



Submitting Resources to the

NIDDK Central Repository

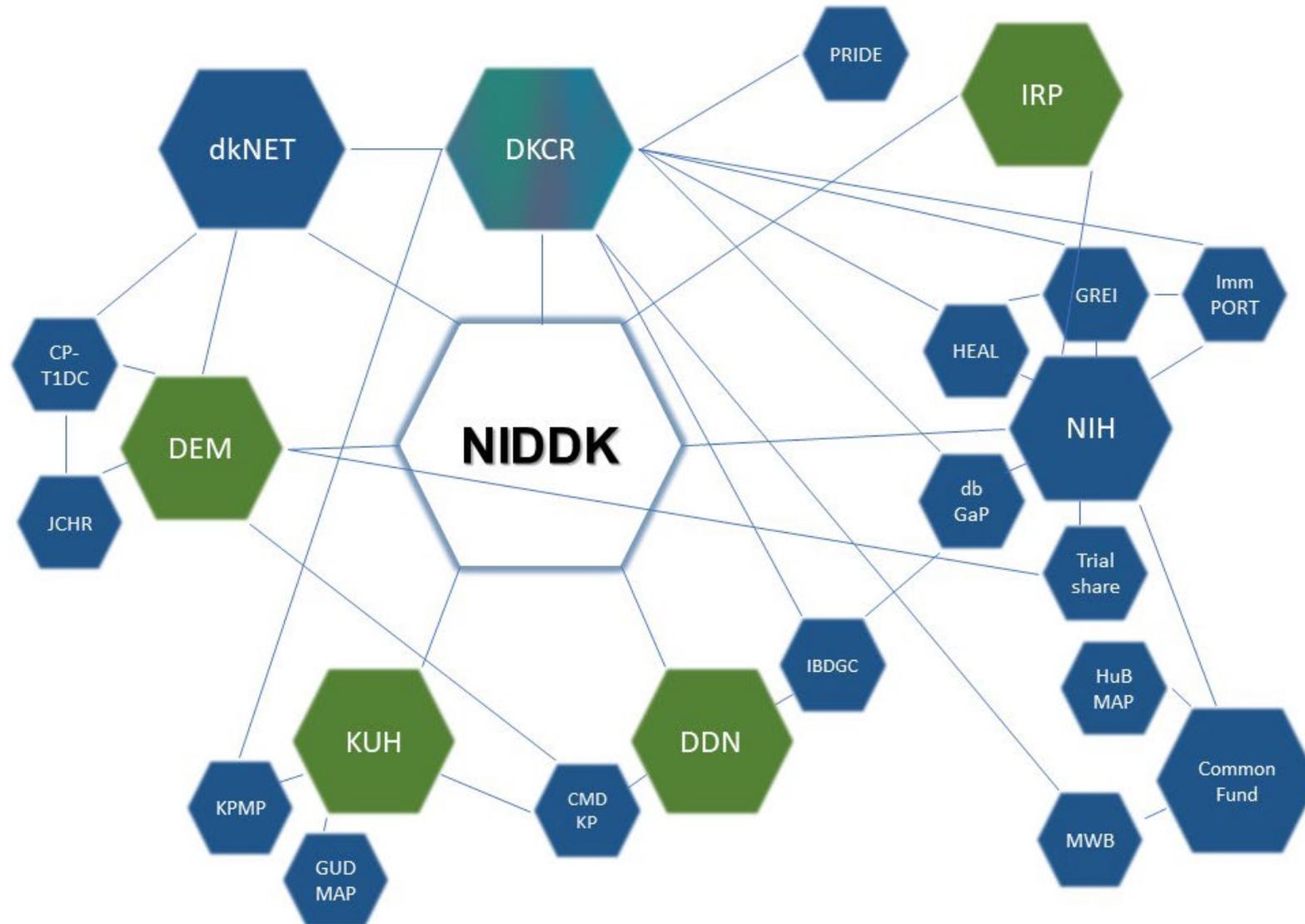
May 31, 2023



NIDDK Central Repository

Supporting the NIDDK scientific and research community

NIDDK Data Sharing Ecosystem



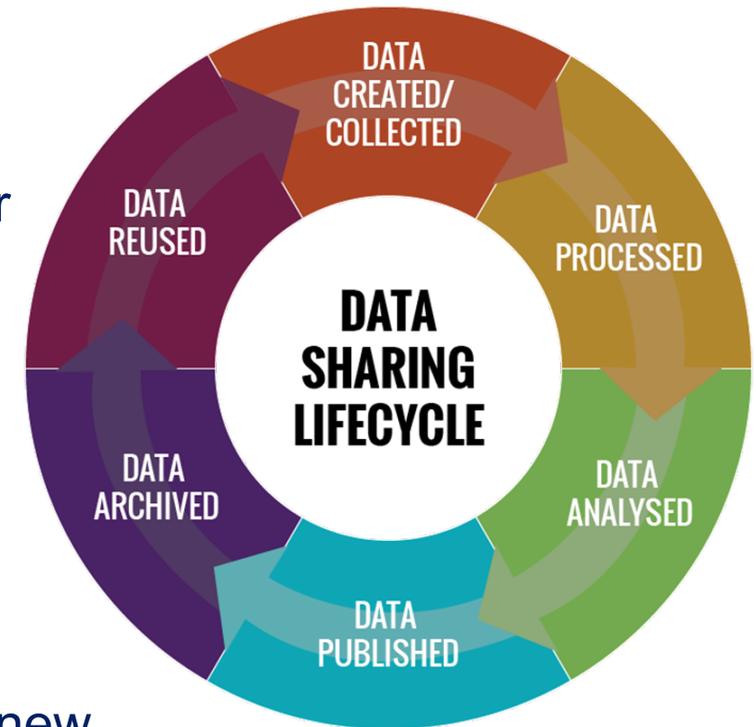
