

UDN DUCAS Clinical Research Support Core Subawards Guidelines – February 2024

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In collaboration with the Network Steering Committee and NIH program staff, the DMCC's Clinical Research Support Core (CRSC) at WUSTL uses a versatile Subawards' administration platform (REDCap) that permits evaluation, management, unbiased prioritization, and tracking of Subawards. Subawards will be funded to support:

1. Local site coordination or data submission (if not supported through an NIH U01 award or Administrative Supplement).
2. Pilot research projects such as gene function studies in model systems or clinical genomics/metabolomics investigations that are needed to facilitate or confirm the diagnosis of UDN participants (or group of participants if investigating the same candidate gene or disease mechanism) identified in the application;
 - a. Pilot research funds, typically not more than \$50K total costs per project, are intended to investigate specific, undiagnosed UDN participants who must be identified and confirmed to be undiagnosed in the Subaward application; more advanced research proposals (e.g., characterizing a gene or genomic variant already known to cause the participant's disease) should be submitted to the NIH using standard grant mechanisms; projects focused on developing or improving a genomics or diagnostic assay are also out of scope.
 - b. DNA/RNA sequencing and other diagnostic investigations will not be supported if reimbursable through insurance billing or covered by an NIH U01 award, NIH administrative supplement or private/institutional sources of support;
 - c. Pilot data about undiagnosed UDN participants may be used to facilitate future, larger research studies (e.g., by submitting an NIH grant application); future research plans, if the project is successful, must be described in the subaward application.

All Subaward applications that include studies in model organisms or cell cultures must include a review by the UDN's Model Organism Screening Center (MOSC), which can only be secured by submission of a summary of the Subaward proposal to the MOSC no later than January 1 (MOSC review criteria and Subaward summary template available in the REDCap application).

Key Dates

Call for Subawards posted: December 1, 2023

MOSC Summary for QC review for gene function and cell culture proposals: January 1, 2024

Proposal due: February 1, 2024 (REDCap link: <https://redcap.wustl.edu/redcap/surveys/?s=7MDDDKA4DNRP3XLJ>)

Awards announced: March 1, 2024

Earliest start date: April 1, 2024

Project period: April 1, 2024-March 31, 2025

Budget

Budgets are limited to a maximum of \$100,000 total cost (includes direct and indirect costs) per Subaward (average \$50,000/subaward) with the potential of larger allocations if approved by the Network Steering Committee. All Subawards must be completed within the grant year (04/01-03/31), must be of 12 months' duration, and principal investigators must have all invoices submitted by 04/15 (15 days after the end of the grant year). **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 for 2 years. For example, if a Subaward proposal requires adaptation of an available model organism or cell culture platform, the applicant may apply for a second year of support contingent upon achievement of the year 1 goals. No phased applications of greater than 2 years' duration will be considered, and no carry forward funding will be permitted between years 1 and 2 of a phased Subaward.

Application Information

- The PIs of the Subaward must include the X01 or U01 funded or Affiliate Site PD/PI as the contact PI and must be collaborating directly with the X01 or U01 funded or Affiliate Site PD/PI.
- After evaluating the scientific/technical merit of subaward applications, additional funding considerations include distributing resources equitably across Sites and balancing research or project areas. Individual sites should consider submitting no more than 1-2 proposals/site (e.g., if studying more than one candidate gene or disease pathway/mechanism) and making proposal prioritization known to the CRSC.
- 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. Projects focused on developing or improving a genomics or diagnostic assay are out of scope.
- Priority will be given to those applications that follow the requirements listed.
- UDN participant ID numbers and confirmation of each UDN participant's undiagnosed status should be provided for all research proposals in a table in the Research Plan.
- Categories of Subaward applications:
 - Clinical Coordination/Data Submission (if not already supported by an NIH U01 award, NIH administrative supplement or through private/institutional resources): support for site operations that will improve clinical evaluation efficiency, increase recruitment of UDN participants from populations that experience health disparities, or ensure adequate UDN participant data submission via the Gateway.
 - Confirm Diagnosis: support model organism, sequencing analysis, pathogenicity prediction, or metabolomics and/or cell culture studies needed to confirm the diagnoses of specific UDN participants.
 - Obtain Pilot Data/Gene Function studies: support studies of specific, undiagnosed UDN participants to obtain pilot data for future grant application (future grant mechanism must be provided in the application).
 - All Subaward applications that include studies in model organisms or cell cultures must include a review by the UDN's Model Organism Screening Center (MOSC), which can only be secured by submission of a summary of the Subaward proposal to the MOSC no later than January 1 (MOSC review criteria and Subaward summary template available in the REDCap application).
- Scientific progress reports will include 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. They will be required at 6-month intervals for all awards; summary reports will be required at the completion of all subawards; no cost extensions will **not** be permitted. Phased Subaward applications will be required to submit scientific progress reports that will determine continuation of funding for year 2 of the Subaward.

Standing Subaward Review Committee (SRC)

- The Subaward Review process will include scientific critiques by 2-3 SRC members with expertise in the area of the application and administrative review to ensure responsiveness of the proposal to the Subaward guidelines.
- 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.
 - 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)
 - Ad hoc members invited based on topics of submitted subawards.
- 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.