NIDDK Central Repository (NIDDK-CR) – Resources for Research (R4R)

Resource Archival and Sharing Plan Worksheet

NIDDK-CR Policy (NOT-DK-24-003) requires that "*projects eligible and planning or required to submit resources to NIDDK-CR must develop and submit a written Resource Archival and Sharing Plan (RASP).*" RASPs must be on a study protocol level and must be submitted to NIDDK-CR for review in advance of study startup (screening/enrolling participants) to obtain approval to deposit study-generated resources into NIDDK-CR. Before RASPs can be submitted to NIDDK-CR for review, these must be cleared by the designated NIDDK Program Staff (Project Scientist and Program Officer) and the project's steering committee. RASPs must be aligned to approved Data Management and Sharing (DMS) plans as applicable.

This worksheet is intended to help project teams in drafting a RASP. Project teams should review NIDDK-CR guidance for submitters before drafting their RASPs. NIDDK-CR recognizes the differences in clinical study designs and that not all projects will have the same information. In general, RASPs should include the following:

A. Study Metadata: Study Protocol Name, Acronym, Consortia/Network Name, grant number, overall lead PI, SDCC PI, Steering Committee Chair, NIDDK Project Scientist/Program Officer, Period of Performance Dates, Project Dates, including estimated date of enrollment, study design.
B. Project Background: Describe the project (main study and any proposed sub-studies), primary and secondary aims, target population, and types of resources being collected.
    1. Provide detailed information for all resource types being collected or generated and describe who will be responsible for managing and performing quality checks, e.g., data coordinating unit.
C. Approach for Transfer of Resources: Describe what resources will be transferred, when they will be transferred, transfer intervals if not all at one time, and how long after submission resources should be made public.
    1. Provide a proposed timeline (estimated dates) for submission to NIDDK-CR in accordance with project design and relevant milestones (primary outcome, secondary outcome, exploratory outcomes) for the different types of resources being generated. If specimens are being collected, include the proposed archival set for each specimen type, the proposed quantity (number of aliquots), and the proposed aliquot volume(s).
    2. Include proposed timelines for opening study-generated resources to the public, aligning with NIDDK-CR policy guidelines and approved DMS plan.
    3. Clearly define terms of use in accordance with the participant's informed consent.
    4. Provide a justification for the proposed approach.
D. Acknowledgments: Provide an example of how the originating study should be acknowledged in public releases. Refer to NIDDK-CR example acknowledgments.
E. Upload to the Resources for Research (R4R) the following documents:
    1. Protocol.
    2. Any data/specimen related Manual of Operations (MOP).
    3. A copy of the proposed specimen labeling. Refer to NIDDK-CR labeling guidance.
    4. Participant informed consent template, ideally before submitting to Institutional Review Board (IRB). IRB-approved versions will be required after NIDDK-CR grants approval to deposit resources.
    5. A list of existing Common Data Elements (CDE) that will be utilized in the project.