Modified 02/01/08

Current Rules for Sample Receipt

Staging Lab Update and Information

In concert with the SAIC-Frederick Extraction Lab, the Core Genotyping Facility has piloted several projects using the new "Staging Laboratory" approach. While the studies to date have been limited, we have seen success such that we feel confident in beginning to utilize the new method. Below is a summary of the process we have developed into a Staging Laboratory workflow.

In the new process, all samples for a study are quantified (via approved CGF protocols). Equal amounts of material are then "staged" in 96-well format for any bio-assay work. By staging a set DNA amount for all samples in the study, the constant replenishment of samples and piece-meal genotyping will be eliminated. Any samples that do not have enough DNA, or have DNA that is at a concentration unsuitable for a particular platform, can be adjusted prior to its arrival at the CGF. The assigned project manager and the quality control division will work with the investigators to ensure that the appropriate subjects meet the criteria for genotyping. In this way, the CGF receives only the amount of material that it needs to complete the genotyping project in a pre-plated fashion specifically designed for the platform to be used. This allows the project to begin quickly without additional sample handling and without leftover DNA that requires storage. In this way, all samples will be received at the CGF at one time and assay work can be done quickly and generate the most informative data set possible. We also believe this will reduce the actual amounts of DNA consumed.

Beginning with the DCEG Rare Cancer iSelect genotyping project, we have begun implementing the Staging Lab process.

As a rule of thumb, if your study does not currently have samples that exist at the CGF it should be handled through the new Staging Lab pipeline. However, if you are adding/replacing samples for a study at the CGF it is likely you should continue to ship samples to us. Before sending samples to any location, please check with CGF to be directed to the appropriate laboratory facility for sample handling.

For Samples Going to the Staging Lab:

1. All genotyping projects must be approved by the DCEG Genotyping Review Committee (GRC) prior to samples arriving at the CGF. For information and instructions please see: http://intranet.dceg.cancer.gov/committees/genotyping-review-committee/genotyping-review-committee/

2. All projects need to have a submitted and approved yellow task outlining the scope of work before any work can begin. This includes information about the number of samples, their location, if extractions are needed, and the amount of material to be staged.

3. All samples coming to the Staging Lab must be transferred to the CSP DNA Repository within BSI. Samples must have a BSI ID assigned to them prior to their transfer to the Lab. Samples may arrive in the form of plates, robot tubes (cluster racks) or vials (volumes from

0.5mL through 15mL). If the samples are in another format (filter paper, gels, etc.) the investigator/study manager must call prior to initiating the sample transfer.

4. The Staging Lab will coordinate the actual sample delivery with the appropriate repository transferring the samples.

5. Samples should be shipped to the following location:

   Until the completion of the new DNA Extraction/Staging Laboratory is complete (at which time the address will be updated) all shipments should be delivered to:

   DNA Extraction Laboratory
   1050 Boyles Street
   Bldg 560, Rm 11-23
   Frederick, MD 21702

6. As part of our commitment to quality control, we are also requiring a basic phenotype file for all samples received for genotyping. This data will be used by project managers, QC/QA and analysts to appropriately check data for inconsistencies prior to reporting. The laboratory staff continues to be blinded to all of this information. Please see the CGF website for instructions and the file template: http://cgf.nci.nih.gov/docs/CGF_Phenotype_Manifest.xls.

For Samples Coming to the CGF:

1. All genotyping projects must be approved by the DCEG Genotyping Review Committee (GRC) prior to samples arriving at the CGF. For information and instructions please see: http://intranet.dceg.cancer.gov/committees/genotyping-review-committee/genotyping-review-committee/

2. If samples are to be shipped, the investigator must notify the CGF at CGFreceipt@mail.nih.gov. This should be done before the repository begins to pull the samples for shipment.

   - Samples will only be accepted if a fully actionable genotyping request is in place to complete once the samples have been received and handled.

   - An estimated cost will be sent via email to the PI and branch head for the total cost of handling and genotyping of the project requested.

3. After the genotyping project is in place at the CGF, the investigator will notify the repository to ship the samples needed according to the guidelines set by the CGF:

   - Samples should be shipped in cryovials in freezer boxes to the CGF. If samples are already at the repository in another format, exceptions may be made at the discretion of CGF management.

- The following are the minimum acceptable volumes and concentrations for samples according to the proposed work. ***Please note:*** These requirements are for samples to enter the sample handling pipeline. Specific material requirements for the genotyping platform(s) requested are available on the CGF website (http://cgf.nci.nih.gov/).

    - Genotyping assays: Minimum volume of 50µl* of DNA at a concentration greater than 25 ng/µl via NanoDrop micro-volume OD.

    - Samples received for WGA: minimum volume of 10µl of DNA at a concentration greater than 5 ng/µl via NanoDrop micro-volume OD. This is the requirement for any sample for which WGA is to be done at the CGF, which includes samples submitted for WGA only or samples that fail above requirements (if WGA is requested by the investigator).

***Any sample containing below 50µl of volume will be increased to 50µl during initial sample handling, unless the sample is being directed to WGA. After volume calibration, if the concentration of the sample is less than 25 ng/µl based on NanoDrop optical density readings, the sample will be removed from the sample handling process.**

- CGF laboratory staff will perform a pre-processing procedure on all samples. Any samples that do not meet the above criteria may be returned to the repository.

- The CGF will also cease combining DNA from different vials; each sample vial received will be handled independently.

- Samples that do not meet the CGF handling requirements may be subject to a higher sample handling fee.

- All shipments should be delivered to:
  Core Genotyping Facility
  8717 Grovemont Circle
  Advanced Technology Center, Room 149
  Gaithersburg, MD 20877-4117

4. The repository must notify the CGF 24 hours prior to sample shipment and email the sample manifest to the project coordinator of the CGF. The electronic manifest should include: study, vial ID, sample volume, and concentration for all samples. The manifest should list samples reflective of the ordering of the freezer boxes. The CGF will respond to the repository that they will accept the shipment, or if problems exist such that the shipment will not be accepted (e.g. fully actionable genotyping request not currently in place for the samples). There should be no shipment of samples without prior CGF approval of the shipment. Shipments may be returned if approval has not been given or the shipment is received in an unacceptable format.

5. The shipment should be accompanied by a hard copy manifest for confirmation.

6. As part of CGF's commitment to quality control, we are also requiring a basic phenotype file for all samples received for genotyping. This data will be used by QC/QA and analysts to appropriately check data for inconsistencies prior to reporting. The laboratory staff continues to be blinded to all of this information. Please see the CGF website for instructions and the file template: http://cgf.nci.nih.gov/docs/CGF_Phenotype_Manifest.xls.