

Angio BioCore – Policies, Policy Statement

Confidentiality Policy: Confidentiality pertains to issues related to either the source of materials analyzed or the data generated from the analysis of these materials. The procurement of human tissues used in investigator-initiated studies that are performed by the ABC is the responsibility of the respective Principal Investigator (PI), under institutionally approved protocols; therefore, the accompanying HIPPA requirements for the specimen acquisition are the responsibility of the individual Users. The ABC does not participate in the collection of tissues, and therefore is not part of the HIPPA confidentiality of human samples used by the Core. Importantly, all specimens processed and analyzed by the ABC are de-identified, i.e. no identifiable personal information is provided, or cannot be retrieved by the Core. Each specimen or work request processed by the Core is assigned a unique identifier by the respective study coordinator, which is adopted by the Core. All ABC personnel are required to complete and pass the HIPAA Security training.

All data generated by the ABC is owned solely by the respective investigator. All data generated is provided to the User, and whenever it applies, copies are archived in a secure server (encrypted, password-protected), which access is restricted to authorized ABC personnel. The ABC does not share any data or privileged research information with any other parties.

Conflict Resolution: Conflicts may arise in the use of the ABC and the services it provides. In the event that a User is not satisfied with the work performed by the Core, the project is reviewed and a strategy is put in place to attempt to rectify the situation. Resolution of issues such as charge disputes or quality of service is discussed with the Core Manager and the Core Director. Issues with work authorship or conflicts of interest, or repeated quality of service complaints will be discussed with the Core Director, who if necessary will seek advice from the Advisory Committee. A written account of these disputes is prepared and archived.

Cost Recovery, Payment Policies: Prior to the initiation of any project, the Core will provide the PI with a detailed budget for the services requested, and upon approval the PI will provide the ABC with an account number to invoice. Adjustments can be made as the study progresses depending on the PI needs. Charges are added up monthly, and a billing statement is sent to the administrative assistant of the User for collection. Whenever available, the ABC will apply cost subsidies supported by grant mechanisms, benefiting active investigators in the respective awards (following approval by the respective grant directors and confirmation of programmatic alignment).

The ABC is a Core of the IU Simon Cancer Center (IUSCC), which is responsible for the billing and accounting. A comprehensive list of the ABC services and rates is available in the Core's website. Note: Users outside of the IUSM or the IUSCC will be charged an additional overhead rate, depending on the services provided.

Prioritization of Work: Investigators from the IUSM and IUSCC have full access to the services provided by the ABC. Researchers interested in using the Core services fill out a Consultation Form, which can be obtained directly from the Core or, alternatively, downloaded from the ABC's website. Projects enter a service queue upon receipt of the Consultation Form.

In situations of an excess of service requests or specimens to process, the following criteria will be used for study prioritization:

- an urgent clinical assay or specimens from a clinical trial will have priority over a research experiment;
- clinical specimens which processing and testing are time sensitive;
- studies required for a grant or a presentation deadline;
- studies for IUSCC or IUSM members will have priority over non-members;

- specimen processing or an experiment will have priority over new assay development or instrument training (as the Seahorse XFp).

Publication and Authorship: It is requested that investigators acknowledge the contributions of the ABC in all manuscripts that include studies performed and data generated by the Core. This includes acknowledgment of grants and awards that supported the implementation of the studies.

Authorship decisions will be practiced in accordance with established academic guidelines (as reference: hms.harvard.edu/about-hms/integrity-academic-medicine/hms-policy/faculty-policies-integrity-science/authorship-guidelines). For work that includes standard Core services or that does not surpass the general technical expertise of the Core, it is not expected the inclusion of ABC personnel in the manuscripts' authorship. In the event that ABC personnel provide a significant level of intellectual contribution, or critical study and/or methodological design or testing (as the development of a new assay), an agreement regarding authorship will be discussed with the PI, preferentially at early stages of the project.