

4) Provide the Core's policy for:

- a. Confidentiality**
- b. Conflict resolution**
- c. Cost Recovery/Payment Policies**
- d. Prioritization of work**
- e. Publication**

A set of policies and procedures is currently in place within the Birck Nanotechnology Center (BNC), and a standing Policy and Procedure (P&P) committee oversees and reviews these policies. These procedures are summarized in a manual which addresses access and required training, safety and emergency response procedures, universal BNC procedures for all research areas, laboratories procedures, Scifres Nanofabrication Laboratory (cleanroom) procedures, and biocleanroom procedures. Subcommittees of the P&P committee include a Training subcommittee, involved in defining, monitoring and updating the training materials and procedures for the various BNC laboratories, and a Disciplinary subcommittee, which considers cases in which users have violated safety or operational rules. The P&P committee includes users, faculty and staff, with representation from each of the major equipment/capability areas within the building. In addition to involvement in broad policy decisions, the members also serve as technical experts in their respective areas of expertise. In this role, the members provide technical inputs to the BNC director in matters that involve potential interference or contamination issues, or other sources of potential conflicts between various groups using the facility. This structure has been in place for 3 years and has been effective in establishing a highly effective and accessible facility, with a well-established process for defining appropriate policies and resolving potential conflicts.

URL link to the Birck Nanotechnology policy and procedure manual:

<http://www.purdue.edu/discoverypark/nanotechnology/facilities/pandp.php>

The BNC-BNL will build on the successful P&P committee concept. Specifically, we will establish a subcommittee of the P&P committee to establish and monitor the policies for the BNC-BNL. This arrangement will allow the BNC-BNL to leverage the activities of the P&P committee and foster links with other labs within the building. The Policy and Procedures committee members have reviewed and approved the following additions to be included in the Policy and Procedure manual to ensure all users are informed during their training sessions to gain access to the facility.

Confidentiality

Purdue – Indiana Clinical and Translational Sciences Institute Cores Use Confidentiality Policy

For users who are themselves Purdue faculty or staff, confidentiality is already required by existing University policy. The University Policies on intellectual Property and on Research Misconduct establish that research and research data at Purdue is to be protected from intentional and unintentional disclosure. Thus, samples, products derived from samples, data obtained from the analysis of samples, and data and analyses obtained from a Core user shall be considered confidential, and shall not be shared, published, reanalyzed, reprocessed, or in any other way shared, or used for additional analyses without the Core user's express and written permission.

The relevant Purdue policies may be found at:

http://www.purdue.edu/policies/pages/teach_res_outreach/viii.4.1.htm

http://www.purdue.edu/policies/pages/teach_res_outreach/viii_3_1_print.html

For Core users from outside of Purdue University, such as corporate partners, investigators from government, other universities, or any other type of institution, the same confidential treatment of research and data shall be applied in the Core. In this case, confidentiality is assured through execution of a confidentiality agreement with Purdue University. External users may contact either Kara Cornell [(765) 494-6210] or Mary Millsaps [(765) 494-1059], in the Sponsored Programs Office to begin this process. Assistance in establishing such agreements will be provided by Core personnel and/or the Core director.

Additional information: <http://www.purdue.edu/sps/contracting/confidentialityinfo.html>

Conflict resolution

Disagreements and or disputes over use of equipment or access to equipment, or for intellectual input and authorship will be raised with the CTSI TTR Liaison. The liaison will also present the disagreement to the Core Director and Faculty Scientific Director to identify a mutually-agreeable solution. The Liaison will also serve on the BNC policy and

procedure committee, with specific charter to bring forward issues that require a review of existing policies and procedures to ensure the best interest of the CTSI core and its users are established. If invention rights or claims are involved, respective technology transfer managers will be consulted and included in the deliberation of the dispute.

The Core Advisory Committee will be convened to mediate the dispute if a mutually agreeable solution is not achieved within 30 days of the dispute notification to the Liaison.

With due process and considering all sides in the dispute as presented by involved parties, the director, or Advisory Board if it is involved in the dispute, will provide a reasonable and workable solution and will make available resources, if possible, to act on the recommended solution. If the solution is not accepted by any of the involved investigators, the matter will be referred to the respective university administrative structures for resolution. In this event, all Core projects that include the involved investigators will be suspended until the dispute is resolved.

Cost Recovery/Payment Policies

Costs will be recovered using the approved University recharge mechanism. The charges will be billed on a monthly basis to all facility users, regardless of whether they are internal or external users. In order to utilize the individual laboratories or equipment in the laboratories the end user must provide the necessary billing information to cover their expenses. Payment is expected the month following the usage of the laboratories or equipment.

Prioritization of work

Equipment can be reserved for use at specific times using the BNC on-line equipment scheduling program (Coral) as identified on the BNC website.

<http://www.purdue.edu/discoverypark/nanotechnology/facilities/equipment.php>

The BNC policies include several provisions to provide fair access to all users, and to allow users with time-critical samples to schedule appropriate times for equipment use. These include restrictions on the number of hours per week that a user can reserve a given piece of equipment and a standard day/time each week when users can begin booking reservations.

In the event of special circumstances, e.g. a short-term need to handle large quantities of time sensitive samples, prioritization of the samples can be requested by the users. These special circumstances will be reviewed and priority access approved by the CTSI TTR Liaison.

Publication

Expectations for authorship for Core personnel will be discussed with initial Core contact. While authorship is not required and will often be inappropriate for Core personnel providing research input to the project, if there is significant intellectual and/or organizational effort of Core personnel to the work described in the manuscript, authorship is warranted and expected. For example, expert data analysis from Core personnel that is required in support of claims in a manuscript or patent warrant authorship. It will be made clear to investigators utilizing the Core that the recovery of Core expenses through the Core cost recovery system does **not** exclude the possibility for authorship for Core research personnel. Similarly, authorship does not substitute for payment of Core expenses for services rendered.

Utilization of the Core should be acknowledged in all publications in which data analysis and/or results were obtained by the direct use of the Core or Core personnel.

In publications that describe research that took place at the Core facility, authors should include a statement acknowledging the use of the facility and the Birck Nanotechnology Center. All publications resulting from services provided by the Core and supported by funding from the CTSI must acknowledge the CTSI and the Birck Nanotechnology Center:

“The author(s) acknowledge the use of the Birck Nanotechnology Center BioNanotechnology Laboratories. This work was supported, in part, by grant NIH/NCRR RR025761.”

5) Describe the methods to be used for assessing Quality and User Satisfaction

- CTSI Core equipment reliability and usage, via Coral, will be obtained to ensure CTSI Core users have the ability to continue their research within the facility by maintaining the quality and availability of heavily used equipment. The results will be provided to the CTSI Core advisory Committee.
- All CTSI users will be surveyed at the mandatory all user meeting held at the Birck Nanotechnology Center. The results of this survey will be provided to the CTSI Core advisory Committee.
- The CTSI Core advisory Committee will review core utilization and quality control in addition to needed services and equipment purchases necessary to maintain a level of excellence within the Core.

6) Which College / School, Division, Department or Center will be ultimately responsible for the financial shortfalls of the Core, if any.

Financial shortfalls of the core facility are not anticipated because the BNC-BNL is funded through a university authorized charge back system that includes recovery of expenses for utilization of laboratory supplies as well as equipment usage. A University provided subsidy covers a portion of the salaries and wages of the research staff. Ultimate responsibility for the budget lies with the Birck Nanotechnology Center.