NIDDK Central Repository Overview

Our mission

Expand the usefulness of extramurally NIDDK-funded multi-center clinical studies' generated resources* by providing access to a wider research community beyond the end of the study

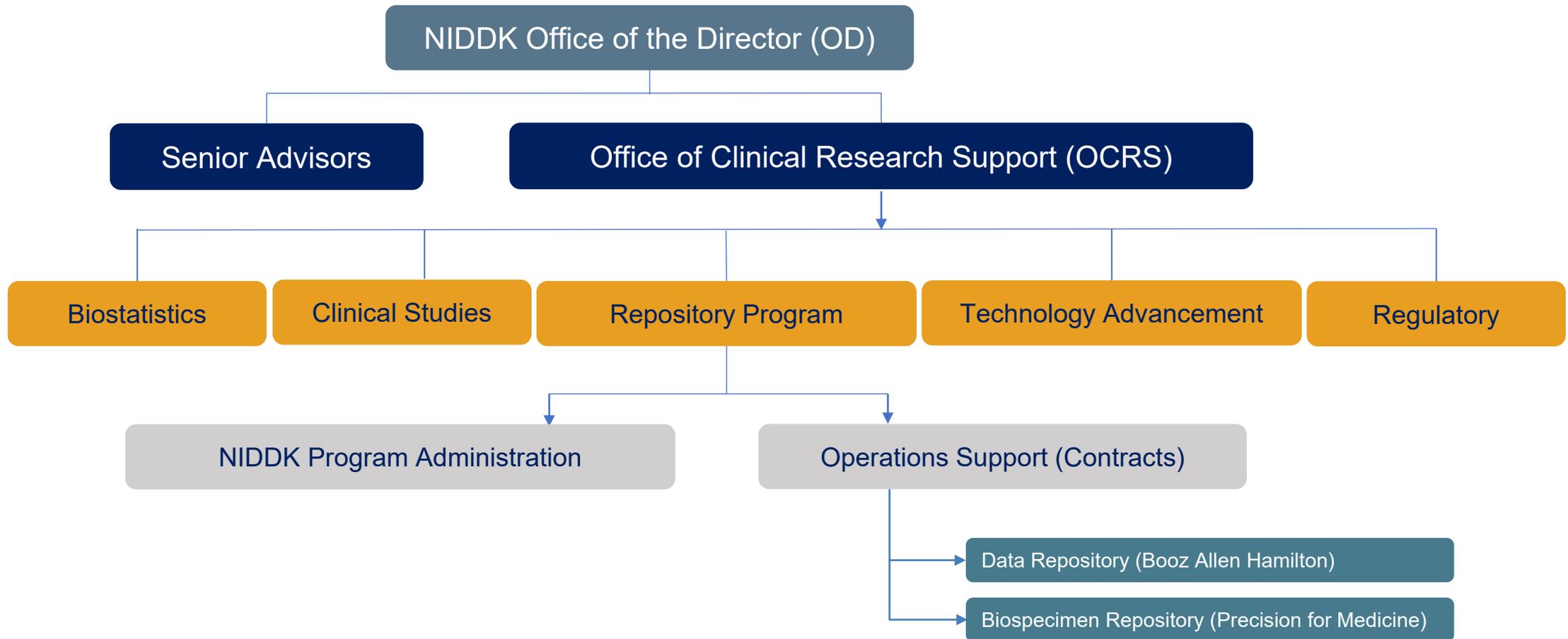
What we do?

