A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, your health care provider cannot release your health information for research purposes unless you give your permission. The purpose of this form is to give your permission to your health care provider to release your personal health information to the research team. Your information may then be used by the research team for the research described in the Consent Form, and may also be shared by the research team with others, including those who support the research, have oversight over the research, or sponsor the research, as explained below. This form also describes the type of personal health information that would be released by your health care provider. If you decide to give your permission and to participate in the study, you must sign this form and the Consent Form. You should be aware that once your personal health information is released by your health care provider it may not be protected by privacy laws, and might be shared with others beyond those described in this form or the Consent Form. If you have any questions about this form or the use of your information, ask a member of the research team.

B. What information will be released?

The research team has marked the boxes below for information needed to participate in this study. If you sign this form, your health care provider will release your personal health information as marked below:

- ☒ All Hospital Records
- ☒ All Clinic Records
- ☒ Emergency Dept. Records
- ☒ Dental Records
- ☒ Immunization Records
- ☒ History & Physical Exams
- ☒ Images
- ☒ Imaging Reports
- ☒ Progress Notes
- ☐ Psychological Tests
- ☒ EEG/EKG/ECHO Reports
- ☒ Lab & Pathology Reports
- ☐ Financial Records
- ☒ Other (describe): Audiology reports

1 HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.
including audiograms and hearing assessments

C. **What about more sensitive health information?**

Certain personal health information is so sensitive that it requires your specific permission. If the research study you are participating in requires any of this information, the boxes below will be marked and you will be asked to initial to permit the release of this information to the research team.

- [ ] I agree to the release of drug and alcohol abuse, diagnosis and treatment records. _____ (initial)
- [ ] I agree to the release of HIV/AIDS testing records. _____ (initial)
- [ ] I agree to the release of genetic testing records. _____ (initial)
- [ ] I agree to the release of mental health diagnosis or treatment records. _____ (initial)
- [ ] I agree to the release of sickle cell anemia records. _____ (initial)

D. **Who will receive and use my health information?**

Your personal health information may be shared with:

1. The research team conducting the research described in the Consent Form, including any affiliated research institutions involved in conducting the research described in the Consent Form;
2. Others at M Health and the University of Minnesota who provide support for the research or who have authority to oversee research (such as systems administrators and other technical and/or administrative support personnel, compliance and audit professionals, individuals involved in processing any compensation you may receive for your participation, and others);
3. The research sponsor(s), any affiliates or partners of the sponsor(s) involved in the research, organizations funding the research, and any affiliates or partners of the funding organization(s) involved in the research;
4. Other organizations who provide accreditation and oversight for the research team; and Others who are authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration or the Office of Human Research Protections, or government agencies in other countries).

E. **Am I required to sign this document?**

No, you are not required to sign this document. However, if you do not sign the document, you will not be able to participate in this research study and will not receive any treatment that may be provided through the study. Any other treatment, payment, enrollment or eligibility for benefits will not be affected by your decision about signing this document.
F. Will I be able to view my records?

To make sure that the research study is not impacted by any actions you take, it is possible that the research team may not allow you to see the information collected for this study, including information placed in your medical records, until after the study is complete. Once the study is over, you may view the records.

G. Optional research activity

The study that you are participating might have optional research activities associated with it, such as the creation of a database for possible future research, as described in the Consent Form and as marked below by the research team. If you agree to permit your information to be used for those optional research activities, you must initial below.

☒ There are no optional research activities. _________ (initial)
☐ The research I am participating in has an additional optional research activity to create a database for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. ______ (initial)
☐ The research I am participating in has an additional optional research activity to create a tissue or biospecimen repository for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. _______ (initial)

H. Does my permission expire?

This permission expires when the research ends and all required study monitoring is over, including any optional research activities I agree to above.

I. Can I cancel my permission?

You can cancel your permission at any time. To cancel your permission, you can write to the researcher at the address at the top of this form. If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for the research study. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.
J. Signature

If you agree to the use and release of your personal health information as described in this document, please print your name and sign below. You will be given a signed copy of this form.

Research Participant’s Name (print) (required even if signed by parent/legal representative)

Research Participant’s Signature ___________________________ Date ________________

Parent or Legally Authorized Representative

If you agree to the use and release of the Personal Health Information of the Research Participant named above, please print your name and sign below.

Parent or Legally Authorized Representative’s Name (print)

Relationship to the Research Participant

Parent or Legally Authorized Representative’s Signature ___________________________ Date ________________

Witness

If this form is being read to the Research Participant because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness’ Name (print)

Witness’ Signature ___________________________ Date ________________