Resource Sharing Plans

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that the results be made readily available for research purposes to qualified individuals within the scientific community.

Reviewer Information

- Reviewers will comment on whether the Resource Sharing Plans listed below, or the rationale for not sharing the following types of resources, are reasonable.
- Unless specified otherwise in the Funding Opportunity Announcement, consideration of these plans should not affect the overall impact score.
- For more information, visit the NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources.

Data Sharing Plan

- A Data Sharing Plan or an explanation of why data sharing is not feasible is expected to be included in all applications where the generation of data is anticipated and direct costs of $500,000 or more in any year of the proposed research is requested.
- Certain Funding Opportunity Announcements may request a data sharing plan for all applications regardless of the amount of direct costs.
- Reviewers should assess the reasonableness of the data sharing plan or the rationale for not sharing research data (see Data Sharing Guidance).

Sharing Model Organisms

- The submission of a model organism sharing plan is NOT subject to a cost threshold of $500,000 or more in direct costs in any one year.
- All NIH grant applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible.
- Reviewers should assess the plan for sharing model organisms or the rationale for why such sharing is restricted or not possible (see Sharing Model Organisms).

Genomic Data Sharing (GDS)

- Applications that involve the generation of large-scale human and/or non-human genomic data are expected to include a Genomic Data Sharing Plan, regardless of the requested costs.
- Reviewers should assess the plan for sharing genomic data or the explanation for why sharing is not possible.
- For more information, including guidance on developing genomic data sharing plans, visit the NIH Genomic Data Sharing (GDS) website.
REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING

In the first 6 months of the project, investigators will develop and publish a comprehensive study methodology manuscript in an open access journal. We will describe in detail the two therapeutic strategies that are tested including the timing of the early access to the CCL protocols and make clear to the scientific medical community the branching decision making points of the early invasive strategy. In our publication we will describe in detail the background and need for a randomized clinical trial, our study population, primary and secondary hypotheses, sources and methods of measuring outcomes, and all covariates used in analyses.

A description of the hybrid consent process using exception from informed consent under emergency circumstances (EFIC) and standard, written informed consent will be also described in a separate publication and the flow of patients during the consent process will be made available for others to replicate or expand the approach to different emergency medical research initiatives. Additionally, our standard operating procedures and methodology will be included as supplemental material, as allowed by the accepting medical journal.

Our prospective randomized study will be registered at www.clinicaltrials.gov to allow public access to the study protocol.

Within 6 months of the end of the final year, we will provide NHLBI/NIH with descriptions of study datasets, codebooks, and programming code used for creating variables and conducting all analyses.

Additionally, the final, cleaned, de-identified study dataset will be available and provided to third party requests for secondary analysis of the data within 1 year following study completion.

All data will be collected on a secure, internet-based database application (REDCap Software Version 5.2.1, Vanderbilt University, Nashville, TN) funded and maintained by the University of Minnesota CTSI that will be housing the DCC. The database for this study will be developed within the REDCap database system by the Principal Investigator, DCC leadership and project manager who have had several years of experience using the database infrastructure. Once the data sheets of the enrolled patients that include characteristics, metrics, diagnoses, laboratory results, clinical exams and outcomes are collected by the study team from each site, all forms will be manually entered into the database for formatting and analysis. Using the REDcap system, we will create a de-identified and cleaned data set, following standard REDcap utilities designed for these functions. The data set will be housed at the University of Minnesota, but will be made freely available to investigators who wish to perform additional analyses or data audits. Requests will be considered by the academic co-investigator group and approved by consensus via in-person meetings, at which minutes will be carefully taken to provide transparency on decision-making and avoidance of conflicts of interest. In addition, the data dictionary will be available for approved requests to assist in the interpretation of the data.

We do not anticipate additional costs of our data-sharing plan
RESOURCE SHARING PLAN

Data sharing plan: Data generated from this study will be shared within the CRIC study group as outlined in the CRIC policy on ancillary studies. Following a proprietary period after publication, data will be made available to the wider scientific community. The timelines for this will follow guidelines developed in the CRIC study in consultation with NIDDK staff.
RESOURCE SHARING

No mice will be generated under this grant application. However “Other Research Resources” generated with funds from this grant will include DNA constructs, cells, RNA-Seq data etc. These resources, as available, would be freely distributed upon request to qualified academic investigators for non-commercial research.

My institution and I will adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the “Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts” issued in December, 1999. http://ott.od.nih.gov/NewPages/Rtguide_final.html. Specifically, material transfers would be made with no more restrictive terms than in the Simple Letter Agreement or the UBMTA and without reach through requirements. Should any intellectual property arise which requires a patent, we would ensure that the technology remains widely available to the research community in accordance with the NIH Principles and Guidelines document.
Data Sharing Plan
The proposed research will include data from approximately 1000 subjects in a smoking cessation trial conducted in the setting of lung cancer screening programs. The final dataset will include demographic, behavioral, medical, and smoking cessation treatment data from participants at baseline, and short-term and long-term (up to 18 months) follow-up points, including laboratory data confirming self-reported abstinence from smoking. We will make the de-identified dataset available to users under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.