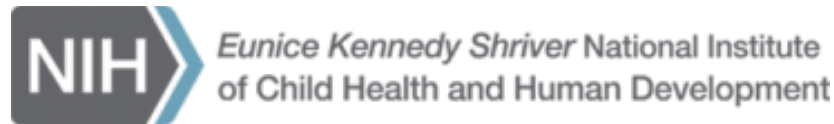




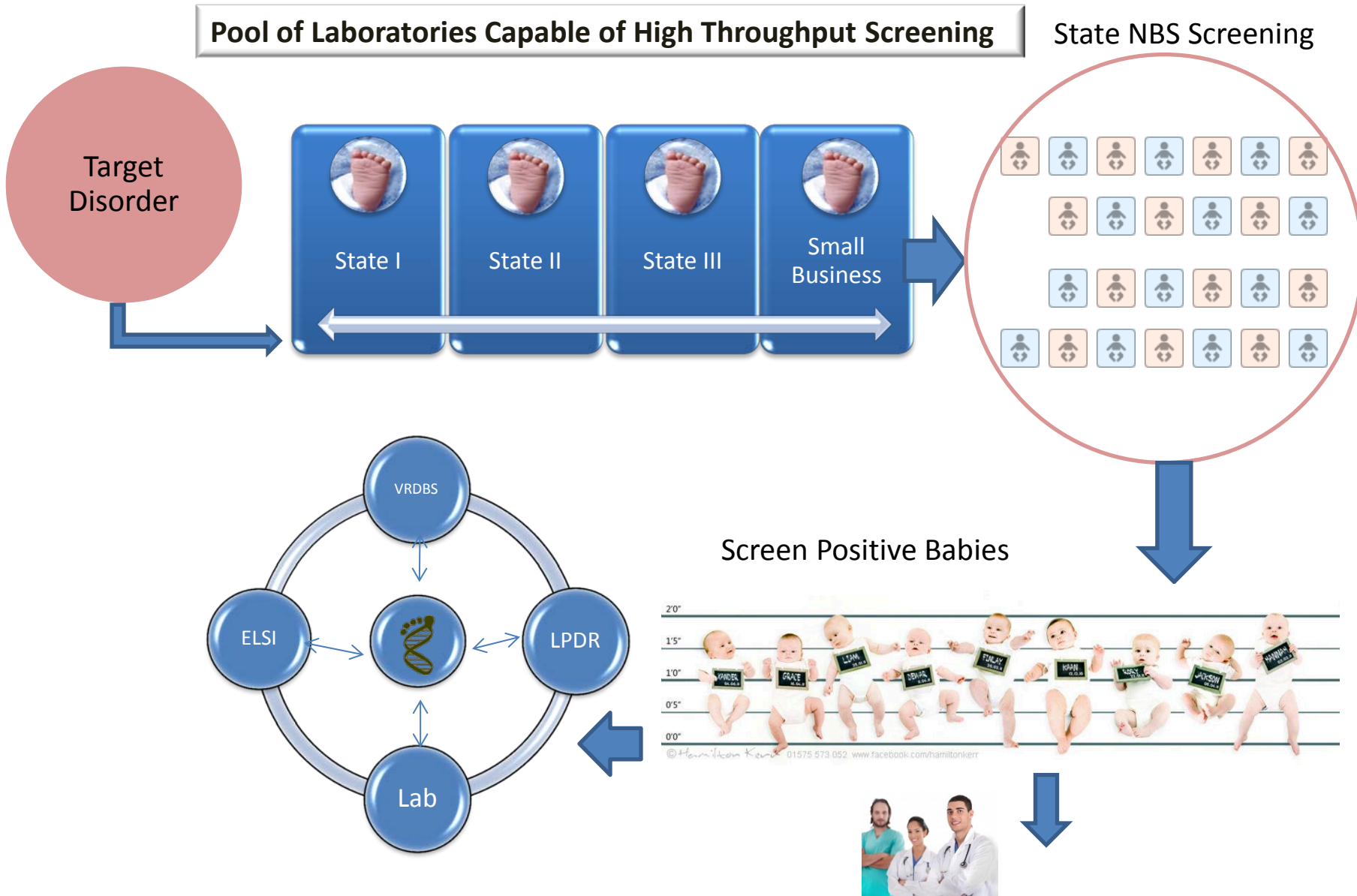
Newborn Screening Pilot Studies

Tiina K. Urv, Ph.D.

