IRB-APPROVED TEMPLATE FOR CONSENT FORM
INSTRUCTIONS ARE IN ITALICS.
DELETE ALL INSTRUCTIONS (RED) IN FINAL COPY.

*Please write the consent using **8th grade language**. If you are not sure, Word software has a readability scoring function under Tools, Spelling & Grammar, Options. This template is scored at 8th grade. Define medical terms when necessary. Consent is obtained from parent(s), guardian(s), or study subjects 18 years or older.*

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: *XXXX*

PRINCIPAL INVESTIGATOR: *XXXX*

CONTACT TELEPHONE NUMBER: *XXX-XXX-XXXX* (24 hours a day, 7 days a week*, if applicable*)

STUDY SPONSOR *(if applicable)*:

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

1) INTRODUCTION

We invite you to be in this research study because *XXX*.

Participation is voluntary. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. Once you understand this study, we will ask you to decide whether you would like to participate or not. By signing this form, you agree to be in this study. If you do not want to be involved with this study, all regular and standard medical care will still be available to you here or at another institution. You also have the right to leave this study at any time, even if you agree to join now.

(IF APPLICABLE) If this study involves a child between 9 and 18 years of age, the child will receive an explanation of the study in a separate form, called an Assent form. If they agree to be in the study, they will be asked to sign this form.

You will be given a signed and dated copy of the consent and the assent form.

(IF APPLICABLE) To help us know if we have satisfactorily explained the study, you will be asked to complete a brief quiz before beginning the study.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This is a study to find out ***XXX. . .*** *(explain using lay terms, briefly explain background and why the study is necessary). Describe any products, procedures, or treatments that are considered experimental in this study, not part of standard care.)*

REQUIRED LANGUAGE (if applicable):
(*Drug Name*) has: *(pick option)* not been approved by the Food and Drug Administration and its use is considered experimental OR has been approved by the Food and Drug Administration for use in *(list main approvals…example: adults only OR patients with xxx disease)* but not for the use that we will be looking at in this study.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

CHOOSE:
This study will be done at Nationwide Children's Hospital and we hope to enroll *xxx* participants.

OR
This study will be done at several sites, including Nationwide Children's Hospital. Overall, *xxx* participants will take part in this study. We hope to enroll *xxx* participants here at Nationwide Children's Hospital.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

Provide a simple description of methods and procedures, and an explanation of the subject's involvement using 8th grade language. If blood will be drawn, state the amount in both ml's & teaspoons/tablespoons. State where blood will be drawn from (vein in arm, indwelling catheter, heel stick, etc.). If the study is randomized, blinded, or uses a placebo, give a lay-language explanation of these procedures. If you cannot use lay language for a medical term, put the definition in parentheses after the word. Do not discuss standard of care treatment in the description, only the procedures/treatments which are part of the research study.

It is best to provide this description chronologically. Inclusion of a table of study events is helpful. List each visit, discussing procedures, questionnaires, etc., give an approximate time for each visit, procedure, questionnaire, etc. State the expected length of the whole study.

EXAMPLE:

Visit 1 - Screening Visit
This visit will take about XX hours. Questions will be asked about medical history, past and present diseases, allergies and medications. It is important to tell the Principal Investigator all the information you can. A complete physical examination will be done. About XX ml (XX teaspoons or XX tablespoons) of blood will be drawn. You will answer questions about your illness (about XX minutes).

SUGGESTED LANGUAGE, IF APPLICABLE:

You may not be able to take some medications while participating in this study. The Principal Investigator will talk with you about stopping medicines that are not allowed during the study.

If the study uses a placebo:
During this study, we will compare (study medicine name) to (placebo/another study medicine name/different doses of *XXX*). A placebo is made to look like (study medicine name), but it will contain no active medicine.

If the study is randomized:
This study is randomized. Randomized means that each subject will be picked by chance, like tossing a coin or drawing straws, to receive either study medicine or (placebo/another study medicine name/different doses of *XXX*). Each subject has a *XX (e.g. 50/50; 1 in 2)* chance of receiving study medicine and a *XX* chance of receiving (placebo/another study medicine name/different doses of *XXX*).

