness or injury, you should notify the study doctor and seek care as you normally would. If you or your insurance company is billed for treatment for an illness or injury that is determined to be related to this research study, TTUHSC El Paso and your study doctor will work with [THE STUDY SPONSOR] to reimburse you or the insurance company for the cost of that care.

OR

This paragraph may be used for investigator-initiated or minimal risk studies:

If your child has a research related illness or injury, care will be available to him/her as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if your child takes part in a research study.

1. **Can my child stop being in the study?**

Yes, you and your child may decide to stop taking part in the study at any time. If your child leaves the study, we cannot remove any information we have collected to that point.

If you and your child decide to stop, let the study doctor know as soon as possible. It’s important that your child stops safely. (\*Adapt and insert as applicable: This may mean slowly stopping the study drugs so that there is not a sudden unsafe change, risk to your child’s health, etc.\*). If you stop, you can decide if you want to keep letting the study doctor know how your child is doing.

Your study doctor will tell you about new information or changes in the study that may affect your child’s health or your child’s willingness to continue in the study.

1. **Can someone else end my child’s participation in the study?**

Under certain circumstances, the investigators, TTUHSC El Paso, or the study sponsor may decide to end your child’s participation in this research study earlier than planned. This might happen because:

• Your child’s health changes and the study is no longer in his/her best interest.

• New information becomes available and the study is no longer in your child’s best interest.

• Your child does not follow the study rules.

• The study is stopped by the Institutional Review Board (a committee that reviews and approves research), the Food and Drug Administration or study sponsor (\*insert sponsor name in parentheses).

1. **What will happen to my child’s [name specific biospecimens here – blood, tissue, sample, etc.] when the research study is over?**

This question **MUST** be answered **ONLY** if you are collecting any biospecimens.

In this study, we will be collecting some of your child’s [describe the biospecimens to be collected.] When the study is done, we will make sure that this [biospecimen] cannot be identified as belonging to your child.

(Choose one response):

We will properly dispose of your child’s de-identified [biospecimen] and it/they will not be used in future studies.

OR

We will keep this [biospecimen] to use in our future research, or in research done by our colleagues. If your child’s unidentifiable [biospecimen] is used in future studies, we will not ask for your consent again before using it/them. You will not know when or if those samples are used for research, and no one will be able to tell you any results of research that used your child’s samples.

The following statements must also be included if appropriate. You may delete either or both: (1) It is possible that these samples will be used in research that could profit the investigator or others. If the sample is used in that way, you and your child will not share in any of the potential profit. (2) The future research might include “whole genome sequencing.” Sequencing allows researchers to identify your child’s genetic code. Changes in your child’s genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

(The following language is required if you are conducting a clinical trial of a drug or device that is regulated by the FDA. If this is not an applicable clinical trial, you may delete the following paragraph.)

A description of this clinical trial will be available on [www.ClinicalTrials.gov](file:///\\elpresefs02\marvizo$\IRB%20Docs\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\HO1TN2D3\''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.

**Contact for Future Research (OPTIONAL)**

I agree that the study doctor, or someone on the study team, may contact me to see if I wish for my child to participate in other research in the future.

YES NO

Initial in the box above

**Your signature indicates:**

* **this research study has been explained to you;**
* **you have been given the opportunity to ask questions and have received answers;**
* **you accept your responsibility to follow the instructions given to you by the research team regarding your child’s study participation and, if applicable, research medication;**
* **you give permission for your child to take part in this study.**

**You will be given a signed and dated copy of this form.**

Printed Name of Child/Children Age of Child/Children

Printed Name of (First) Parent/Guardian/ Relationship to the Child/Children

Authorized Representative

AM/PM

Signature of (First) Parent/Guardian/ Date Time

Authorized Representative

Printed Name of (Second) Parent/Guardian/ Relationship to the Child/Children

Authorized Representative (when required)

AM/PM

Signature of (Second) Parent/Guardian/ Date Time

Authorized Representative (when required)

If signature of second parent not obtained, indicate why by selecting one:

IRB determined that the permission of one parent is sufficient

Second parent is deceased

Second parent is unknown

Second parent is incompetent

Second parent is not reasonably available

Only one parent has legal responsibility for the care and custody of the child

I have discussed this research study with the child and his or her parent/guardian/authorized representative, using language that is understandable and appropriate. I believe I have fully informed the child and his or her parent/guardian/authorized representative of the possible risks and benefits, and I believe they understand this explanation. I have given a copy of this form to the parent/guardian/authorized representative.

