Reset Form

INDIANA NEWBORN SCREENING (NBS) PROGRAM
CONDITION NOMINATION
State Form 57125 (R2 / 5-25)
INDIANA DEPARTMENT OF HEALTH

Date of Nomination *(month, day, year)*:	

OVERVIEW OF NOMINATION

SECTION 1 – NOMINATOR *(Must be an Indiana resident aged 18 years or older.)*

Name	Professional Organization *(if applicable)*
Role (i.e., physician, individual advocate, family advocate etc.)	
Address *(number and street, city, state, and ZIP code)*	
E-mail address	Telephone number

SECTION 2 – CO-NOMINATOR
(One co-nominator is required.)
(All individual or family advocates nominating a condition must include a physician co-nominator with expertise in the condition.)

Name	Professional Organization *(if applicable)*
Role (i.e., physician, 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? ☐ Yes ☐ No ☐ 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?

- ☐ Criterion 1 *(Please explain)*:
- ☐ Criterion 2 *(Please explain)*:
- ☐ Criterion 3 *(Please explain)*:
- ☐ Criterion 4 *(Please explain)*:
- ☐ 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

- ☐ Core Condition of RUSP
- ☐ Secondary Condition of RUSP
- ☐ Previously Nominated but not added to RUSP
- ☐ Candidate Status from Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)

Sample Collection Required

- ☐ Yes
- ☐ No

Type of Sample Collection

- ☐ Dried blood spot
- ☐ Saliva
- ☐ Urine
- ☐ Point of care screening
- ☐ 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-nominator, my organization, or a family member have no conflict of interest to report.

☐ I, the co-nominator, 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-Nominator	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.

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NEXT STEPS: Submit completed and signed nomination form:

Electronically via email:
NewbornScreening@health.in.gov

Or mail to:
Indiana Department of Health
Public Health Genetics
ATTN: Public Health Genetics Director
2 N. Meridian St.
Indianapolis, IN 46204

The Public Health Genetics Director will confirm receipt of the nomination within one week and may request further information. Submission will be reviewed by the Perinatal Genetics and Genomics Advisory Committee for evidence review and evaluation. The process, along with updates throughout the process, will be posted online at https://www.in.gov/health/gnbs/gnbs-programs/newborn-screening-program/nbs-condition-nomination/.