If the study is blinded (NOTE: provide specific blinding details, as applicable, in addition to the wording below):
This study is blinded. Blinded means that the Principal Investigator, the study nurse, and the study sponsor, *name of sponsor,* will not know who is receiving (*study medication name)* or placebo. In case of a medical emergency, there is a way for the study staff to quickly find out what each subject is receiving.

If screening for illegal drugs is required (NOTE: Please specify in the protocol how results will be shared and with whom. Consider legal implications of this testing):
To detect the presence of illegal drugs, a screen may be performed using blood or urine. (If applicable:) The results of any drug screens will be given to you and your child.

If genetic studies will be done as part of the study, the following topics need to be addressed in this section:

1. *Provide specifics about what genetic testing will be done as part of this study*

   SUGGESTED LANGUAGE: We will be testing your (blood or tissue or DNA) for gene xxx to see whether there is a connection between this gene and xxx illness

2. *Discuss whether results from this study will be shared with the study participants. If the results will not be shared with the study participants, state why. If the results will be shared with the study participants, state how.*

If there is the potential for the study to show "incidental findings" *(Incidental findings are results from radiographic studies, laboratory studies, survey or questionnaire results, genetic testing, etc. that show that a potential problem is present, but this problem was not specifically looked for in the study. Examples: finding a tumor on a Head CT done as part of a behavioral study; finding a suicide risk on a routine behavioral screen being done as part of a development study.):*

REQUIRED LANGUAGE: The *XXX* tests may provide information that we were not specifically looking for in this study. This information is called "incidental findings". We will discuss these results with you if we believe that they may have a significant impact on your health or family's health. If you

ask us to do so, we can also help you set up follow-up meetings with the personal physician that you identify to us or other medical professionals who are not involved in this study but who can discuss this information with you. These follow-up visits will not be part of this study. Therefore, you and your insurance company would be responsible for any fees and costs related to them.

If you are using social media as part of this study, please refer to IRB SOP, Social Media.

If using social media such as phone, texting, direct visual communication (example, Skype):

REQUIRED LANGUAGE: As part of this study we will be contacting you via *(method)*. In order to make sure that your privacy is maintained we will provide you with *XXX (study specific phone OR study specific password for Skype or text messages OR other)*. Please make sure that only you use this *XXX (phone OR password OR other*).

If using social media such as Facebook, LinkedIn, wikis, blogs, etc:

REQUIRED LANGUAGE: As part of this study we have made a study-specific *XXX(facebook group page, wiki, blog, etc)* and you are invited to participate. Please note that there will be other people using this *XXX (page, wiki, blog, etc)* and because of this we will not share any private information about you on this site. To maintain your privacy, we ask that you do not post any private information on these sites as well. The *XXX (page, wiki, blog)* will be read by our study team *(XXX frequency)*. If you have an urgent issue, please call us at the number provided on page 1 of this form.

If there is potential for commercialization of research findings:
REQUIRED LANGUAGE: You will not receive any money or other compensation for any new products that might be developed or sold from research that used your blood or tissue.

5) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

If this study is minimal risk:

REQUIRED LANGUAGE:
We believe that there is very little chance that bad things will happen as a result of being in this study.

INCLUDE IF APPLICABLE: It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

If this study is greater than minimal risk, *describe any risks and discomforts to the subject and how these risks will be minimized. Give the risks in descending order of frequency as suggested below. The IRB strongly believes that disclosure of accurate estimates of the frequency of risks is an important part of the informed consent process and is necessary to the prospective subjects' understanding of risks. Provide the frequency if available.*

REQUIRED LANGUAGE, IF APPLICABLE:
All study medications may cause some side effects or other reactions. The side effects and discomforts most commonly associated with the medicine and procedures used in this study are

listed below. There is no way to give absolute assurance that you will or will not experience any of these or other side effects.

The common side effects are. . .

Occasional side effects are. . .

Rare side effects are. . .

Allergic reactions can happen with any drug. Common allergic symptoms may include *(list)*. A severe and possible life threatening allergic reaction can happen, although that is rare. Symptoms of a severe allergic reaction include: *(list)*

If any of the symptoms listed above are severe, you must get medical help right away.