- Support receipt and distribution of data and biospecimens in a manner that is ethical and equitable
- Enable investigators not involved with the original work to test new hypotheses without the need to collect new data and biospecimens



*also includes selected non-NIDDK funded studies within the mission research areas of significant benefit to the scientific community

NIDDK Central Repository Organizational Structure



NIDDK Central Repository Stats

Overview by the numbers

International resource directly supporting extramurally NIDDK-funded active & concluded studies providing access to

High impact interventional and observational collections from NIDDK supported clinical research with

- High quality, quantitative and qualitative clinical phenotype data including imaging and reference panels
 - Well maintained, wide range of human derived material including macromolecules, blood derivatives, cell/cell lines, tissue, urine, stool
- ✓ 5,430 registered users from around the globe
 - ✓ 95% approval rating for external resource requests



NIDDK Central Repository

Supporting NIDDK research and scientific community

Collections available



142 data
98 specimen

Requests for resources



928 data
2737 specimen

Public releases



230 reported

NIDDK Central Repository FAIR Sharing

FAIR sharing and TRUST worthiness

FAIR Principles	Areas of Concentration	Activity Accomplished	Impact
FINDABLE	<ul style="list-style-type: none"> Enable users to discover and refer to data in a consistent way Ensure that archiving takes place from ingestion to dissemination according to defined workflows 	<ul style="list-style-type: none"> Developed and published unique digital object identifiers (DOIs) through DataCite 	<ul style="list-style-type: none"> Unique and persistent identifiers increases data findability and reusability
ACCESSIBLE	<ul style="list-style-type: none"> Demonstrate the integrity and authenticity of data during ingestion, archival storage, and data access processes Retain appropriate expertise to address technical data and metadata quality Accept data and metadata based on defined criteria to ensure relevance and understandability for data users and ensure maintainability 	<ul style="list-style-type: none"> Enriched data and specimen descriptions Mapped and exposed studies' metadata through external catalogs 	<ul style="list-style-type: none"> Enables requestors to accurately identify data and specimens for their research needs broadening exposure and accessibility
INTEROPERABLE	<ul style="list-style-type: none"> Demonstrate data reusability and interoperability with other platforms Develop a plan or demonstrate current use of standard metadata 	<ul style="list-style-type: none"> Designed variable mapping to standard terminology Partnered with interagency DOI servicer and generalist repositories 	<ul style="list-style-type: none"> Facilitates meta-analyses across studies through standardized annotation supporting interoperability
REUSABLE	<ul style="list-style-type: none"> Demonstrate how the repository will allow the reuse of data over time Maintain all applicable licenses covering data access and use and continue to monitor compliance Establish a continuity plan that ensures ongoing access to and preservation of data holdings Implement documented processes/procedures in managing archival data storage Develop methods for long-term preservation and management 	<ul style="list-style-type: none"> Implemented data package versioning Updated and reorganized documentation Harmonized specimen inventory data and metadata attributes 	<ul style="list-style-type: none"> Increases meaningful reuse of data and specimens by the research community

