Children's Hospital & Regional Medical Center | **Seattle Children's Hospital Research Institute**

Permission to Use, Create and Share Health Information for Research
Research Study Title: Genetic Susceptibility to West Nile Virus
IRB Study #: 12010

The federal Privacy Rule protects your/your child's health information. The Privacy Rule is part of the Health Insurance Portability and Accountability Act (HIPAA).

If you/your child agree to take part in this research study (named above), the researchers may use, create or share your/your child's health information as part of the research. The researchers will do so **only** if you give permission to use, create or share your/your child's health information as part of the research. This form gives you information to help you decide if you will give such permission. **Please read this form carefully**. After reading this form, you can refuse to sign this form.

What does "health information" include? It includes:

☒ Name ☒ Address ☐ Social Security Number ☒ Medical and/or birth history ☒ Demographic information

☒ Results of physical exams ☒ Results of laboratory and/or radiology tests

☒ Interview and/or focus group data ☒ Survey and/or questionnaire data

☐ Results of behavioral tests ☒ Information related to your health condition

☒ Information in your medical record relevant to this study ☐ Other (please specify) * _____

* If using a translated HIPAA Form, this information must also be translated

What the researchers may do with health information

Researchers may create new health information about you/your child during the study. Researchers may use health information in your/your child's records.

Researchers may also share health information about you/your child collected during the study with the following:

1. The sponsor of this study and its representatives. Sponsor Name: **National Institutes of Health (NIH)**
2. Researchers at other centers taking part in this research study.
   Name(s) of other center(s): **University of Washington, University of Utah**
3. Government agencies, ethics review boards, data and safety monitoring boards, and others responsible for watching over the safety, effectiveness, and conduct of the research.
4. Your health care insurance company if it is paying for care provided as part of the research study.
5. Other health care providers involved in your/your child's care.
6. National Institutes of Health and its grantholders for the purpose of research administrative activities (e.g., tracking overall research activity).
7. Others, as provided by law.

The Privacy Rule applies to doctors, hospitals and other health care providers. Some of the groups listed above are not required to follow the Privacy Rule and may share your/your child's information with others, if other laws allow. However, other privacy protections may still apply.

Research Records

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research records may not be available to you/your child while the study is going on. This does not affect your right to see what is in your/your child's medical (hospital) records.

The researchers may publish or present the research findings. You/your child will not be identified in any findings that are published or presented.

The federal Privacy Rule does not apply to health information that is not identified in any way. The researchers may decide to remove any information that could identify you/your child. If they do this, the information may be used and shared by the researchers and the sponsor as the law allows. This may include use in other research studies.

Permissions to Take Part in Research

If you agree to take part or allow your child to take part in the research, you will be asked to sign a **research consent form**. The research consent form gives you details about the research. The consent form describes the risks and benefits of the research. It explains the purpose of the study, what will happen and other important information for you to know.

To be in this research study, you must also sign this permission form (Permission to Use, Create and Share Health Information for Research). If you do not want to sign this permission form, this will not affect the care and treatment you or your child receive.

How Long does the Permission Last? What if You Change Your Mind?

☒ This permission is valid until the end of the research study;

or

☐ This permission will not expire, because this is a research database or repository study (i.e. specimens and/or data are stored permanently).

Except for the research database and repository studies, your/your child's information will be destroyed or any personal identification will be removed at the end of the research study. If you change your mind and want to cancel your permission, please let us know in writing. Write to Principal Investigator (PI)/Researcher:

[Name and Address of PI].
Michael Bamshad MD
1959 NE Pacific St. HSC RR349
Seattle, WA 98195-6320

If you cancel your permission and you/your child are a patient at Children's, please send a copy of your letter to:

Director of Health Information and Privacy, Health Information Management, A-4902, Children's Hospital and Regional Medical Center, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

If you cancel your permission, no other health information about you/your child will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons;
- to verify the research data;
- if required by law.

If you agree to take part or allow your child to take part, you will be given a copy of this permission form after you have signed it.

Permission

I agree to the use, creation, and sharing of my or my child's health information for purposes of this research study (named on page 1). For Children's patients, your medical record # will be recorded on this form and used to place a copy of this form in your medical record.

Printed Name of Participant	Signature of Participant (if 18 years or Older)	Date
Printed Name of Participant's Parent or Legal Representative	Signature of Research Participant's Parent or Legal Representative (if younger than18 years)	Date

Researcher Obtaining Authorization

Printed Name of Research Team Member*	Signature of Research Team Member	Date

***INSTRUCTIONS TO RESEARCHER**

1. File signed original of this form in Research File ☐
2. Provide copy of signed form to Research Participant/Parent ☐

For Children's Patients

3. Complete or attach patient label: ☐

Participant's Medical Record # _____

Participant's Date of Birth _____/_____/_____

4. Send copy of the signed form to Health Information Filing: Mailstop A-4902 ☐