If you are worried about anything while in this study, please call the Principal Investigator or study coordinator at the telephone number on page 1.

SUGGESTED LANGUAGE, IF APPLICABLE
It is important that you give the study staff a complete medical history. Not giving them this information or not completely following the directions of the study could harm you.

Taking a placebo means that you are not receiving the study medication. It is possible that there may be no change in your condition, and it could even get worse.

Drawing blood and starting IVs by placing a needle in a vein may cause pain, lightheadedness, fainting, bleeding, bruising, or swelling at the puncture site. Infection is a rare possibility. If needed, numbing cream may be used on the skin to decrease the discomfort. Although there are no known side effects from the numbing cream, skin irritation or an allergic reaction is possible.

In order to take part in this study, it will be necessary to stop some or all medicines currently being taken. This is sometimes called a Washout Period, and there is a possibility that the symptoms, *XXX,* will get worse when these medicines are stopped.

It is possible that non-paternity could be discovered in this study. The genetic markers used in this work could reveal that the individual who donates a sample as the subject's father is not the true biological father. We will make every effort to keep such information confidential, but we cannot ensure that the information will not be released if required by law.

If social media is being used as part of this study:
REQUIRED LANGUAGE: The privacy policies of *(name of media)* are not as strong as those for medical or research records. Thus, there is the risk that someone else may be able to view communications related to this study. Also, it is possible that the actual transmission can be intercepted and looked at by people not associated with this study. Please be careful about what you post on *(name of media)* and do not share your password with others. If you have either lost your password or think that someone is viewing your communications, please let the study team know immediately.

If Radiologic studies are part of this study, *consider the following when describing the risks related to these studies:*

1. *Focus only on the studies that are being done for research purposes. If the procedure or study is for clinical reasons only, then you do not need to elaborate on risks related to it.*
2. *If sedation will be used as part of the study (example, sedation prior to an infant MRI study) then note adverse events related to the sedation.*
3. *If the study involves tight spaces or restrained areas (example, MRI) then note these issues*
4. *In regard to actual radiation risk, place in words that would be understandable to the participants. A common approach is to compare the radiation dose to the annual background radiation for an individual living in central Ohio. Discuss the radiation risk with radiology staff who can assist you with the appropriate wording.*

SUGGESTED LANGUAGE, IF APPLICABLE (Choose one):

The study drug belongs to class of medications for which an increased risk of suicide and suicidal thoughts (thoughts of harming or killing oneself) have been seen in people who take them. You should call the Principal Investigator at 614-XXX-XXXX immediately if you notice any changes in your mood, ideas, or behavior. Common warning signs that might be a signal for risk of suicide include talking or thinking about wanting to hurt oneself or end one's life. Other signs include withdrawing from friends and family, becoming depressed or a worsening of depression, becoming preoccupied with death and dying, and giving away prized possessions.

Immediate help is available if thoughts or feelings of hurting oneself come up**.** If these thoughts or feelings occur, you should immediately call one of the numbers below or go to the closest Emergency Room.

Netcare 24 hour hotline 614-276-2273 **Suicide Hotline 614-221-5445**

OR

This study involves questions or surveys that may make you feel depressed. You should call the Principal Investigator at 614-XXX-XXXX immediately if you notice any changes in your mood, ideas, or behavior. Common warning signs that might be a signal for risk of suicide include talking or thinking about wanting to hurt oneself or end one's life. Other signs include withdrawing from friends and family, becoming depressed or a worsening of depression, becoming preoccupied with death and dying, and giving away prized possessions.

Immediate help is available if thoughts or feelings of hurting oneself come up**.** If these thoughts or feelings occur, you should immediately call one of the numbers below or go to the closest Emergency Room.

Netcare 24 hour hotline 614-276-2273 **Suicide Hotline 614-221-5445**

REQUIRED LANGUAGE:

There may be other risks of being in this research study that are not known at this time.

6) <u>SPECIAL INFORMATION ABOUT PREGNANCY</u>:

(Delete any portion of this statement that does not apply to your study. If the section itself is not applicable, delete this section and renumber.)

