

## Submitting Investigator Research Interaction with the Dermatopathology Core

The Submitting Investigator (SI) needs to make several choices when submitting samples, defining the type of interaction with the core and potential for future use of submitted tissues. The choice of interaction should be made by the submitting investigator with advice from the Dermatopathology Core PI, Dr. Bhawan, or co-investigator, Dr. Lafyatis.

### Study or Service:

The Submitting Investigator (SI) can choose one of two types of interactions with the Core, designated "Service" or "Study".

A Service Interaction is designed to simply provide the SI histologic or immunohistochemical Core services, without any clinical data submission to the Data Coordinating Center (DCC) Database. All murine studies will thus be Service Studies. Human Service studies will require SI site IRB approval, but will be exempt from further review by BUMC IRB, as only samples stripped of identifiers will be accepted for such studies. A Service interaction does not otherwise limit the scope of Core Services, including IHC, or analyses of histologic or IHC antigen expression.

A Study Interaction includes all other types of studies, but particularly work that is associated with submission of clinical data to the DCC. All interaction that will utilize banked Core Human Samples will by definition be Study Interactions. I understand that before work can begin on this project I will need to submit my IRB approval letter.

I agree to the following interaction for these samples (please initial one box):

\_\_\_\_\_Service

\_\_\_\_\_Study

**Samples:** A major goal of the Core Center is to provide access to pathological samples for investigators who otherwise to not have such access. Thus, an important decision by the SI is whether the remainder of submitted samples will be returned to the investigator or be retained by the core. Samples can only be banked by the core for studies in which the IRB approved consent permits future use of samples. An unsigned consent should be provided to the Core. Investigators utilizing samples submitted by other Core SI, will be required to submit all manuscripts to SI for review and comment and to include all SI as co-authors, unless an SI refuses. SI providing samples for core utilization will have specimen processing and initial work as defined on the core website carried out without charge.

I agree that the remainder of my submitted specimens (please initial one box):

\_\_\_\_\_should be returned to me

\_\_\_\_\_can be used for future studies by the core

**Authorship:** Core Principal Investigator (PI) and/or Co-investigator will in some but not all cases reasonably anticipate co-authorship on publications arising from Core activities. The defining line for this will not be any different from collaborations that might occur outside the core structure, but to avoid misunderstandings authorship questions will be defined at the time core service requests are initiated. Guidelines follow:

1. In cases where cores are supplying key samples, analytic input, or developing new technologies, then Core PI (Dr. Bhawan) or Co-investigator (Dr. Lafyatis), whoever is helping direct the study, should generally be included as co-author(s). This would include:

- Use of skin samples collected as part of other Core activities and provided to the Study Investigators as sections, or sections stained for Investigators.
- Use of analytic capabilities of the Core that requires Core PI or Co-I input.
- Development of new staining or immunohistochemical staining, targeting a new antigen not previously provided by the core.

2. In cases where the core is simply providing technical services, then Core PI (Dr. Bhawan) and/or co-investigator (Dr. Lafyatis) should NOT generally be included as co-authors. This would include:

- Use of the skin pathology core services to process and/or stain/immunostain samples supplied by the SI without any analysis provided by the Core, i.e. simply returning stained or unstained slides to the Investigator.

I agree that I will use core service in a manner that (please initial one):

Requires co-authorship by the core PI (Dr. Bhawan)\_\_\_\_\_or core co-investigator (Dr. Lafyatis)\_\_\_\_\_

Does not require co-authorship\_\_\_\_\_

In addition to Core PI/co-I authorship rights, Submitting Investigators will also have rights as co-authors based on sample contributions to cores. Publications resulting from any studies carried out with samples generated by one or more SI will include all Submitting Investigators, unless a SI explicitly and in writing wishes to be excluded from authorship. Please initial one of the below:

Consistent with my agreement (above) for having the remainder of my specimens returned to me, I do not anticipate future authorship on manuscripts generated using banked core specimens.

\_\_\_\_\_

Consistent with my agreement (above) for having the remainder banked by the Core, I anticipate that I will be contacted to review and at my discretion agree to be co-author on manuscripts generated using my banked core specimens.

\_\_\_\_\_

Agreed to:

Submitting Investigator: \_\_\_\_\_ (printed) \_\_\_\_\_ (signed)

Date: \_\_\_\_\_

**Access to Core Services:** Access to core services will be first-come, first-served unless a core becomes backed up, in which case access will be prioritized on the basis of:

1. NIH-supported studies
2. Private, non-NIH-supported studies
3. Industry supported studies (investigator-initiated)
4. Non-supported studies

The idea here is that agency funding has provided scientific review of the project, thus these guidelines will provide some measure of priority based on the stringency of the review process. Core Investigators will have first priority access to Core Services. Non-Core Center investigators will pay a tiered rate that covers a higher percentage of costs. Industry-sponsored studies will not have any direct access to core services.

**Data Confidentiality:** All data generated by samples sent from Investigators to Cores will be confidential to that SI until publication or the investigator releases the data for core use. Violations of this policy will be reviewed by the Advisory Committee.

**Subject Confidentiality:** All samples and clinical data will be coded before submission to Cores. Any samples or data sent without obliteration of identifiers will be returned immediately to the Investigator. Violation of confidentiality will be reported to the local IRB and recurrent violations reported to the Advisory Committee for considering restriction of Core access.

**Security:** All electronic data will be stored in password protected files, and paper files in a locked room. All electronic files will be backed up and data stored for 5 years unless IRB related restriction regarding destruction of data.