

GPCRC Data Coordinating Center, 11-9-17
Ancillary Studies Biospecimen Requests: Steps taken to request fulfillment

- I. Prior to submitting the request to the NIDDK Repository:
 1. Steering Committee must approve the Ancillary study.
 2. Investigator must notify SDRC that funding has been obtained to assay the samples and for analysis.
 3. If the ancillary study is being funded by industry, then the investigator's institution must complete a collaboration agreement with the company based on the GPCRC "industry collaboration template."
 - a. NIDDK must review and approve the Collaboration Agreement.
 4. Investigator should notify the SDRC that analysis of the samples will begin within 3 months.
 5. SDRC identifies the patient-samples according to the study criterion.

- II. Process to submit the request to the NIDDK Repository:
 1. Investigator must complete a SDUC (NIDDK Central Repositories Sample and Data Use Agreement), including institutional signature.
 - a. A co-investigator at a different institution that is receiving the samples MAY be asked to complete a SDUC also.
 - b. In case of an industry collaboration, ONLY the GPCRC investigator will complete the SDUC.
 2. Investigator submits to the SDRC:
 - a. A Notice of Grant Award or proof of study funding.
 - b. An email or document agreeing to pay the repository costs for retrieving, aliquoting, and shipping the samples. *If over \$5000, the invoice must be paid prior to shipment.***
 - c. A FedEx/UPS/or other account number to charge the cost of sample shipment.
 - d. The laboratory contact, email, phone and address.
 - e. The name, address, email, phone number of the person to receive the invoice.
 3. SDRC submits all documentation to the repository website:
 - a. Documentation of study approval by the GPCRC SC or Ancillary Studies Committee.
 - b. All items listed in II.2 above.
 - c. A file identifying the request sample aliquots.
 4. Repository staff reviews the SDUC (s) and the request supporting documentation.
 5. NIDDK approves and signs the SDUC. This process can take 2 weeks.
 6. SDRC may need to provide alternate sample identifiers if a chosen specimen is unavailable, degraded, or hemolyzed. This process can take several weeks.
 7. Repository staff will invoice the investigator for shipment handling and costs.
 - a. Rutgers (RUCDR) will not pull the request until all documentation has been received and approved, and if the cost is over \$5000, the invoice has been paid.**
 8. Fisher or Rutgers will email the ancillary study contact person to arrange the shipping date.

- III. Post-receipt of samples by the investigator:
 1. Investigator analyzes all samples.
 2. Investigator notifies SDRC that the sample assays/genotyping are complete.
 3. Investigator sends all assay or genomic data results to the SDRC.
 4. SDRC provides clinical dataset as defined by the study proposal.

SDRC contact for Ancillary Studies: Laura Wilson lwilson9@jhu.edu

Current GPCRC SDRC Costs:

The SDRC may charge for the cost of programming and managing an ancillary study biosample request. This can range from \$20,000 and upwards depending on the complexity of the study request for identification of the sample, the extent of the requested clinical dataset, the number of phases of the study, and the funding source (i.e., GPCRC study investigator internal funds, industry collaborator).

Current NIDDK Repository Costs:

Cost of samples from the BioSample Repository

- Pulling vials for shipment (includes liquid in vials as well as other material, e.g. tissue):
\$2.91/sample

Requesting investigators will provide a shipper account number (e.g. FedEx or UPS) so that the repository can bill the shipment using their institutional rates.

Cost of samples from the Genetics Repository

- Option 1 - Custom nucleic acid distribution
\$24.09/sample
Investigators request specific DNA yields, concentrations, volumes, sample organization, and sample container for their distribution.
- Option 2 - Fixed volume and concentration
\$16.14/sample
DNA will be provided at a FIXED concentration of 75ng/ul in a FIXED volume of 100ul (a yield of 7.5 ug per samples) in a FIXED sample format with no specific order of samples requested. These samples will be distributed in sealed PCR plates to the requesting investigators.
- Option 3 - Fixed volume at stock concentration
\$5.00/sample
DNA will be provided at a FIXED volume of 20ul of stock DNA (with varied concentrations) in a FIXED sample format with no specific order of samples requested. These samples will be distributed in sealed PCR plates to the requesting investigators.

All prices include shipping cost.

Payment Policy

It is the policy set forth by NIDDK that full payment be received prior to shipment of samples on invoices exceeding \$5000.00 and all international orders. A purchase order should be attached to requests as required by the requesting institution. Requestors should confirm local payment policy as needed. Central Repository staff will provide a cost estimate after submission so that purchase orders can be created.