If you are pregnant or become pregnant while taking part in this research, the study medicine or study procedures may cause unknown harm to both your pregnancy or your fetus. Participation in this study will not be offered to females who are pregnant or breast-feeding. A pregnancy test will be done for any female who is sexually mature enough (started having periods), to become pregnant. The pregnancy test may be done using blood and/or urine. You (and your parents) will be told the results of the pregnancy test.

Pregnancy should be avoided, and an effective method of birth control must be practiced during the whole study. The best way to avoid pregnancy is abstinence (not having sexual intercourse). Talk to the Principal Investigator about medically approved forms of birth control such as:

- Birth control pills
- Intra Uterine Device (IUD)
- Hormone implants
- Contraceptive Injection
- Barrier Method (diaphragm with spermicidal gel or condoms with contraceptive foam)

If at any time, there is a suspicion of pregnancy, you must call the Principal Investigator or study coordinator right away. In the case of pregnancy during this study, your participation in the study will be changed, including the possibility that the study drug will not be given anymore. This will be discussed between you and the Principal Investigator.

IF APPLICABLE: A young man receiving this study medicine should avoid sexual activity that could lead to pregnancy.

7) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

SUGGESTED LANGUAGE (Choose one):

Although there (may/will) be no benefit to you from being in this study, we hope to learn something that could help others.

OR

Possible benefits to you might be *(list.)* And, we might learn something that could help others.

8) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE? *(If this is not a treatment study, delete this section.)*

Your participation is this study is voluntary. It is not necessary to participate in this study in order for you to get care for your condition. Other treatments such as *XXX* are available. If you decide not to be in this study, the Principal Investigator will talk to you about other treatments or refer you to your regular doctor for care.

9) WHAT ARE THE COSTS AND REIMBURSEMENTS?

Please discuss any funding of the study (i.e., what will be covered and what will not) with the Sponsored Projects Office before writing this section. This section should clearly state what the participants will be responsible for paying and what will be covered by the study.

This section should discuss two issues:

1. *Reimbursement for Expenses: This includes not only actual study-related expenses, but costs such as travel, parking, overnight stays, meals, etc. State if all of the study-related costs will be paid by the study sponsor, and if not, then what will be and what will not be paid for. If study-related costs are not fully paid for, clarify if the participant will be responsible for costs if the third party payer (insurance) does not cover. State any additional costs that the participant may have to pay (travel, parking, tests, medications, etc.). The IRB encourages providing parking vouchers if possible. NOTE: Reimbursement is payable to the person incurring the expense. This reimbursement may be taxable. Discuss with Research Finance.*

2. *Compensation for Time and Inconvenience: This focuses on compensation (money, gift cards, etc.) that are included in the study protocol. Include the amount of payment, broken down by visit, and how and when the payment(s) will be disbursed. Compensation is taxable if a participant receives more than $600 from research in a calendar year. A social security number must be obtained. Research Finance will issue a 1099 tax form to the participant. Compensation is payable to the study participant.*

EXAMPLE LANGUAGE IF APPLICABLE:

All costs related to the research parts of this study will be covered by the research team. However, the parts of the study that would be done for routine clinical care will be billed to you and to your insurance company or third party payer. You may have to pay any costs that the insurance company or third party payer does not pay. The study team will discuss these costs with you.

There will be additional costs related to travel and meals during this study. We (will or will not) provide money to help with these costs. A parking voucher will be provided each time you come in for a study visit. This reimbursement may be taxable. The study team will discuss this with you.

For your time and inconvenience, you (study participant) will receive $*XX.xx* per study visit up to $*XX.xx*. If you receive more than $600 compensation from research in a calendar year, you will be asked for your social security number and you will be issued a 1099 tax form to file with your income taxes.

10) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

If this study is minimal risk:

REQUIRED LANGUAGE:
We believe that there is very little chance that injuries will happen as a result of being in this study.

If this study is greater than minimal risk:

REQUIRED LANGUAGE (CHOOSE MOST APPLICABLE). NOTE: If these sections do not apply for your study please modify the wording (example, deletion of calling 911 if the study is being conducted in the ICU). Contact the IRB for guidance with wording changes.

If a Sponsor is asking for changes to this section, please contact the IRB and Legal Services since these changes must be approved by Legal.

