



The University of North Carolina at Chapel Hill

Collaborative Studies Coordinating Center

Fee for Service Recharge Center

The SPIROMICS and SOURCE family of studies has substantial data and biospecimens that are available to the widest possible group of researchers to promote the highest quality collaborative science possible. However, grant and contract resources are often focused on the conduct of the study itself with increasing demands of a large observational program for ongoing activities. Providing necessary services involves associated costs, which individually are quite modest but added together for all operating units and across the multitude of active investigative studies can overtax the existing and funded study resources. More importantly, contract funding is limited to defined activities directly related to contract deliverables and may not be used to subsidize or support other study-related activities.

The SPIROMICS and SOURCE Data Coordinating Center (DCC) known as the Genomics and Informatics Center (GIC) has a guiding policy for charges for services available. Exceptions exist and can be requested and will be considered on a case-by-case basis. Estimates for service can be requested and are free of charge.

Turnaround time for service depends on the size and complexity of the requested service and the clarity and accuracy of the information provided to the DCC in the request. Requests may be delayed if the DCC receives incomplete information. Requests for additional work or service, after a request has been completed, will likely result in additional service fees. The DCC makes a conscious effort to accommodate outside requests, however, please note that work related to SPIROMICS and SOURCE funded study deliverables takes priority over all other requests.

For all services, estimated service fees will depend on the scope of work (e.g., dataset creation, data collection and management, regulatory activities, laboratory sample lists, access to the Secure Research Workspace, consultation, etc.). The fees for services will increase in a stepwise fashion based on complexity. The DCC will evaluate whether the request meets the requirements of issuing a Subcontract Agreement rather than fee-based service invoicing.

Table 1. Collaborative Studies Coordinating Center DCC/GIC Service Fees by Category

	Categories		
Services	Simple (base rate)	Moderate	Complex
Dataset Creation	\$3,253.00	\$5,958.00	\$10,053.00
Quality Assurance/Quality Control (QA/QC)	\$2,119.00	\$3,993.00	\$6,065.00
Regulatory Activities	\$1,526.00	\$2,015.00	\$2,725.00
Data Collection	\$8,152.00	\$15,987.00	\$24,703.00
Data Access	\$2,498.00	\$4,079.00	\$7,037.00
Secure Workspace	\$1,892.00		
Principal Investigator Consultation	\$330.00 per hour		
Biostatistician Consultation	\$288.00 per hour		

Description of Services

Dataset Creation	<p>DCC guidelines for determining service cost categories:</p> <p>Simple = one exam visit, ≤ 100 variables (listing of variables provided with SPIROMICS variable names)</p> <p>Moderate = multiple exam visits and/or outcome data, ≤ 100 variables (listing of variables provided with SPIROMICS variable names) Laboratory sample list tracking batches Simple randomization for plating</p> <p>Advanced = multiple exam visits and/or outcome data > 100 variables One exam visit with a complex algorithm for selecting cases/controls Laboratory sample list tracking batches Complex randomization for plating</p>
QA/QC	Execute quality control analyses and standards on blinded duplicates for study laboratory data or for receiving, storing, and distributing study data. This includes adding blind duplicate IDs to the laboratory pull lists.
Regulatory Activities	Support IRB and sIRB requirements of a project. Liaise with the sIRB of record (be that UNC or otherwise). Track the approval of documents as they make their way through IRB review. Advise the PI regarding regulatory requirements. Maintain or execute Data Use Agreements (DUA) and Data and Materials Distribution Agreements (DMDA).
Data Collection	Generally speaking, this is the cost to (1) receive data from external sources such as Reading Center or Labs or (2) develop and deploy data collection instruments in CDART or other web-based platforms (e.g., REDCap or Qualtrics).

(1) For data files from Reading Centers or Labs, cost depends on number, structure, and complexity of the data files.

(2) For data collection instruments, this includes the expert creation of a paper form, utilizing best practice for data collection and standardization. The DCC collaborates with the investigator to create QxQ instructions for the data collection process. Data queries deemed appropriate by the investigator and DCC statistician are facilitated by the DCC. The DCC is responsible for storing the collected data in a standardized format (SAS/STATA). The final deliverable is the data distribution to the sponsor, complete with codebooks in XML/CSV format and data dictionaries for any derived datasets.

The guidelines for Simple/Moderate/Advanced are based on:

- a) The number of forms
- b) The number and complexity of any derived variables
- c) The number and complexity of data queries

These will be negotiated between the DCC PI/PD and the Principal Investigator leading the data collection effort.

Data Access/ Transfer	Any transfer of data between entities such as providing data to consortia, receiving and processing data from central labs or reading centers, or transferring data to and from the secure research/virtual workspace.
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The guidelines for Simple/Moderate/Advanced are based on:

- a) The number of data sets
- b) The size and complexity of the structure of the data sets
- c) The number of times the data is requested to be transferred

Secure Workspace Access	Give access to the secure workspace. This includes, but is not limited to, management and oversight of UNC affiliation, user identification creation, and related background checks.
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PI Consultation	Faculty level expertise on an hourly basis for topics such as study design and budgetary considerations.
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Biostatistician Consultation	Master's or PhD level expertise on an hourly basis for services such as derivation of variables, statistical analysis plan development, and manuscript analysis.
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