



**INDIANA NEWBORN SCREENING (NBS) PROGRAM
CONDITION NOMINATION**

State Form 57125 (R / 12-23)
INDIANA DEPARTMENT OF HEALTH

Date of Nomination (month, day, year):	
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OVERVIEW OF NOMINATION

SECTION 1 - NOMINATOR

Name	Professional Organization (if applicable)
Role (i.e., health professional, researcher, clinician, advocate, etc.)	
Address (number and street, city, state, and ZIP code)	
E-mail address	Telephone number

SECTION 2 – CO-SPONSOR
*(One co-sponsor is required; must be a different role or professional organization.)
(Individual advocates should reach out to a health professional, researcher, clinician, or advocacy group to help complete the clinical aspects of this form.)*

Name	Professional Organization (if applicable)
Role (i.e., health professional, researcher, clinician, advocate, etc.)	
Address (number and street, city, state, and ZIP code)	
E-mail address	Telephone number

SECTION 3 – RESUBMISSION INFORMATION

Was this condition previously nominated for addition to newborn screening in Indiana? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure	Date of previous nomination (month, day, year) *Condition cannot be re-nominated less than twelve (12) months from previous nomination.
Which criterion(a) has additional information now? <input type="checkbox"/> Criterion 1 (Please explain): <input type="checkbox"/> Criterion 2 (Please explain): <input type="checkbox"/> Criterion 3 (Please explain): <input type="checkbox"/> Criterion 4 (Please explain): <input type="checkbox"/> Criterion 5 (Please explain):	

SECTION 4 – OVERVIEW OF THE CONDITION

Nominated Condition	Other Names for Condition
Description of Condition	
Type of Condition	Affected Gene/Locus (if applicable)
Incidence	
Recommended Universal Screening Panel (RUSP) Status <input type="checkbox"/> Core Condition of RUSP <input type="checkbox"/> Previously Nominated but not added to RUSP <input type="checkbox"/> Secondary Condition of RUSP <input type="checkbox"/> Candidate Status from Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)	
Sample Collection Required <input type="checkbox"/> Yes <input type="checkbox"/> No	
Type of Sample Collection <input type="checkbox"/> Dried blood spot <input type="checkbox"/> Saliva <input type="checkbox"/> Urine <input type="checkbox"/> Point of care screening <input type="checkbox"/> Other: _____	

CONFLICT OF INTEREST DISCLOSURE

This form should be used to indicate a conflict of interest that may exist when the nominator(s) has an economic interest in, or acts as an officer or a director of, any entity whose financial interests would reasonably appear to be benefitted by the addition of the nominated condition to the Indiana newborn screening panel. The nominator(s) should also disclose any personal, business or volunteer affiliations that may give rise to a real or apparent conflict of interest.

NOTE: A conflict of interest exists if a nominator(s) has a relationship (parent, grandparent, etc.), affiliation, or other interest that would directly benefit the nominator, financially or otherwise, based on the outcome of the nomination.

A disclosure of a conflict of interest does not automatically mean the condition being nominated to Indiana’s newborn screening panel will not be considered; rather, a disclosed conflict of interest warrants additional discussion between the Indiana Department of Health and the nominator(s). The Indiana Department of Health may refuse to accept a nomination from any person with a conflict of interest.

I, the nominator, my organization, or a family member have no conflict of interest(s) to report.

I, the nominator, my organization, or a family member have the following conflict of interest(s) to report (*please specify below*):

I, the co-sponsor, my organization, or a family member have no conflict of interest to report.

I, the co-sponsor, my organization, or a family member have the following conflict of interest(s) to report (*please specify below*):

CERTIFICATION

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature of Nominator

Date (*month, day, year*)

Signature of Co-Sponsor

Date (*month, day, year*)

CRITERIA FOR MANDATED SCREENING OF A CONDITION

All five criteria should be met before evaluation and review will occur by the subcommittee. Please ensure responses are as complete and thorough as possible.

Criterion 1: Mandated screening should be limited to conditions that cause serious health risks in childhood that are unlikely to be detected and prevented in the absence of newborn screening.

Does this condition cause serious health risks that, without newborn screening, would go undetected until symptom onset in childhood?
 Yes No Unsure

Please explain below the serious health risks and the timing for when symptoms usually appear:

Criterion 2: Conditions identified by newborn screening should have safe, effective, and approved treatment options available to all Indiana patients.

Is there a safe, effective, and approved treatment option(s) available to all patients in Indiana?
 Yes No Unsure

Please explain below the treatment option(s):

Criterion 3: Mandated screening for a condition should be affordable, feasible, and accurate.

Is the screening for this condition affordable, feasible, and effective?
 Yes No Unsure

Please describe below the screening (e.g., cost, method, specificity/sensitivity/positive predictive value):

Criterion 4: Conditions identified through newborn screening should have an approved confirmatory test that is feasible and available to all patients.

Is the FDA-approved confirmatory testing for this condition feasible and available to all patients in Indiana?
 Yes No Unsure

Please explain below the approved confirmatory testing option(s) below (e.g., method, cost/insurance coverage, location of clinics/lab that can perform confirmatory testing):

CRITERIA FOR MANDATED SCREENING OF A CONDITION (continued)

Criterion 5: Long-term management and care for the condition should be readily available to all patients and shown to improve quality of life.

Is long-term management and care for the condition readily available to all patients in Indiana?

Yes No Unsure

Please describe below the long-term management and care required for the condition:

Key References: Please include any pertinent publications, articles, or websites used to complete this form.

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

NEXT STEPS: Submit completed and signed nomination form:

Electronically via email:
NewbornScreening@health.in.gov

Or mail to:
Indiana Department of Health
Genomics & Newborn Screening
ATTN: GNBS Director
2 N. Meridian St.
Indianapolis, IN 46204

The Genomics and Newborn Screening Director will confirm receipt of the nomination within three business days and may request further information. Submission will be reviewed by the Indiana Perinatal Quality Improvement Collaborative's Perinatal Genetics & Genomics Advisory Committee for determination of next steps. The process, along with updates throughout the process, will be posted on the Genomics & Newborn Screening program website at www.nbs.in.gov.