Blank Children's Hospital
UnityPoint Health

PCIRB Approval::MM/DD/YY
Protocol Version:
Revised: MM/DDYY
IRB: P-CIRB-YYYY-000
CIRB Expiration: MM/DD/YY

Name: _____
MR#: _____
DOB: _____

INFORMED CONSENT / PARENTAL PERMISSION FOR PARTICIPATION IN RESEARCH

Include this in the Confidentiality section of each consent

- Iowa-Wide Oncology Research Coalition (I-WORC)

Where the consent refers to injury and 'your study doctor' we will use the following phrase (Insert current PI name), your study doctor or a member of the study team

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or if you have a research related problem or if you think you have been injured by this study, you may contact Dr. Mallory, your study doctor or a member of the study team at 515-241-8912..

If you have questions about your rights as a research participant or any problems that you feel you cannot discuss with the investigators, you may call the office of the Institutional Review Board at 515-241-8598. The Institutional Review Board (IRB) is a group of people who review the research study to protect your rights. The IRB is a resource available to you.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Research Subject Advocate, at 515-263-5483.

Lastly, if you have questions about the privacy or confidentiality of your medical information, you may call the Privacy Officer of UnityPoint Health – Des Moines at 515-241-6039.

Use of the optional signature line will be for research staff members such as CRAs or nurses obtaining consent for non-treatment studies or other studies not requiring the signature of an investigator.

Signature

Physician/PNP/or other designee obtaining consent Date

Add the following if you are using the Short Form Consent Process:
The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

Signature of Witness Date

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*

Patient's Participation Statement[1]
(Age 14-17)

Dr. Mallory, one of my study doctors, or a member of the study team has told me about this research study. I understand how it may or may not help me and that it may cause me to not feel well. I also understand that this research may help doctors to understand more about the possible ways I may be treated. I have thought about being in this research study. I have asked and received answers to my questions.

I agree to be in this research study. I know I do not have to agree to be in the study. Even though I agree now, I know I may feel differently later on and I may change my mind at any time. I know that I may talk with my parents, guardians, other people I trust and/or doctors about whether to be in the study at any time.

Once I turn 18 years old, I may be contacted by someone on the study team regarding my continued participation on this study.

_____
Name of Patient

_____ _____
Signature of Patient Date

_____
Name of Investigator/or Designee Conducting Assent Interview

_____
Signature of Investigator/or Designee Conducting Assent Interview

[1] In Iowa, the age of majority is 18 years or upon marriage (Iowa Code 234.1)

Patient's Participation Statement[2]
(Age 7-13)

We have been talking to you and your family about a research study. A research study is when doctors work together to find out new information to help people.

Sometimes good things can happen to people when they are in a research study. These good things are called "benefits." We hope that this study will benefit you but we don't know for sure if it will. Sometimes bad things can happen to people when they are in a research study. These bad things are called "risks." Your doctor will tell you about the "risks" that can happen on this research study. We hope that other children can benefit from the information we learn.

You and your family can choose to be part of this study or not. You and your family can also decide to stop being in this study at any time once you start. There may be other options for your illness that your doctor can tell you about. Make sure to ask your doctors any questions that you have.

Once you have turned 18 years old, you may be contacted by someone on the study team to see if you want to continue participating on this study.

_____I agree to take part in this study

_____I do not agree to take part in this study

_____
Name of Patient

_____ _____
Signature of Patient Date

_____
Name of Investigator/or Designee Conducting Assent Interview

_____
Signature of Investigator/or Designee Conducting Assent Interview

[2] In Iowa, the age of majority is 18 years or upon marriage (Iowa Code 234.1)