

Mission & Goals of the Region 4 Genetics Collaborative

- 1) Increase access to information about newborn screening and genetic resources, services and family support systems
- 2) Facilitate data collection and analysis to guide decision-making regarding screening cut-offs, diagnosis and long term treatment of heritable disorders
- 3) Support state public health agencies in improving infrastructure for genetic service delivery to children with heritable disorders
- 4) Provide a forum for families, public health, and clinical providers to share best practices and models for improving newborn screening, follow-up and genetic care coordination
- 5) Link Region 4 states with regional and national initiatives for improving the quality of newborn screening and genetic service delivery



Region4
Genetics Collaborative

Funded by the Federal Maternal and Child Health Bureau, Health Resources and Service Administration of the Center for Disease Control and Prevention, the Region 4 Genetics Collaborative provides a forum for seven states (Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio and Wisconsin) to work together to ensure that all children have access to state-of-the-art genetic services.

The provision of optimal genetic services to children relies on a partnership between public health programs, screening/diagnostic laboratories, clinical providers and families of children with inherited conditions. As lead agency of the collaborative, the Michigan Public Health Institute, Systems Reform program, provides the infrastructure necessary to facilitate effective collaboration.

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Inborn Errors of Metabolism Information System (IBEM-IS) Patient Registry



*Improving the quality of newborn
screening and genetic services delivery*



Region4
Genetics Collaborative

www.region4genetics.org


If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, #815 Professional Building, 2450 Riverside Ave. Minneapolis, MN 55454.

Introduction

What is IBEM-IS?

The Inborn Errors of Metabolism Information System (IBEM-IS) was developed by the Region 4 Genetics Collaborative. The IBEM-IS is a web-based registry system, designed to monitor health outcomes for infants and children with inborn errors of metabolism. The IBEM-IS will allow the medical community to understand more about the natural history and outcomes for rare inborn errors of metabolism, develop treatment protocols, and support clinical research.

Why your information matters



The experiences and information you share will provide useful information to advance the understanding of Inborn Errors of Metabolism. The IBEM-IS collects and manages this data, and assists physicians and researchers in every facet of patient care, from investigating the cause to making the diagnosis to tracking the effectiveness of treatment.

Your Contribution

With your participation, your child's information will contribute to helping to extend and improve the lives of people with inborn errors of metabolism by:

- Assisting in better understanding of inborn errors of metabolism
- Improving the care of future patients with the development of evidence-based treatment protocols
- Offering a valuable resource for pediatricians and researchers conducting clinical trials and studies

If, during the course of this study, there are significant new findings discovered which might influence your willingness to continue, researchers will inform you of the developments.

Participating in the Registry

Is my child eligible to participate?

Your child is eligible to participate if he or she has been diagnosed with an inborn error of metabolism.



Why should I participate?

You will have the satisfaction of knowing you have contributed to expanding the knowledge on Inborn Errors of Metabolism (IBEM). Your participation will aid others with IBEM conditions and the continued development of treatments. Developing improved care for people with Inborn Errors of Metabolism may be an eventual benefit to you as well. Participation in this registry is voluntary. Your decision regarding participation in this registry will not change the clinical management or other services you receive. If you choose to participate, you also may be offered opportunities to participate in future research studies that may become available through involvement in the registry.

How do we register?

When you decide to register:

- 1) Meet with your pediatric specialist to fill out consent forms and patient history
- 2) Registration will be completed by your physician
- 3) Follow up information will be captured at your regular visits, when necessary

Frequently Asked Questions

What about confidentiality?

To minimize risk to your personal medical information, your consent will be obtained prior to your participation in the IBEM-IS Registry and your data will be stored in a secure, protected database with safeguards like that of an electronic medical record. Only the researchers will have access to your protected health information. < MENTION HIPAA >

How does the Registry work?



Who manages the IBEM-IS Registry?

The Inborn Errors of Metabolism Registry is hosted on an independent, web-based server (DocSite®) that is fully HIPAA compliant and designed to support data privacy.

Only the DocSite® server and each individual participating institution or clinic will have secure access to the protected health information of subjects that particular institution has enrolled in the registry. Secure, password protected access will be granted on an individual participant level.

