Arkansas Children's
HIPAA Research Authorization

Basic facts about the study:

Study title: *[title]*

Principal investigator (the main person leading the study):
[Name]
[Address Line 1]
[Address Line 2]
[Email]
[Phone]

Study sponsor (the group paying the research site or staff to do this study): *[name; delete this sentence if there is no sponsor]*

About this form:

We are asking you to join the research study explained in this form and in the informed consent form. For our study, we need to get health information about you. You may also do some study activities that produce new health information about you. This form explains what kind of information we may use or produce and how we will use it. To join this study, we need your permission to collect, create, and share this information.

When you see the word "you" in this document, it means anyone who signs this form and joins the research study.

About the health information we may collect from you in the study:

We will only collect details we need for the study. We may ask you to give us the details below from your health records:

- *[use bullets to list specific information that you will record]*

We need these details because [*list purpose of the study]*.

Some of these details will include information that could identify you.

About new health information that may come from the study:

If you join this study, the activities you join may result in some new health information about you. This may include:

- *[use bullets to list information that will be created]*

How study staff may share your information:

We may share your health information with:

- Staff at Arkansas Children's (AC) and University of Arkansas for Medical Sciences (UAMS), including:
  - The research study staff
  - The UAMS Institutional Review Board (IRB)
  - The Compliance Offices at Arkansas Children's and UAMS as well as other institutional oversight offices
- Researchers outside of AC/UAMS:
  - *[list in bullets; delete this section if n/a]*
- Companies or organizations that help pay for the research, such as:
  - *[The sponsor listed above; delete if there is no sponsor]*
- Companies that work with us on the research, such as:
  - *[list in bullets; delete this bullet if there are none]*
- Other companies related to the research, such as *[delete if not applicable]*:
  - The study sponsor's legal counsel (lawyers)
  - Anyone who may buy any companies listed above in the future
  - Companies that administer the payment management system
- People outside of AC/UAMS who make sure we do the research the right way, such as:
  - The U.S. Office for Human Research Protections
  - The U.S. Food and Drug Administration *delete if the study is not subject to FDA oversight*
  - Other parties as required by law.

We think everyone involved with research understands how important it is to keep your health information private. But people outside of AC/UAMS may not have to follow the same laws AC/UAMS follows to protect your health information.

How long this authorization lasts:

When you sign this form, you agree to let us collect, produce, and share health information about you as we describe in this form. Your authorization *[choose one option below; delete the others]*:

- ☐ Ends at the end of the research
- ☐ Ends on *[date or event of expiration]*
- ☐ Does not end

[Insert this sentence only if records may be accessed in this way; delete if not applicable]
We may collect some information from your medical records even after your direct participation in the research project ends.

Signing this form is your choice:

You do **not** have to sign this form. **But, if you do not sign it, you cannot be in the study.** If you decide not to be in the study, it will not affect the care or benefits you get from AC/UAMS.

If you want to be in the study, sign this form and the research consent form. If you sign this form, you are allowing us to create, collect, use, and share your health information.

How to quit the study and what happens to your information if you quit:

If you sign this form and decide later that you do not want us to use your health information for the research, you must send a letter to:

Arkansas Children's Hospital
Health Information Management Director
1 Children's Way
Little Rock, AR 72202

In your letter, include:

- The study title (from the top of this form)
- A statement saying you changed your mind and are ending your "HIPAA Research Authorization"
- Your signature

After we get the letter, we will take you out of the study and stop collecting your health information. But we may still use and share your health information we collected before we got your letter.

If you quit the study, it will not change your care or benefits from AC/UAMS.

Your access to study records about you:

[Only use this paragraph if access to their medical records may be denied during the study. Delete if this does not apply.]

During the study, if you ask for your research related records, the research staff will decide if you can see them. If study staff is not able to let you see your records during the study, you can ask to see your records when the study is over.

Signature, date, and identity of person signing:

Researchers and staff can collect health information about _____ and use it for the study described here and in the research consent form.

Signature:_____

Date:_____

Print name:_____

Relationship to participant:_____

Staff will give you a copy of your signed form. Keep this form with the research consent form. That is a separate document that gives you more details about the study.