If it is anticipated that injuries due to the study drug or study procedures will lead to significant costs (hospital stays, frequent clinic visits, etc.), discuss with the IRB and Legal before moving forward.

(Internal or federally funded study or Investigator-Initiated)
If your child is hurt by the Study Drug/Device or the procedures that are part of the Study, you should seek medical treatment for the injuries and tell the Principal Investigator as soon as possible at the number on the first page of this form. If it is an emergency, call 911 or go to the nearest emergency department.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

(Non-federally Funded/Industry supported Study)
If your child is hurt by the Study Drug/Device or the procedures that are part of the Study, you should seek medical treatment for the injuries and tell the Principal Investigator as soon as possible at the number on the first page of this form. If it is an emergency, call 911 or go to the nearest emergency department.

If your child is injured by the Study Drug/Device or properly performed Study procedures and you and your child have followed the directions of the Study team, the Sponsor will pay for the medical expenses necessary to treat the injury. Costs of injuries arising from your child's underlying condition will not be paid for by the Sponsor. The Sponsor will also not pay for things like lost income that are a result of the injury or illness.

In the event the Sponsor provides any reimbursement for medical treatment, the Sponsor must comply with federal reporting requirements relating to the reimbursement of such costs, including providing to Medicare your Health Insurance Claim Number of, if none is available, your social security number. By signing this consent, you agree that if asked by the Principal Investigator, you will provide such information to the Study Principal Investigator for disclosure to the Sponsor.

If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of an injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

11) WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE DRUG OR TREATMENT? *(If this is not a treatment study, delete this section and renumber.)*

REQUIRED LANGUAGE: If new information is found out during this study that might change your mind about participating or might affect your health, a study staff member will discuss it with you as soon as possible.

12) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study you must call the Principal Investigator or the study coordinator to see if there are any medical issues about stopping. If you stop being in the study, there will not be a penalty or loss of benefits to which you are otherwise entitled. *(If applicable, describe any consequences of withdrawing, e.g. any adverse consequences, etc.)*

If at any time the Principal Investigator believes that this study is not good for you, the study staff will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator or the sponsor, *(provide sponsor name)*, may decide to stop your participation in the study.

IF APPLICABLE: Describe any procedures for orderly termination of participation by the subject. Include any discussion from the protocol for termination of participation.

13) OTHER IMPORTANT INFORMATION

REQUIRED LANGUAGE (if applicable): It is important that health care providers know about all medicines that you are taking. This includes the medicine being tested in this research study. Because of this, we plan to tell your primary care doctor (if you have one) that you are in this research study. This is done so care can be taken in prescribing other medicines and looking at any unexplained symptoms that may occur. You cannot take part in this study if you do not want us to tell your primary care doctor.

Also, being in more than one research study at the same time may cause injury. Please tell us if you are in any other research study so a decision can be made about being in more than one study at the same time. We may need to notify the other study team to see if you can participate in this study.

SUGGESTED LANGUAGE (choose the paragraph(s) that apply to your study):

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or withdraw your consent to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time. *(If you are not sure whether your study should be posted on ClinicalTrials.gov, refer to "Guidance for Sponsors, Investigators, and Institutional Review Boards" at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf.)

(Study Results, choose one): If you are interested, the final study results will be shared with you once they are available. Please provide us with an email or address where we can send these results. *OR* The final study results will not be shared with you individually. However, at some time, a final study summary will be available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by *(sponsor name)* for the time and knowledge needed to do this study.

REQUIRED LANGUAGE:
Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

14) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE? *(See the two language options below. DO NOT USE BOTH.)*

OPTION 1: *IF YOU **ARE NOT** USING OR SHARING PHI (see SOP IRB-035 for description), USE THIS LANGUAGE:*

Efforts will be made to keep your study-related information confidential. However, there may be circumstances when this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Your records may be reviewed by the following groups (as applicable to the research):

REQUIRED:
- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors

REQUIRED IF APPLICABLE:
- Sponsor *(give name)*
- Other research sites *(give name)*
- The Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research) *(if federally funded)*
- Registries or Research Databases *(give names).* This is so that they can make sure that the data submitted to them is complete and valid. This only applies to the registries or research databases described in the earlier parts of this consent form.
- Your insurance company (if charges are billed to insurance).