NIDDK Central Repository TRUST worthiness

FAIR sharing and TRUST worthiness

TRUST Principles	Areas of Concentration	Activity Accomplished	Impact
TRANSPARENCY	<ul style="list-style-type: none"> • Enable users to discover the data and refer to them in a consistent way through proper citation • Retain competent staff with expertise in data archiving to effectively carry out the repository's mission 	<ul style="list-style-type: none"> • Standardized repository citation guidance • Consolidated platform documentation 	<ul style="list-style-type: none"> • Improves access to resources, policies, and procedures and citation promoting transparency
RESPONSIBILITY	<ul style="list-style-type: none"> • Ensure integrity and authenticity of the data • Require data to be curated, accessed, and used within disciplinary and ethical norms 	<ul style="list-style-type: none"> • Improved technical data and metadata quality 	<ul style="list-style-type: none"> • Ensures consistency within and across collections upholding ethical standards and confidence in resources over time
USER FOCUS	<ul style="list-style-type: none"> • Accept data and metadata based on defined criteria to ensure that the data remains relevant and understandable to the scientific research community 	<ul style="list-style-type: none"> • Enforced uniform data and specimen intake guidelines and templates 	<ul style="list-style-type: none"> • Streamlines access and promotes resource reutilization increasing visibility and impact of resources
SUSTAINABILITY	<ul style="list-style-type: none"> • Ensure long-term preservation and maintain preservation documentation • Follow documented processes and procedures in managing archival storage of the data 	<ul style="list-style-type: none"> • Developed and published new Data Preservation and Access Practices 	<ul style="list-style-type: none"> • Strengthens stakeholder engagement
TECHNOLOGY	<ul style="list-style-type: none"> • Operate on reliable and stable core infrastructure that will maximize service availability • Maintain a system that will analyze potential threats, assess risks, and create a consistent security system 	<ul style="list-style-type: none"> • Implemented hash data validation scanning • Employed external links validation • Released improved business logic-based integrity validation 	<ul style="list-style-type: none"> • Increases data quality and improves data citation accuracy

NIDDK Central Repository Features and Services

Submit and request access to resources through **Resources for Research (R4R)** platform

Features

- Domain-specific repository
- Sustainable support model
- Cloud-based environment
- Controlled-access resources
- Common format data file types
- Data package version control
- Unique persistent identifiers (DOI)

Services

- Assist with project planning before data are collected
- Provide support during life of the project (selected studies)
- Acquire, curate, maintain, and distribute resources



NIDDK Central Repository Sharing Policy and Practices

Sharing policy encourages **timely analyses** by study investigators, and increases likelihood of **secondary research** while resources are still relevant

Intent of the policy:

- Increase impact and scientific value, and maximize investigators and participant contributions
- Balance the interests of the study investigators with those of the larger scientific community by defining and setting limits to proprietary periods

[2013 NIDDK-CR Sharing Policy](#)

NIDDK-CR Sharing and Usage Policy is being revised to align with NIH DMS policy and NIDDK DMS Guidance



NIDDK Central Repository Usage Eligibility

*Who is **eligible to deposit** at the NIDDK-CR?

