Creighton University School of Medicine Guidelines

GUIDELINE: Guidelines for Research Core Facilities

GOVERNING BODY: Executive Committee

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LCME ACCREDITATION STANDARD REFERENCE: 3.2

PURPOSE

To define the criteria for a Research Core Facility and to provide standard operating principles.

GUIDELINE

Core Facilities will have standardized operating procedures to ensure resources are used effectively and responsibly to support Creighton University Research and core facilities are held accountable to the same standards.

SCOPE

All Core Facilities operating within the School of Medicine

PROCEDURE

Requirements for a Research Core Facility:

- Serves a broad user base from multiple departments and available to users from any School or College in the University
- Provides a scientific service or capability that would be too costly for an individual investigator to support on their own or be more cost-effective to provide as a core
- Has a positive strategic impact to the CUSOM research community
- Encompasses an educational component for faculty and learners in learning new research techniques
- Each Core is required to have the following personnel:
 - o Core Director: faculty member who has expertise in the relevant field
 - Core Manager and/or Technical Director: experienced technician or key operator, at a B.S., M.S., or Ph.D. level, managing the day-to-day service activities

Operations

- Personnel expectations:
 - Core Director
 - Responsibilities to include: overall oversight of the core; on-going review of usage data; supervision of core staff; resolving user concerns and communicating them to the Core Facility Advisory Committee; set user fees subject to approval by the Core Facility Oversight Committee; membership in the Core Facility Oversight Committee.
 - Core directors are expected to pay the same fee-for-service rates as other Creighton users.
 - The appointment and removal of Core Directors is under the authority of the dean, but may be delegated to his representative under certain

- situations, for example, to ensure consistency with university-approved and funded programmatic grants.
- Core directors should have his/her percentage of dedicated time to this role indicated in their annual contract with the School of Medicine.

Core Manager or Technical Director

- Core Managers and Technical Directors will be hired by the Core Director with the approval of the Associate Dean for Research. The interview process will incorporate the opportunity for input by the Associate Dean for Research, representative faculty core clients, and other core directors enabled during the interview process. Hiring of core personnel and funding for positions is at the discretion of the dean.
- Core Managers/Technical Directors are in a customer service role and are expected to be available to clients during regular business hours. Core staff must be present 40 hours a week, Monday Friday between the hours of 7am-6pm. Remote work/work outside of the office is not allowed, except in rare circumstances subject to approval by the Core Director prior to remote work.
- Core Managers/Technical Directors may be allowed time for professional development activities at the discretion of the Core Director and with prior approval. Funds may or may not be available to support professional development opportunities.
- Responsibilities include: prioritization of excellent customer service, facilitation of educational opportunities; providing training to new users; assistance in troubleshooting for clients; review of invoices to ensure accuracy; annual review of maintenance contracts; financial oversight of revenue and expenditures; communication of invoices to the PIs, appropriate Director and administrator each month; tracking of usage data by capability and user; communication about experimental feasibility, turnaround time and other experimental outcomes for specific projects, when applicable; marketing of core capabilities to both internal and external users; ensuring accuracy of website content in coordination with the Director; maintenance of equipment; and any other miscellaneous tasks related to core functions as assigned by the Director
- Core Managers/Technical Directors are required to keep a lab notebook or equivalent for assisted experiments or when the client is paying the core to complete the experiment.
- Core Managers/Technical Directors should establish and manage a Research Resource ID
 - https://scicrunch.org/resources/about/resource
- To ensure the Core Manager/Technical Director is fully utilized, he/she may be cross-trained to the other core facilities. This will not only provide back-up during requested time off but also ensure the core managers/technical directors can refer to appropriate cores when

necessary.