If you have a bad outcome or adverse event from being in this study, the Principal Investigator and staff or other health care providers may need to look at your entire medical records. We expect that the results from this study may be published in the future but your identity will not be revealed.

OPTION 2: *IF YOU **ARE** USING OR SHARING PHI (see SOP IRB-035, HIPAA Requirements for description), THIS IS REQUIRED HIPAA LANGUAGE:*

Information collected for this study may include information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to *(Principal Investigator)* and the study staff to collect, use, and disclose your PHI for this research study and for future research purposes (including purposes that are currently unknown) unless otherwise allowed by applicable laws. Information collected is the property of Nationwide Children's Hospital or one of its affiliated entities or the Sponsor.

If sensitive information (such as information relating to mental health, abuse, drug use, HIV, genetics, etc.) will be collected as part of the study, include this language:
Some of the information collected as part of this study will be sensitive, such as information relating to your *XXXX (the applicable sensitive information: mental health, drug use, HIV status, genetics, physical abuse, etc.)*. This sensitive information may be used or disclosed for future unknown research purposes.

The reason why this PHI is collected, and what information will be used is listed below. The PHI will only be shared with the groups listed, but if you have a bad outcome or adverse event from being in this study, the Principal Investigator and staff or other health care providers may need to look at your entire medical records. In the event of any publication regarding this or any future studies, your identity will not be revealed.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

PHI that may be used or disclosed: *(List ONLY PHI. List all that apply. PHI includes: Names (individual, employer, relatives, etc.); Address (including city, state, zipcode and county); Telephone/Fax Numbers; Social Security Numbers; Dates (except for years); Birth Date; Admission Date; Discharge Date; Date of Death; E-mail Addresses/URLs; Medical Record Numbers; Health Plan Beneficiary Numbers; Account Numbers; Certificate/License Numbers; Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers); Device Identifiers and Serial Numbers; Biometric Identifiers (e.g. finger or voice prints or full face photographic images); Any other unique identifying number, characteristic, or code)*

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study: *(List)*

REQUIRED:
- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors

REQUIRED IF APPLICABLE:
- Sponsor *(give name)*
- Other research sites *(give name)*
- The Food and Drug Administration (FDA)

- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research) *(if federally funded)*
- Registries or Research Databases *(give names).* This is so that they can make sure that the data submitted to them is complete and valid. This only applies to the registries or research databases described in the earlier parts of this consent form.
- Your insurance company (if charges are billed to insurance).

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made: *(List the reason(s) that you need to use/disclose this PHI, e.g., to locate medical charts, to contact you in the future, for future tracking, etc.)*

REQUIRED LANGUAGE (NOTE: Please provide the mailing address of the Principal Investigator):
You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at *(PROVIDE MAILING ADDRESS)*. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

REQUIRED IF A CLINICAL/TREATMENT STUDY: While you are participating in this study, you may not be able to get access to your medical records related to this study because it could interfere with the results of the study. As soon as the study is finished, you will have access to these medical records.

REQUIRED LANGUAGE IF APPLICABLE:

There is a risk that someone could get access to the information (data) we have collected about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. The Genetic Information Nondiscrimination Act of 2008 (GINA) says that group and individual health insurers may not use your genetic information to determine whether you are eligible for insurance, how much you have to pay, nor can they request or require that you take a genetic test. We cannot guarantee that this will fully protect you. Your privacy and the confidentiality of your data are very important to us. We will make every effort to protect them.

REQUIRED LANGUAGE:

As stated above, your PHI may be used or disclosed for future research purposes, and as part of such future research purposes, your PHI may even be disclosed to people or entities that are not listed above, such as other researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies sponsoring future research. This future research may be related to your medical problem, but it may be related to other diseases or conditions as well. Any future research projects, however, will be reviewed and approved by an Institutional Review Board, which protects the rights, welfare, and safety of human research subjects.

