

CPAC Policies

Confidentiality/Sample Management:

Data generated by the core is kept on a secure server with access to core personnel only. Data or information (verbal and/or electronic) are not shared with any outside parties. We treat all information received from our customers as confidential and privileged. Unless authorized by the customer, we will not disclose, copy, distribute, or share data. The PI will have ultimate control over any public disclosure of the scientific results generated in CPAC.

Samples delivered to CPAC are required to be de-identified; if samples are not de-identified, they will be returned to the PI immediately.

Sample retention is not provided by CPAC. Any remaining sample materials will be disposed once data has been generated and accepted by the customer. Before any such disposal, every effort will be made to alert PIs that have samples remaining in CPAC storage.

Conflict resolution: If a resolution cannot be reached at the core director level, the issue will be taken to the core advisory committee for discussion and resolution.

Cost recovery/payment policy:

If recovery of payment becomes an issue, the IU Simon Comprehensive Cancer Center (IUSCCC) business managers will contact the customer and/or their department to collect charges owed. If there is a dispute regarding specific charges, the conflict resolution policy above will be followed.

Prioritization of work:

IUSCCC and IU School of Medicine investigators have full access to services provided by CPAC. Investigators planning to use CPAC must fill out an authorization form, which must be updated annually (contact Zack Gunter at tzgunter@iu.edu for a copy of the form).

Projects enter the queue upon receipt of the authorization form *and* the materials that are to be tested.

In the event that there is a backlog in activities, Prioritization of work will be based on IUSCCC membership followed by IUSM affiliation, and finally by non-members.

Acknowledgement, authorship, and collaboration:

All research work performed by CPAC should be acknowledged in all ensuing publications. Please add the following statement to the acknowledgments section:

"Mass spectrometry work ('and any other work') was provided by the Clinical Pharmacology Analytical Core at Indiana University School of Medicine; a core facility supported by the IU Simon Comprehensive Cancer Center Support Grant P30 CA082709."

Fees paid for services provided by CPAC should not negate the potential of co-authorship by CPAC scientists. These acknowledgements and achievements are important for the existence and continued funding of CPAC. Given that many validation procedures and CPAC offered services require advanced intellectual involvement by CPAC scientists, it is expected that this acknowledgement will be in the form of co-authorship.

Acceptance Criteria

Analytical method acceptance criteria are in accordance with the FDA Bioanalytical Method Validation-Guidance for Industry, May 2018; as well as the International Council on Harmonization (ICH) Q14 final guidelines, November 2023