Printed name of authorized research personnel who

conducted the discussion and obtained consent

AM/PM

Signature of authorized research personnel who Date Time

conducted the discussion and obtained consent

(Investigator: If population includes subjects who are unable to read the written permission form [English/Spanish] and lack an authorized representative, contact your IRB administrator for additional instructions and language.)

**INVESTIGATORS: THIS IS THE TTUHSC EP HIPAA AUTHORIZATION FORM.** If your study is not using Protected Health Information and does not need HIPAA Authorization, you can delete these pages.

**Please note:** If you have more than one child who will take part in this study, a separate HIPAA authorization must be signed for each child.

Also, note that TTUHSC EP HIPAA policies **prohibit** investigators from making **ANY CHANGES** to this document without prior written approval from the HIPAA Privacy Officer. Approval will need to be attached to the submission.

**TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO**

**AUTHORIZATION TO USE AND/OR DISCLOSE YOUR CHILD’S PROTECTED HEALTH INFORMATION for a RESEARCH STUDY**

**STUDY TITLE**: (Same as on page 1)

This form is intended to tell you about the use and/or disclosure (sharing) of your child’s personal **Protected Health Information** (PHI) if you decide to let your child participate in the research study described on the previous pages. The health information about your child that may be used or disclosed is described below. This information is usually found in their medical records. Only the health information about your child that is needed for this research study will be used or disclosed. When you consider allowing your child to take part in this research study, you are also being asked to give your permission for his/her Protected Health Information to be released from their doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached parental permission document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.
2. If you choose to cancel this Authorization, please give notice in writing to:

**TTUHSC-EP Privacy Officer**

**Office of Institutional Compliance**

**5001 El Paso Drive**

**El Paso, TX 79905**

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your child’s Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

• your child’s treating physicians and healthcare providers and their staff,

• associated healthcare institutions and hospitals where your child may have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about your child or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC EP Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your child’s current or future health information from some or all of your child’s health records, including:

|  |  |
| --- | --- |
| • hospital records and reports  • admission history, and physical examination  • X-ray films and reports; operative reports  • laboratory reports, treatment and test results (including sexually transmitted diseases, HIV or AIDS)  • any other Protected Health Information needed by the research personnel listed above.  (\* use separate form for disclosure of psychotherapy notes) | • immunizations  • allergy reports  • prescriptions  • consultations  • clinic notes  • mental health records  • alcohol / substance abuse records |

For the purposes of this study, your child’s Protected Health Information may need to be reviewed or disclosed to individuals or organizations within and/or outside of TTUHSC EP who sponsor, approve, assist with, monitor or oversee the conduct of research studies. This includes, but is not limited to, the TTUHSC EP Institutional Review Board, TTUHSC EP compliance reviews, the US Food and Drug Administration (FDA) or governmental agencies in other countries. Some of these individuals or organizations may share your child’s health information further, and your child’s health information may not be protected by the same privacy standards that TTUHSC EP is required to meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you change your mind, send a letter to the person identified above telling us to stop collecting and sharing your child’s Protected Health Information. When we receive your request, your child may be asked to leave the research study if all the necessary information has not been collected. We may still use the information about your child that we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

**You have the right to refuse to sign this form. If you choose not to sign this form, your child’s regular health care will not be affected. However, not signing this form will prevent your child from participating in this research study and prevent your child from receiving research related health care services provided under this study.**

I have had the opportunity to review and ask questions regarding this Authorization to use or disclose my child’s personal health information, and I will receive a copy of this form. By signing this Authorization, I am confirming that it reflects my wishes.

Printed Name of Child Age of Child

Printed Name of Parent/Guardian/ Relationship to the Child

Authorized Representative

Signature of Parent/Guardian/Authorized Date

Representative