I agree to allow my PHI to be stored and used for future research as described above: (initial your choice)

_____ YES _____ NO

15) STORED SAMPLES

If you plan to store unused samples and related information (e.g. gender, diagnosis, treatment, etc.) for future research:

With your permission, we would like to store unused *(select applicable type(s) of samples: blood, tissue, other (list))* samples that will be collected from you during the study and information related to such samples for research that will be performed at a later time, perhaps even years from now. No additional samples will be taken, but any unused samples will be stored for an indefinite amount of time. Information related to the samples may or may not include personal identifiers, such as your name, address, etc. There could be widespread sharing of these samples and associated information, but an Institutional Review Board, which protects the rights, welfare, and safety of human research subjects, will review and approve each new project.

Use of your samples for future research may help researchers learn more about how to prevent, find, and treat various diseases and conditions, even diseases and conditions that are different from yours. Genetic material (such as DNA and RNA) may be removed from the stored samples and used for genetic testing, which could uncover information about your inherited traits.

Using your samples for future research will probably not help you, and you will not be told the results of any future research. Your doctor will also not be told the results of any future research. We do hope any research performed involving your samples and related information will help other people in the future.

Your samples and information will be used only for research and will not be sold. There is a possibility that future research may lead to development of products that will be sold to the public. If this happens, there is no plan to share any financial gain with you.

If the results of future research are published, your name and other personal information will not be given.

If you decide at any time that you do not want your samples or related information stored for future research, you must make this request in writing to the Principal Investigator at *(PROVIDE MAILING ADDRESS)*. Once we receive your written request, we will destroy your samples and related information. However, once your samples and related information have been de-identified, we will not be able to destroy them because we will not be able to link your samples or information back to you. Also, if we have already shared your samples or information with another individual or entity, we will not be able to destroy any of the samples or information that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage of the samples or related information at any time and destroy the samples or information without sending notice to you or obtaining your consent.

You do not have to agree to use of your samples or related information for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my samples and related information to be stored and used for future research as described above: (initial your choice)

_____ YES _____ NO

16) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

REQUIRED LANGUAGE, CHOOSE ONE (NOTE: For higher risk studies or studies where it is anticipated that questions may arise after hours, a 24 hour access is needed. If you list the NCH Operator for the 24 hour access, then you need to provide more details regarding who should be contacted [example: "Ask the Operator to contact the Cardiologist on call"]):
If you have questions, concerns, or complaints about anything while on this study or you have been injured by the research, you have 24 hour access to talk to the Principal Investigator at *XXX-XXX-XXXX*.

OR

If you have questions about anything while on this study or you have been injured by the research, you may contact the Principal Investigator at *XXX-XXX-XXXX* , Monday – Friday, between *(time)*.

REQUIRED LANGUAGE:
If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

Subject's Name _____ **Date of Birth**_____

SUBJECT or SUBJECT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (SUBJECT TO THE SUBJECT'S GENERAL MEDICAL CARE)

I have read this consent form and I have had an opportunity to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participating in this study or a research-related injury, I may contact the Principal Investigator. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

REQUIRED HIPAA LANGUAGE (If you include HIPAA language [OPTION 2 above] in this document):
I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. If allowed by law, I understand that my right to any information that is created or collected by Nationwide Children's Hospital for this study can be temporarily suspended if necessary for the purposes of this research project. I also understand that my right to access to this information from this study will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study or I give permission for my child to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____
SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

_____ _____
SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE & TIME AM/PM**

Permission of the second parent not obtained because (select all that apply):
_____ Not required by the IRB (risk level 1 or 2).
_____ Other parent is deceased.
_____ Other parent is unknown.
_____ Other parent is not reasonably available.
_____ Only one parent has legal responsibility for the care and custody of subject.

_____ _____
PERSON OBTAINING CONSENT **DATE & TIME AM/PM**
I certify that I have explained the research, its purposes, and the procedures to the subject or the subject's legal representatives before requesting their signatures.

_____ _____
PRINCIPAL INVESTIGATOR **DATE & TIME AM/PM**
(PI signature is not required. If you do not plan on the PI signing, delete this line.)

REQUIRED (if applicable): If this study involves investigational drugs, please send a copy of this consent form to the Pharmacy along with the prescription or no drugs will be dispensed.