NIDDK Central Repository (NIDDK-CR)

Resource Archival and Sharing 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 Request"* proposal to onboard a study*.* This proposal 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 a Resource Archival and Sharing Request 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. The Resource Archival and Sharing Request must be aligned to approved Data Management and Sharing (DMS) plans as applicable.

This worksheet serves as a practical tool for project teams, aiding them in the process of drafting a Request proposal to onboard a study protocol. It is recommended that project teams familiarize themselves with NIDDK-CR guidance for submitters before commencing their request proposals. NIDDK-CR acknowledges the diversity in clinical study designs and the varying information each project may have. However, in general, a request to onboard a protocol should include the following:

A. **Study Metadata**: NIDDK-CR requires that basic study and contact information (who, what, where, when, and how) be provided for each protocol being onboarded to help NIDDK-CR verify and properly manage the study-generated resources over time and for potential future users to find them. In addition, information on who will be responsible for managing and performing quality checks for all resources collected or generated must be provided before resources can be approved for submission.

B. **Study Description**: NIDDK-CR displays basic study information for each protocol (main study and any proposed sub-studies), including primary and secondary aims on the Resources for Research (R4R) website to make the community aware of the research being conducted by NIDDK and to encourage potential collaboration with parent projects via ancillary study or other mechanisms.

C. **Approach for Transfer of Resources**: NIDDK-CR requires that a transfer approach be developed and uploaded or directly entered into the R4R web platform describing what, when, and how resources collected or generated will be transferred and made publicly available to maintain compliance with NIH sharing policies and for NIDDK-CR to forecast services and support requirements long term.

D. **Acknowledgements**: For studies with more than one funder, NIDDK-CR recommends submitters provide an example of how the study should be acknowledged in public releases. Studies funded by NIDDK as the sole sponsor should use NIDDK-CR standard acknowledgment statement (https://repository.niddk.nih.gov/pages/acknowledgements/).

E. **Appendices**: Upload to the R4R web platform the following documents:
   1. Protocol.
   2. Any data or specimen related Manual of Operations.
   3. A copy of the proposed specimen labeling. Refer to NIDDK-CR labeling guidance.
   4. A copy of the participant informed consent template, ideally before submitting to the Institutional Review Board (IRB) or ethics review committee. IRB-approved versions will be required after NIDDK-CR grants approval to deposit resources.