Submitting Investigator Research Interaction with the P30 Proteomics 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 samples. The choice of interaction should be made by the submitting investigator with advice from the Proteomics Core Principal Investigator, Dr. Varga, or Co-Investigator, Dr. Hinchcliff.

Study or Service:
The SI can choose one of two types of interactions with the Core, designated "Service" or "Study".

A Service Interaction is designed to simply provide Proteomic Core services to the SI, without any clinical data submission to the Data Coordinating Center (DCC) Database through Boston University Medical Center. Service studies will require SI site Institutional Review Board (IRB) approval, but will be exempt from further review by Northwestern University IRB, as only samples stripped of patient identifiers will be accepted for such studies. A service interaction does not otherwise limit the scope of Core Services, including proteomic bioinformatics support through Dartmouth University's P30 Microarray and Bioinformatics Core.

A Study Interaction includes all other types of studies, but particularly work that is associated with submission of clinical data to the DCC. All interactions that will utilize banked Core Human Samples (those samples submitted by other investigators for research community use) will, by definition, be study interactions. The undersigned understands that before work can begin on this project he/she will need to submit an IRB approval letter to Boston University Medical Center.

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

_____Service _____Study

Samples: A major goal of the Proteomics Core Center is to provide access to serum samples for proteomic studies for investigators who otherwise do not have such access. Thus, an important decision by the SI is whether the remainder of submitted samples will be destroyed after initial proteomic analysis or be retained by the Proteomics Core for future studies. Samples can only be banked by the Core for studies in which the IRB approved consent permits future use of samples. In this case, an unsigned copy of the consent should be provided to the Proteomics 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.

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

_____be destroyed and not used for future studies

_____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. Varga) or Co-investigator (Dr. Hinchcliff), whomever is helping direct the study, should generally be included as co-author(s). This would include:
    - Use of serum samples collected as part of other Core activities and provided to the Study Investigators.
    - Use of analytic capabilities of the Core that requires Core PI or Co-I input.

2. In cases where the core is simply providing technical services, then Core PI (Dr. Varga) and/or co-investigator (Dr. Hinchcliff) should NOT generally be included as co-authors. This would include:
    - Use of the Proteomics Core services to process and/or analyze samples supplied by the SI without any analysis provided by the Core, i.e. simply returning multi-analyte profile information 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. Varga)_____or core co-investigator (Dr. Hinchcliff)_____

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 provided 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 destroyed, 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 P30 subsidized 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. 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 removal 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 10 years unless there is an IRB related restriction regarding destruction of data.