1. NIDDK extramurally supported clinical studies with significant NIDDK programmatic involvement
 - Including but not limited to clinical trials, prevention and control trials, and epidemiological studies
2. Other NIDDK supported clinical studies
 - Including but not limited to ancillary studies to NIDDK supported studies eligible to deposit
3. Secondary research resulting from the use of NIDDK-CR resources
4. Non-NIDDK funded clinical studies within NIDDK research mission of significant benefit to the scientific community



NIDDK Central Repository Usage Requirements

Eligible studies interested in sharing through NIDDK-CR must comply with submission requirements

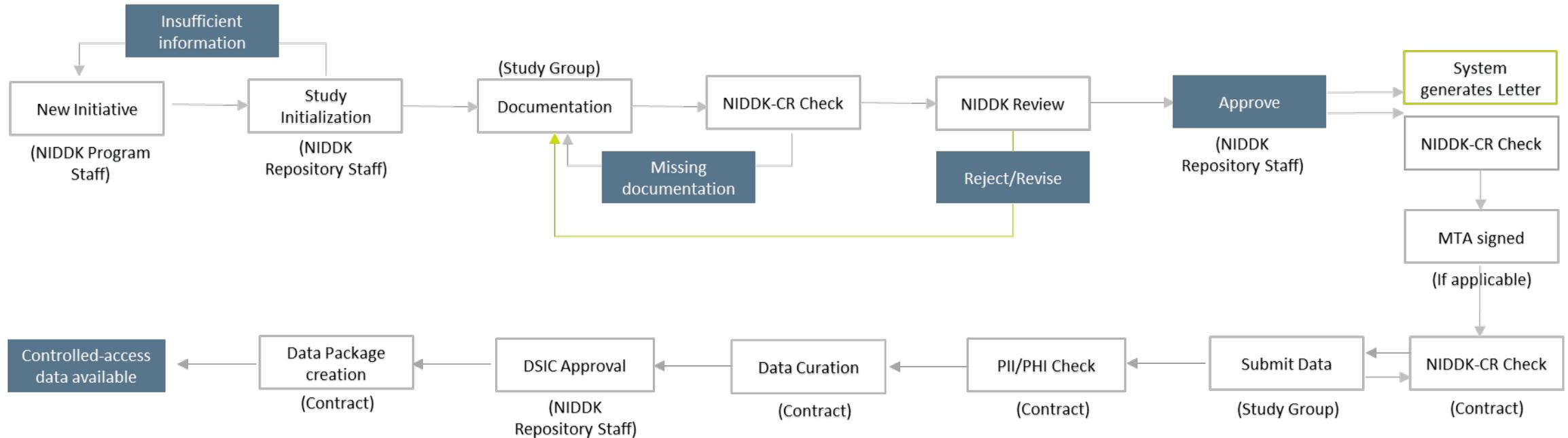
- Data and biospecimen sharing plans must be approved before first participant enrolled
- Informed consent language must address future research use and be submitted for clearance
- Deposit all data/metadata and a representative specimen archival set (as applicable) at the pre-determined timepoints/milestones per study design
- Submit data in Limited Data Set (LDS) format
- Provide required study documentation (e.g., protocol, MOP, codebook, data dictionary, data collection instruments/CRFs) and supplemental information (e.g., list of publications, SAS programs/formats) in

[NIDDK-CR Submission requirements](#)