Regular meetings with all core staff, as facilitated by the Directors or Administration

Core Administrator

- Responsibilities include: financial oversight of the cores; payment processing; tracking core usage data; communication to core directors concerning financial or operational concerns or updates
- The Core Administrator is under the oversight of the Director of Research Compliance and should also report any major issues to the Associate Dean for Research.
- There is no expressed confidentiality assumed by the core or the core operator for any core instrument. However, if user confidentiality is desired, users must provide a written request to the core director at least one week prior to equipment usage.
- Where competition for equipment/services access occurs, the Core Facility Oversight Committee or Core Director may prioritize funded research before unfunded activity.
- Cores will operate with regular hours and ensure the hours are publicly posted.
- Establishment of a new core or new core capabilities
 - Funding to establish a new core facility will typically arise from revenues, grant funding mechanisms and/or institutional funding.
 - A brief proposal for a new core or to purchase a new capability should be prepared by the prospective Core Director or the interested faculty describing the need for the new core or capability. The proposal should contain an estimate of expected costs, potential users, grants that would be supported, and a general rationale for the purchase. These proposals will be reviewed and discussed by the Core Facility Oversight Committee who will then make recommendations to the dean.
- Cores may not generate a profit and are expected to be subsidized by the administration. The long-term financial goal of each core is to recoup nonlabor costs of the core through user fees and grants.
- Core facility rates will be set by the Associate Dean for Research and the Core Facility
 Oversight Committee based on input from the Core Director to ensure standardization
 of charges. The majority of the capabilities should have a fee-for-service structure.
 - When applicable, core usage rates will be set at the following 4 categories:
 Internal Assisted, Internal Unassisted, External Assisted, External Unassisted
 - External rates are expected to be higher than internal rates and should be publicly posted.
 - The Core Managers/Technical Directors will provide time, free of charge, to consult on a project and develop a plan for conducting the research. After the initial meeting, the Core Manager/Technical Director will provide the customer with an outline of the research plan, along with an estimate of hours to complete the project, the corresponding price, when billing will start and what will be charged (including supplies, if applicable). The customer must agree to the plan and pricing prior to the work being initiated. Both the estimate of

work/cost and the customer agreement should be documented. If the estimate of work/cost increases over the course of the project, the customer must be notified before going over the estimate. The customer must agree in writing before the project proceeds.

- Vouchers for use of a core will be made available to CU faculty who lack funds (grants, start-up, or indirect cost funds, for example) for the proposed use. Vouchers are for use of the facility, not to include purchase of any necessary reagents. Approval of voucher requests occurs using the following process:
 - Users request a core voucher from the Core Manager or obtain it from the website.
 - Users complete the core voucher application, which includes information about their project and the amount of funding they are requesting.
 - The application is then reviewed by the Core Director and two other Core Directors for approval.
 - Users are notified by the Core Manager upon decision of approval or disapproval of the request.
 - Users receive invoices to track voucher usage but will not be billed.
- All fee schedules are available upon request and are also available on the core webpage.

Reservation System

- All use of core capabilities must be scheduled by the user in advance on the reservation system http://reservations.creighton.edu/
- If a reserved time is not used or is cancelled less than 24 hours before the scheduled time, the user will be charged at the normal rate. An exception may be made in case of equipment malfunction, university closure or other emergencies.
- Users are charged for core facility usage that exceeds their reserved times.
- Timely cancellation is strongly encouraged to allow other users access to the core capability.
- Programmatic grants establishing core capabilities may require priority access to those
 capabilities for the term of the grant, subject to approval by the administration prior to
 grant submission. In such cases, if the facilities are not booked within 48 hours of the
 scheduled time, then the facility will be available for reservation by any qualified user.
 Priority scheduling and access for such programmatic grants is limited to 75% of normal
 work hours to allow for availability to other users.

Training of Users

Each potential independent user must receive required training on the core facility
equipment, regardless of whether other members of a lab have already been trained.
The first 2 hours of training will be free to facilitate the educational nature of our cores.
Beyond the first 2 hours per capability, users will be charged using the assisted rate fee
for the instrument, at the discretion of the Core Director.

