BIOMARKERS CORE LABORATORY

630 West 168th Street, PH-10-105 New York, NY 10032. Tel: 212.305.9306

Biomarkers Core: User Policy and Submission Guidelines

The following page provides an overview of the user policy and sample submission guidelines for the analytical and bioprocessing services of the Biomarkers Core Laboratory (BCL).

User Policy

- 1. The Biomarkers Core is not CLIA certified. The data generated from BCL is to be used only for research purposes and not for clinical and diagnostic applications.
- 2. Investigators are solely responsible for collecting and archiving the result files.
- 3. Acknowledgement: If the data generated in the BCL is used for the publication, the Core Lab must be acknowledged in the publication. It is essential for us to demonstrate our impact, meet our reporting requirements, and secure future funding support. A recommended sentence is "We acknowledge the support of the Biomarkers Core Laboratory at the Irving Institute for Clinical and Translational Research, Columbia University Irving Medical Center, for their technical support."

Sample Submission Guidelines: Analytical Services

Service requests

1. Project consultation with the Core Director

We strongly encourage investigators to contact the BCL Director prior to submitting a new service request. This will facilitate a discussion on the project, scope, feasibility, appropriate analytical strategy and other sample requirements. Please set up a consultation to initiate new pharmacokinetic projects involving LCMS method development.

- 2. A new protocol submission request should be initiated in iLab for every new project. This should be accompanied by a research project details form and a request details form. Incomplete entries will not undergo further processing.
- The BCL will not accept samples without an active service request. Additional request details forms should be submitted if more assays or samples need to be added to an existing protocol.

Samples and Sample delivery

- 1. Samples can be submitted as aliquots of serum, plasma, saliva, or urine. Please contact us to discuss the feasibility of other sample types.
- 2. Samples with the wrong matrix (serum vs. plasma), collection tube, additives, or with inadequate sample volumes will be rejected. Please contact us for the sample volume and matrix requirements specific for each assay. If multiple assays are needed and volume is limited, please let us know the priority of the assays.
- 3. Samples (plasma or serum) collected from gel separator tubes are not acceptable for LCMS analysis.
- 4. Hemolyzed, icteric or lipemic samples are unacceptable for certain analytes and may not be processed. This will be noted in the sample list and results report.

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- 5. **Sample list:** The **sample list template** should be downloaded and filled in with sample details (de-identified subject ID, species, matrix, time points if any, collection date etc.,) in the order (including any randomization) in which, you would like us to analyze them. This should be emailed to us prior to dropping the samples off.
- 6. Samples should be delivered to the lab in freezer boxes, arranged in the same sequence as the sample list. The sample vials should be labeled legibly. Freezer boxes should be labeled with the service request number and PI's name.
- 7. Left-over samples, if any, will be kept only for one month after data has been sent and then will be discarded. Please contact us if you would like them to be returned.
- 8. **Drop off hours:** Samples can be dropped off Monday- Friday from 9am 5pm. Please use dry ice while transporting them.
- 9. **Lab Location: PH10-105**. Please contact us prior to dropping samples off to ensure the respective staff member is available to receive them.

External Investigators

- 1. You may ship the samples to us using an overnight delivery service.
- 2. Only ship samples Monday Wednesday to ensure that samples are received by Friday.
- 3. Please package your samples with dry ice to keep them frozen. Include a hard copy of the sample manifest with the shipment.
- 4. Contact the Biomarkers Core Lab and provide the tracking number and the estimated date of arrival of your package/samples.

Shipping Address

ATTN: Dr. Renu Nandakumar Biomarkers Core Laboratory Columbia University Irving Medical Center 622 West 168th Street PH-10-105 New York, NY10032

Ph: 212-305-9306

Email: rn2374@cumc.columbia.edu

Data Delivery

Data will be available for you to download at the sharepoint site (https://cumccolumbia.sharepoint.com/sites/IICTR-labresults) within the folder named after the PI and can be accessed using Columbia UNI and password. Access to additional group members will be granted following an electronic request from the PI.

Sample Submission Guidelines: Blood Processing and Biobanking

1. Investigators should set up a consultation with the Core Lab Director to discuss the project objectives, scope, assays, sample collection, and processing requirements, before initiating blood collection.

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- 2. For projects that are using the CRR Outpatient or Inpatient phlebotomy services, requests for BCL's specimen processing services should be included in the CRR application.
- 3. For projects utilizing phlebotomy services at other sites within CUIMC, requests should be submitted through BCL <u>iLab</u> website. A copy of the approved IRB protocol should also be submitted for additional review. Please contact us for the instructions on how to register and submit a service request through iLab.
- 4. Processing supplies (cryovials and freezer boxes) should be purchased and delivered to the lab prior to starting the blood collection.
- 5. Primary tubes should be labeled (no PHI should be included), placed in biohazard bags and secondary containers, and delivered along with a **biospecimen delivery form** detailing the protocol number, subject ID, blood draw times or any other relevant sample information such as any medication that will interfere with the clotting. We will not accept samples labeled with the IRB Protocol number.
- 6. Sample Drop off: Samples can be dropped off only between 9am to 4pm. We will not accept samples dropped outside this window.
- 7. Freezers: BCL will store the aliquoted samples at -80°C for the duration of the study and or until the assays are completed, whichever comes first.