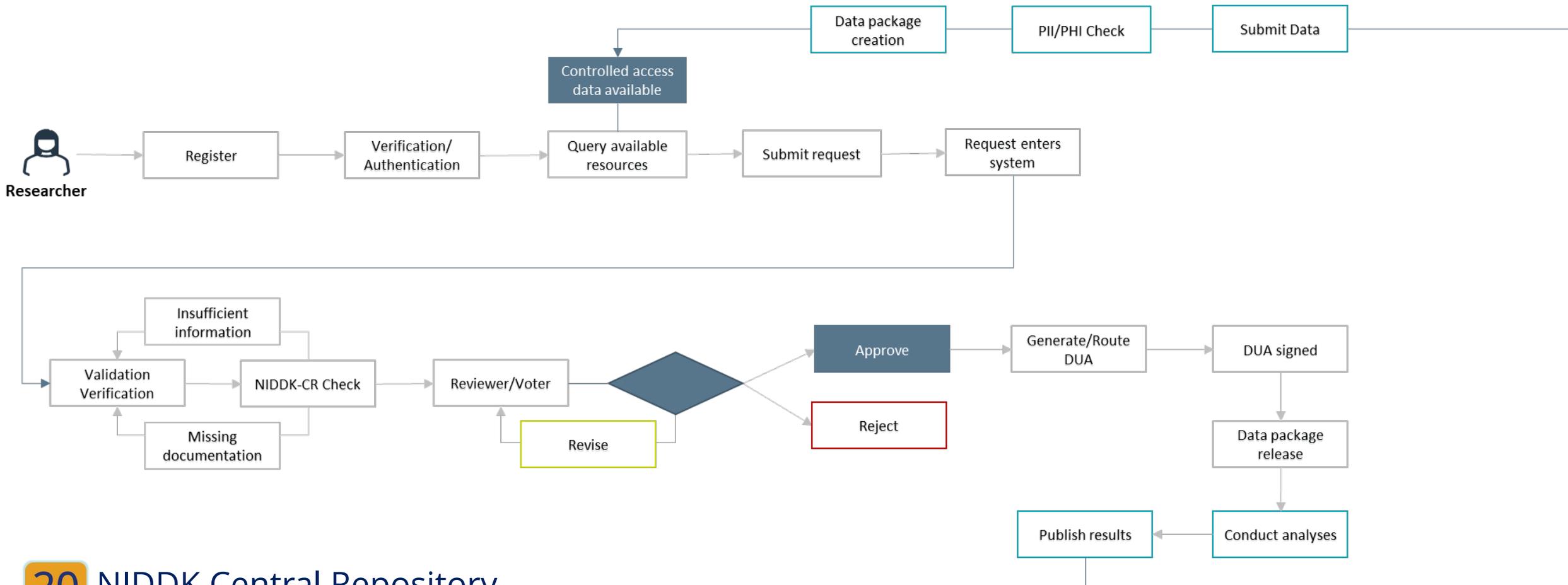
NIDDK Central Repository Submission Workflow

Eligible studies interested in sharing through NIDDK-CR must be approved to deposit



NIDDK Central Repository Request Workflow

Qualified researchers interested in requesting access to NIDDK-CR must be register users



Additional NIDDK Central Repository Support

NIDDK-CR supports studies not eligible to deposit fulfill DMS Policy requirements:

- Catalogue resources shared through other repositories supporting federated sharing
- Federated studies may have dedicated study pages containing study metadata and attributes, study information, and study documentation
 - Provide links for access to resources external to NIDDK-CR
 - Requestors must follow the source repository's policies and procedures to access data stored outside NIDDK-CR
- Encourage use of Common Data Elements (CDEs), clinical standards, ontologies, and terminologies to facilitate interoperability of datasets in other repositories

THANK YOU



For Repository Program Administrative inquiries, email us at NIDDK-CRadmin@niddk.nih.gov

For information on assigning permanent identifiers for your NIDDK-funded research outputs contact us at NIDDKDataCite@niddk.nih.gov

For more information on services and support or to provide feedback visit our website at <https://repository.niddk.nih.gov> or email us at NIDDK-CRsupport@niddk.nih.gov

**NIDDK Central Repository 20th Anniversary Seminar & Workshop:
Promoting Secondary Research to Accelerate Medical
Breakthroughs**
Learn more and register at [NIDDK-CR R4R Workshop](#)