

UDN DUCAS Clinical Research Support Core Subawards Guidelines

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Updated February 27, 2026 (added REDCap link)

Link to REDCap application:

<https://redcap.wustl.edu/redcap/surveys/?s=7MDDDKA4DNRP3XLJ>

Overview

In collaboration with the Network Steering Committee and NIH program staff, the UDN Data Management Coordinating Center's (DMCC's) Clinical Research Support Core (CRSC) at Washington University in St. Louis (WashU) will continue to use a REDCap-based Subaward administration platform that permits evaluation, management, unbiased prioritization, and tracking of Subawards. **To be eligible for Subaward funding, X01 and U01 Sites must be actively recruiting UDN participants and meeting their enrollment goals.** Most awards will be capped at \$50K **direct** costs (see Budget section). Local site coordination or data submission applications may require less based on number of participants enrolling. Funding limits will be contingent upon the availability of funds and will be specified at the time proposals are solicited. Subawards will be funded to support:

- *Local site coordination to support data submission* (if not supported through an NIH U01 award or Administrative Supplement). **REDCap category:** Local site coordination or data submission projects.
- *Pilot research proposals investigating **undiagnosed** UDN participants* that may facilitate future, larger research studies or provide targeted research needed to confirm the diagnosis of specific UDN participants (or group of participants if investigating the same candidate gene or disease mechanism) such as gene function studies in model systems or clinical genomics, metabolomics, or immunologic investigations. UDN participants being studied must be identified and confirmed to be undiagnosed in the Subaward application. **REDCap category:** Pilot proposal investigating undiagnosed UDN participants.
- *Pilot projects focused on strategies that study **exposome factors, immunologic signatures, or AI-based diagnoses***. Proposals should develop/refine strategies that use available databases, methods, and resources for identification and diagnosis of UDN participant cohorts with undiagnosed rare phenotypes (UDN participants being studied must be identified in the application, including the participant's diagnostic status and UDN identifying number). **REDCap categories:** Pilot project Exposome (previous Environmental Triggers), Pilot project Immune signatures, Pilot project A.I. based.

More advanced research proposals (e.g., characterizing a gene or genomic variant already known to cause the participant's disease) are out of scope and 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.

Due Dates

Notice of funding opportunity announcements for Subawards will be posted by **February 13, 2026**.

Applications must be submitted through the CRSC REDCap portal at WashU by **March 31, 2026** at 5:00 PM CST.

Request for MOSC approval for model organisms or cell culture studies must be submitted to the MOSC by **March 2, 2026**.

Budget

Budgets are limited to a maximum of \$50,000 direct cost per Subaward unless there is strong justification for a larger award and it is approved by the Network Steering Committee. Awarded budgets will be specified at notice of award. All Subawards must be completed within the grant year (06/01/2026 - 03/31/2027), must be of 10 months' duration, and principal investigators must have invoices submitted as requested, and completed by 04/15/2027 (15 days after the end of the grant year). No carryover 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 and funding information

- The PIs of the Subaward **must include** the X01 or U01 site PD/PI as the contact PI and must be collaborating directly with the X01 or U01 site PD/PI. Sites may submit more than one application for this opportunity for distinct aims, and site PD/Pis must be included on all applications.
- To be eligible for Subaward funding, X01 and U01 Sites **must** be actively recruiting UDN participants and meeting their enrollment goals.
- 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, private/institutional sources of support, or the DMCC supported sequencing core.
- Funding for any Subawards extended to two years will be contingent upon achieving projected milestones, summarized in a one-page report for CRSC and reviewer evaluation.
- 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 may submit more than one proposal when scientifically justified (e.g., if studying more than one candidate gene or disease pathway/mechanism) and making proposal prioritization known to the CRSC;

however, with limited CRSC funds, we recommend that applicants submit no more than 1–2 per site.

- **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 already funded through U01 or Administrative Supplements. Projects focused on developing or improving a genomics or diagnostic assay are out of scope.
- Pilot data proposals 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.**
- 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 X01 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 metabolomic, immunologic and/or cell culture studies needed to confirm the diagnoses of specific UDN participants (if not already supported by an NIH U01 award, NIH administrative supplement or through private/institutional resources) or obtain pilot data for future grant application (future grant mechanism must be provide 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 March 2, 2026** (MOSC review criteria and Subaward summary template available in the REDCap application).
 - Pilot projects focused on strategies that study exposome factors, immunologic signatures, or AI-based diagnoses that explain the phenotypes of undiagnosed UDN participants. UDN participants being studied must be identified in the 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 **5-month** intervals for all awards; summary reports will be required at the completion of all Subawards; there will be **NO** cost extensions permitted. Phased Subaward applications will be required to submit scientific progress reports that will determine continuation of funding for year 2 of the Subaward.

