

Clinical Research Support Core Subawards – October 2023

Background: In collaboration with the Network Steering Committees and NIH program staff, the Clinical Research Support Core will develop and implement a versatile subawards' administration platform that will permit evaluation, management, unbiased prioritization, and tracking of subawards. Subawards will be funded to support local site coordination or data submission (if not supported through an NIH U01 award or Administrative Supplement), to confirm a diagnosis with metabolomics or gene function studies, and to obtain pilot data to facilitate future, larger research studies. There will be \$50-\$100,000 direct costs available per subaward (average \$50,000/subaward) with the potential of larger allocations if approved by the Steering Committee. All subawards must be completed within the grant year of submission (04/01-03/31), will be of 12 months' duration (year 1 will include one-time 6 month subawards), and principal investigators must have all invoices submitted by 03/01 of the grant year. The start date for the one-time 6 month subawards in year 1 will be 09/01/2023 to permit final invoices to be submitted by 02/29/2024. No carry over funding will be permitted. The Subawards Review Committee will consider a limited number of phased applications each year with milestones that will determine funding for subsequent phases and may extend beyond 1 year.

Standing Subaward Review Committee (SRC):

- 1) Permanent members with expertise in Clinical Site coordination/operations, clinical genetics, metabolomics, model organisms, bioinformatics, data submission to the Gateway, genomics, NIH program staff, and ad hoc members with expertise required for consideration of specific subawards
 - a. Permanent members: F. Sessions Cole (Chair), Herman Taylor, Rachel Mahoney, Meghan Halley, Shinya Yamamoto, Matt Might, Sarah Marshall, John Mulvihill, Stephanie Tomlinson, May Malicdan, Summer Thyme, Lindsay Burrage, Julian Martinez, Laura Mamounas (ex officio)
 - b. Ad hoc members invited based on topics of submitted subawards
- 2) SRC members must complete the [Confidentiality and Conflicts of Interest Agreement](#) before each review. This agreement includes guidelines about disclosing and reviewing conflicts of interest as well as situations where members cannot be part of the review process.

Subaward submission dates and format:

- 1) Subaward recipients must be an X01 or U01 funded or Affiliate Site PD/PI and/or collaborating directly with an X01 or U01 funded or Affiliate Site.
- 2) Distributed funding across Sites and project areas will be taken into consideration. Sites should consider only submitting 1-2 proposals and making proposal prioritization known to the SRC.
- 3) Subawards will not support more advanced research proposals (e.g., characterizing a gene or genomic variant already known to cause the participant's disease) since these types of proposals can be submitted to the NIH using standard grant mechanisms and will not support projects funded through U01 or Administrative Supplements.
- 4) In year 1 (04/01/2023-03/31/2024), the subaward submission date will be 10/01/2023, and will be 6 month awards that will start on 09/01/2023 and end on 02/29/2024. The total subaward budget available in year 1 is \$500,000.
- 5) In years 2-4, subaward submission dates will be February 1 and will be 12-month awards.
- 6) Brief summaries (~1/2 page) that describe achieved vs. planned project progress and assurance that funds will be spent by the end of the grant year will be required at 6-month intervals for all awards (at 3 months for year 1 subawards); summary reports will be required at the completion of all subawards; no cost extensions will not be permitted.
- 7) Format of subawards:
 - a. Clinical Site operations and data submission
 - i. Plan (total 2 pages): overview of current plans for and progress of site-led efforts to increase efficiency of applicant evaluation, throughput, and follow up and/or to increase diversity of UDN applicants and participants; Scope of Work; description of how activities/personnel funded as part of the subaward proposal contribute to existing or new activities but are not

fully financially supported by other means (e.g., U01 grants, administrative supplements, institutional support)

- b. Gene function studies and other research
 - i. Research plan (total 5 pages): Title, PI/Program Director, key personnel, Specific Aims, Research Strategy, Scope of Work and Deliverables and Milestones
 - ii. For studies that propose use of model organisms, subaward applications should provide evidence of variant pathogenicity and include a bioinformatics review by the Model Organism Screening Core that supports the application.
 - iii. For applications that propose use of other strategies for functional confirmation, availability of relevant resources (e.g., primary cells or cell lines, proposed metabolomics signature or environmental exposure) should be provided.
- c. Additional materials required for subaward applications: Detailed Budget, Budget Justification, Performance Location Sites, Resource and Data Sharing Plan (if applicable), NIH Biosketches and Other Support for all key personnel, IACUC approval (if applicable), IRB approval (if applicable), documentation of executed material transfer agreements and financial subcontracts required for the proposed project (if applicable)
 - i. Starting in year 2, the Subawards Review Committee will be willing to consider a limited number of 2 year phased applications. Continuation of phased funding will be contingent on achieving initial milestones and can extend no longer than 2 grant years.