PSHCI Tissue Bank Tissue Request Instructions

Requests for biologic specimens and/or questionnaire data to be used in studies must be submitted in writing. The Scientific Review Committee (SRC) requires the following:

1. You should get IRB approval or an IRB exemption prior to applying for tissue. If you have an IRB protocol make sure it is up to date, valid and provide it on the tissue request form.
2. a brief introduction to the proposed study,
3. the study's specific aims,
4. methodology,
5. a precise statement of the type of material needed,
6. a justification of the study's sample size.
7. fill in the Biological Safety and Recombinant DNA Assurance Form found at:

   http://infonet.hmc.psu.edu/safety/biological/rDNA/Fillable%20Assur%20Form%20Reader.pdf or provide your valid BSRD number for your laboratory.
8. Fill in the tissue request form and submit it with the rest of your paperwork.
9. Fax to x0704 or send by email to dbeard@psu.edu **ALL** the required paperwork.

The investigator should involve a statistician in the preparation of the application. Efficient multi-stage designs with stopping rules for both positive results and for futility should be utilized when feasible so that depletion of resources is minimized. Demonstration that the investigator is appropriately qualified and that the laboratory is equipped to do the research is also required.

Review Procedure

Proposals for research involving patients registered in the tissue bank or biological materials collected through members of the PSHCI must be submitted to the SRC for review and evaluation. The SRC review panel consists of the Director of Clinical trials for the PSHCI, appointed members of the SRC from both the Basic Science and Clinical departments, along with other reviewers or their designees, as appropriate for the specific proposal. These reviews will ensure that the project is one to which PSHCI should commit resources.

Proposals either already approved by the IRB or those not needing IRB approval generally require up to one week to be reviewed. This expedited review process may be utilized when requesting the use of biological materials for which funding has already been secured.

Grant proposals for external funding must undergo a full review by the SRC before submission to the awarding agency. This constructive review by PSHCI scientific and administrative staff will improve the proposal and increase its chances for success. Depending on the type of grant or request, both draft and full proposals can be reviewed. All required draft or full proposal materials for review are submitted to the Tissue Bank through the tissue bank manager, Dan Beard.

If the request is part of a clinical trial, the proposal should be first submitted to the appropriate Disease Team for approval. Members of the Disease team panel are asked to comment in writing on the concept or proposal and recommend whether the investigator should proceed with the submission or if a conflicting project is already approved. The Disease Team should transmit its review to the SRC within five days of receipt of the materials, if possible.

The format of the materials required for the review and timetable for their submission are described below:

The Concept (**A Draft of the Research Proposal**) - The two- to five-page concept can be a working draft of the proposal; however, it must include sufficient detail about the purpose and scope of the proposed project. Specifically, the sample size must be justified.

The Proposal - In general, the proposal must contain the following:

• The **specific objectives** of the project as they will be listed in the full proposal.

• Sufficient **theoretical background, references, and methodological detail** such that participants and reviewers can judge if:

The project is responsive to the Request for Proposal (RFP), where applicable.

The project addresses the stated objectives.

• **Endpoints** that are sufficiently detailed to allow the SRC to determine if statistical input is needed for the project.

• Normally, the PSHCI **statistician will be assigned to review** the proposal and will be responsible for providing any statistical sections needed for the grant proposal and associated protocols.

Timetable

An SRC meeting will be arranged to discuss the submission, and a letter of approval or disapproval will be sent after the meeting. The PI should be available during the SRC meeting to answer any questions that arise. Because the schedule for writing proposals is often a demanding one, e-mail or fax are the preferred means of communication during the review process. The SRC meets the fourth Tuesday of each month.