Intellectual and Developmental Disabilities Branch



Model for Newborn screening Pilot Studies



Sources Sought – Newborn Screening Pilot Studies

Requirements:

To be deemed capable of performing this requirement, the offeror must submit a written capability statement that clearly demonstrates their experience and ability to provide the following capabilities:

- Technical expertise and high throughput capacity to test a large number of samples (~50,000) for disorders using newborn dried blood spots with appropriate screening technology either immediately or with a short set up period (less than 3 months).
- Ability to provide efficient confirmatory testing procedures for presumed positive results.
- The capacity and resources needed for tracking positive cases.
- The ability to arrange appropriate follow up care and referral of identified newborns in a time frame comparable to other currently used newborn screening assays.
- An administrative structure that is conducive to prospective, rather than retrospective, pilot testing (including documentation of ability to obtain human subjects approval within 6 months of being presented with an NICHD nominated condition).
- Documented quality assurance and quality control procedures in place for accurate assessment of findings.

The screenshot displays the FEDBIZOPPS.GOV website interface. At the top, there is a navigation bar with links for Home, Getting Started, General Info, Opportunities (highlighted), Agencies, and Privacy. Below the navigation bar, there are links for Buyers (Login | Register), Vendors (Login | Register), and Accessibility. The main content area features the National Institutes of Health logo and the title 'Newborn Screening Pilot Studies'. The solicitation number is NIH-NICHD-IDD-SBSS-2015-3, and the agency is the Department of Health and Human Services. The notice is categorized as 'Sources Sought'. There are buttons for 'Return To Opportunities List' and 'Watch This Opportunity'. The synopsis section provides details about the notice, including the date added (Jan 22, 2015 11:26 am) and the background information. The background section explains the goal of newborn screening and the importance of early detection. On the right side, there is a 'GENERAL INFORMATION' section with various details such as Notice Type, Posted Date, Response Date, Archiving Policy, and Classification Code.

FEDBIZOPPS.GOV Federal Business Opportunities

Home Getting Started General Info **Opportunities** Agencies Privacy

Buyers: [Login](#) | [Register](#) Vendors: [Login](#) | [Register](#) [Accessibility](#)

NEWBORN SCREENING PILOT STUDIES

Solicitation Number: NIH-NICHD-IDD-SBSS-2015-3
Agency: Department of Health and Human Services
Office: National Institutes of Health
Location: National Institute of Child Health and Human Development

Notice Details Packages [Print](#) [Link](#)

Original Synopsis
Jan 22, 2015
11:26 am

[Return To Opportunities List](#) [Watch This Opportunity](#)

Solicitation Number: NIH-NICHD-IDD-SBSS-2015-3
Notice Type: Sources Sought

Synopsis:
Added: Jan 22, 2015 11:26 am

This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses, veteran owned small businesses; HUBZone small businesses; woman-owned small businesses; or small disadvantaged businesses and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

Background:

The goal of newborn screening is to detect potentially fatal or disabling conditions in newborns, thereby providing a window of opportunity for early treatment, often while the child is still asymptomatic. Such early detection and treatment can have a profound impact on the clinical severity of the condition in the affected child. If left undiagnosed and untreated, the consequences of the targeted disorders can be dire, many causing irreversible neurological damage, intellectual, developmental and physical disabilities, and even death. In 2006, the American College of Medical Genetics (ACMG) developed newborn screening guidelines that recommend that all newborn infants be screened for 29 "core conditions" and that 25 secondary conditions identified during the core evaluations be reported. These

GENERAL INFORMATION

Notice Type: Sources Sought
Posted Date: January 22, 2015
Response Date: Feb 04, 2015 2:00 pm Eastern
Archiving Policy: Manual Archive
Archive Date: -
Original Set Aside: N/A
Set Aside: N/A
Classification Code: A -- Research & Development
NAICS Code: 541 -- Professional, Scientific, and Technical Services/541712 -- Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)