Contract Information

- WashU has the right to terminate the agreement at any time if the prime funding source becomes unavailable. If such an event occurs, reimbursement for costs incurred will not be provided unless Washington University receives reimbursement from the DMCC at Harvard for such costs.

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 will encompass expertise in Clinical Site coordination/operations, clinical genetics, metabolomics, model organisms, bioinformatics, data submission to the Gateway, genomics, environmental triggers, immunologic causes, and AI-based diagnoses. They will include representatives from the DMCC, the Model Organism Screening Centers, the Sequencing Cores, the Metabolomics Core, NIH program staff, the UDNF, and Chair of the CRSC.
 - Ad hoc members with expertise required for consideration of specific 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.

UDN DUCAS Clinical Research Support Core Subaward Instructions

Updated January 2026

Instructions for Application Submission

Required for all submissions

- The UDN site PI must be listed as the Contact PI for each Subaward.
- Provide the name and email of your departmental pre- and post-grant administrator to be included on correspondence or address questions.
- Budget
 - The role of the Contact PI (UDN site PI) and her/his effort as contact PI must be included on the detailed budget and budget justification. If no effort is requested, explanation of the Contact PI role must be included in the budget justification.
 - Direct costs, indirect costs, and total cost details should be provided in both the summary section of the application (Project Budget) and on the detailed budget attachment form.
 - Budget details, summary, and budget justification must contain the same information.
 - Budgets will be announced at the time proposals are solicited. Budgets have been limited to a max of \$50,000 direct costs per Subaward unless there is strong justification for a larger award and approved by the Steering Committee. The exact

amount will be dependent on funding and identified at the time proposals are solicited.

- A limited number of 2-year-phased applications will be considered. Continuation of phased funding will be contingent on achieving initial milestones and can extend no longer than 2 grant years.
 - Detailed budget and budget justification pages are required for each year separately.
- NIH biosketch and other support documents are required for all key personnel (even if no effort is requested) including the Contact/UDN site PI.
- Scope of work instructions and template are provided in the REDCap application. Requirements include deliverables and milestones.
- IACUC approval, IRB approval, documentation of executed material transfer agreements and financial subcontracts that are required for the proposed project must be included, if applicable.
- Resource and Data Sharing Plans should be included for data submission applications.
- 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 March 2, 2026 (MOSC review criteria and Subaward summary template available in the REDCap application).

Clinical Coordination/Data Submission

- Specific Aims and Research Plan (total 3 pages).
 - Specific Aims should also be provided in the REDCap application
- 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.
- Include a description of how activities/personnel funding requests, as part of the Subaward proposal, will contribute to new activities that are not financially supported by other means (e.g., U01 grants, administrative supplements, institutional support).

Confirm Diagnosis/Obtain Pilot Data/Gene Function studies

- Specific Aims and Research Plan (total 6 pages).
 - Specific Aims should also be provided in the REDCap application.
- Subaward applications must include table with UDN participant ID numbers and confirmation of unsolved status as a table in the Research Plan.
- Subaward applications that propose use of model organisms or other strategies for functional confirmation should provide evidence of variant pathogenicity and include a bioinformatics review by the Model Organism Screening Core that supports the application.
- Include a description of how research/personnel funding requests, as part of the Subaward proposal, will contribute to new activities that are not financially supported by other means (e.g., U01 grants, administrative supplements, institutional support).
- 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) should be provided.

Exposome factors, immunologic signatures, or AI-based diagnoses pilot project

- Specific Aims and Research Plan (total 6 pages)
 - Specific Aims should also be provided in the REDCap application
- Subaward applications must include table with UDN participant ID numbers and confirmation of UDN participant diagnostic status as a table in the Research Plan
- Subaward applications are strongly encouraged to identify the environmental, immunologic, or AI scientists who will collaborate with UDN Site PI and Site members.