FOA#: RFA-AR-15-014

This FOA invites applications from single institutions, or consortia of institutions, to participate in a consortium of chronic pediatric disease research groups focused on clinical validation of child patient reported outcomes (cPROs). The goal of the PEPR consortium is to validate existing and emerging pediatric item banks and instruments available at the NIH Patient-Reported Outcomes Measurement Information System (PROMIS®) (www.nihPROMIS.org) in (1) clinical research settings, (2) clinical care settings and/or (3) as ancillary components of clinical trials in children in either setting.

The purpose of this FOA is to capitalize on recent advances in the science of PROs to measure the patient experience in clinical care and research in children with a variety of chronic diseases and conditions using PROMIS tools and approaches coupled with detailed clinical phenotyping and/or biospecimen collection in well-characterized human cohorts. The long-term goal is to develop (1) reliable, validated clinical tools for cPROs to improve the assessment of outcomes in clinical trials or other research settings, and personalize ongoing care of chronic diseases in children and (2) examine the impact of environmental stressors on children’s health including their symptoms and quality of life.

Areas of interest include, but are not limited to:

- Studies that focus on utilizing and optimizing the use of pediatric PRO instruments applicable in a variety of chronic diseases in the research or patient care settings.
- Validation of currently available and soon to be released PROMIS Pediatric banks/instruments in large, well characterized cohorts.
- Test and validate PROMIS domains and instruments assessing disease activity and response to therapy in clinical populations and settings.
- Comparisons of patient burden and precision of PROMIS domains and tools compared to current disease-specific instruments.
- Evaluation of PROMIS short forms, profiles and/or CAT responsiveness to change with pharmacologic or non-pharmacologic interventions, establishing minimally important differences (MID) in clinical research or care settings.
- Studies that contribute evidence (e.g., cognitive interviews) to improve the content or construct validity of existing pediatric PROMIS domains in clinical research and care settings.
- Studies that ultimately contribute robust clinical evidence necessary to ‘qualify’ PROMIS pediatric banks for use in industry trials.
• Development of new domains that extend the measurement science of PROs (e.g., environmental stressors/exposures) that fit the PROMIS domain framework and can be initially developed adhering to PROMIS standards.
• Studies testing the items and item banks in different racial, ethnic and underrepresented groups with chronic diseases to demonstrate their clinical validity. Such testing could also include conducting cognitive interviews and patient-centered focus groups to ensure PROMIS domains accurately capture the patient experience in those groups.
• Studies that aim to optimize mode of administration of PROMIS measures to age appropriate or special populations.
• Studies that develop instruments that assess cPROs in early childhood (birth to 5 years) that complement existing PROMIS pediatric banks.
• Projects that develop cPRO instruments that measure psycho-social exposures that impact health.
• Studies that include pediatric patients with multiple chronic diseases.

**LIMIT ON NUMBER OF PROPOSALS PER ORGANIZATION**
Only one application per institution is allowed.

**KEY DATES**
If you are interested in this funding opportunity, please send a one-page summary of the proposed research and your biosketch to Eric Boberg (e-boberg@northwestern.edu) by March 27, 2015.

The sponsor application due date is June 2, 2015, by 5:00 PM.

**COLLABORATION OPPORTUNITIES**
The Office of Research Development offers assistance in identifying and facilitating collaborations, putting together interdisciplinary teams, programmatic and administrative development of large, cross-school proposals, and leveraging institutional resources for outreach and education. Contact Fruma Yehiely (yehiely@northwestern.edu), Director of ORD, for more information.

**CONTACT AND ADDITIONAL INFORMATION**
Fruma Yehiely, Director of ORD, 847-491-1074, yehiely@northwestern.edu
Limited Submissions web site: [http://www.research.northwestern.edu/ord/funding/limited-submissions/](http://www.research.northwestern.edu/ord/funding/limited-submissions/)