Department of Public Health
and Human Services
Montana Newborn Screening Program

State of Montana

Condition Nomination Form for Inclusion in the Montana Newborn Screening Panel

Date of Nomination ___________

Completion of Conflict-of-Interest Disclosure Forms:

By checking the box below, I agree that I, and all Co-Sponsoring Organizations (if they contributed to the completion of this nomination packet), have signed and dated the Conflict-of-Interest Disclosure Forms, and the forms are included with this Nomination Package.

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NOTE: All conditions reviewed by the committee will undergo the same process.

Nominator	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number
Co-Sponsoring Organization #1 (if any)	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number
Co-Sponsoring Organizations #2 (if needed, additional sponsors may be included on page 6)	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number

Have you nominated this condition before? If yes, please describe what has changed since your last submission.

_____ Yes _____ No

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Please answer the following questions to the best of your ability.

Section I. Condition Background Information	
Nominated Condition	
Symptoms and age of onset	
How is this disorder currently identified?	
Why should it be screened at birth?	
How is this disorder treated?	☐ Is there a treatment available? ☐ Is the treatment in the experimental phase? ☐ Is the treatment FDA approved / non-experimental?
Proposed Screening Test Method	

Status of NBS Condition in the U.S. (Optional, but please provide if known)	
State(s) currently screening for the condition.	
State(s) currently mandated to screen for the condition.	

Patient Registry(ies) or Databases (Optional, but please provide if known)	
List registries or databases currently established for the condition.	

Please address the following statements to the best of your ability. Please indicate if the following statements are true and provide information and resources to support your position.

NOTE: Sources used to support your answers must be listed in **Section III. Key References.** Sources should be cited in your responses with the corresponding reference number listed in **Section III**; please use reputable sources only. Explanations and sources should be as robust as possible to support a complete application.

Section II. Criteria			
	True	**Unsure**	**No**
1. It can be identified at a period of time (24 to 48 hours after birth) at which it would not ordinarily be clinically detected.			
2. A test with appropriate sensitivity and specificity is available.			
3. There is a significant risk of illness, disability, or death if babies are not treated promptly (within the recommended time frame for the condition).			
4. Effective treatment is available and access to follow-up care and counseling is generally available.			
5. There are demonstrated benefits of early detection, timely intervention, and efficacious treatment.			
6. The benefits to babies and to society outweigh the risks and burdens of screening and treatment.			

	True	Unsure	No
7. There are minimal financial impacts on the family.			
8. There is a public health benefit to conducting the test.			
9. There exist responsible parties who will follow up with families and implement necessary interventions.			
10. The condition's case definition and spectrum are well described.			

FOR LAB USE ONLY

	True	Unsure	No
The public health laboratory can support the testing resources and expertise necessary to provide accurate and timely results.			
Please provide support for your answer.			

Section III. List of Key References Please list and attach as PDF(s).	
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Additional Co-sponsoring Organizations

Co-Sponsoring Organization #3	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number
Co-Sponsoring Organizations #4	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number
Co-Sponsoring Organizations #5	
Name (include professional degrees)	Organization
Affiliation (i.e., advocacy group, health professional, subject matter expert, researcher, clinician, advocate, etc.)	
Address	
Email Address	Telephone Number

Submission Check List	
	Nomination form
	Conflict of interest forms
	PDF copies of publications / articles used as references

Submission:

Submit Nominations Electronically to: HHSNewbornAdvisoryCommittee@mt.gov

Next Steps:

The Newborn Screening Program will confirm receipt of the nomination packet and may request additional information. Submissions will be reviewed by the Newborn Screening Advisory Committee for determination of next steps. The Newborn Screening Program will be in contact with you and remain available to you regarding your submission.