Authorship/Acknowledgements

• Usage of the Cores should be acknowledged in research publications and when appropriate, authorship considered for core facility personnel.

Core Facility Oversight Committee (CFOC)

- The CFOC plays an essential role in the effective oversight of the core facilities.
- Comprised of the Core Directors, Core Administrator, and the Associate Dean for Research, who chairs the meetings. Voting members include the Associate Dean for Research and the Core Directors.
- Ordinarily meets monthly.
- The CFOC plays an important role in making recommendations to the Associate Dean for Research and dean regarding the cores. Responsibilities of the CFOC include:
 - Vetting New Core Facility or core capability requests
 - Facilitating application for extramural funding of core equipment purchases.
 - o Review of core usage and the viability of cores and core capabilities
 - Setting rates for internal and external users
 - Review of maintenance contracts
- Each quarter, representative users are invited to the CFOC meeting for a discussion of user needs and concerns and to communicate changes in core facility operation or capacity.

Responsibilities of Users

- Complete required training and sign the user agreement for each core before accessing it independently. Users are not allowed to enter the facility using someone else's card access. Core Managers grant independent access to the facilities.
- Reserve time on the reservation system in advance of use of fee-for-service capabilities.
- Provide their Fund and Organization numbers prior to any core equipment usage to facilitate billing.
- Save their data and removing it from the core in a timely manner.
 - All core data collected is subject to removal after 6 months or with notification from the Core Manager or Administrative Staff
- Cancel any unneeded reservation at least 24 hours in advance to avoid charges.
- Complete biosafety forms if necessary to inform core facility staff of experimental protocols and sample origin to assess and address potential biosafety concerns.
- Responsible use of the cores. Users are expected to be good lab citizens by cleaning up after themselves, logging off equipment at end of use, following core guidelines and being respectful of core personnel and other users. Violation of these expectations are subject to penalties described below:

Consequences of violation of core guidelines by users

• First offense: Written notification of violation of core policies sent to user and PI in a timely manner, with information concerning the details of the violation. Users are

- invited to discuss policies with the core personnel. The Core Director will be included in this initial communication.
- Second offense: A conversation will be scheduled with the user, PI, Core Manager, and Core Director to discuss the violation of core policies and explain further consequences if the problems persist. A summary of this discussion will be provided in writing to the Office of Research and all participants.
- Third offense: Documentation of violations will be sent to user and PI informing them that the user can no longer access the facilities until completion of an agreed upon retraining plan. The user, PI, Core Manager, and Core Director will collaboratively determine the retraining plan, which may incur additional fees, and expectations of future use, which will be sent to all participants in the discussion and the Associate Dean for Research. Completion of the retraining plan should be documented by the Core Director and written permission obtained by the user prior to restarting core use. All access will be revoked.
- Permanent revocation of access is at the discretion of the Core Facility Oversight Committee.

Process for handling user concerns.

Core facilities are expected to provide excellent customer service, maintain well-functioning cores, and enable acquisition of research data by users.

- If a core capability stops working while you are using it, please contact the Core Manager as soon as possible to resolve the issue.
- For issues regarding billing, please consult the Core Manager.
- For problems and complaints regarding the cores, please consult the Core Manager and/or Core Director.
- For issues with completion time of a project, please consult the Core Director.
- If issues cannot be resolved with communication with core personnel, the problem should be taken to the next higher level of oversight- Core Manager, Core Director, and then the Associate Dean for Research and CFOC.
- For problems and complaints regarding the cores that are not resolved after consultation with the appropriate Core Director, please escalate to the Associate Dean for Research in a timely manner Corrective action and consequences may accrue for repeated and serious deficiencies.
- If you suspect research misconduct, please report issues to the Director of Research Compliance or Creighton's anonymous hotline by phone at 855-256-0478 or from the following website: https://secure.ethicspoint.com/domain/media/en/gui/43718/.

ADMINISTRATION AND INTERPRETATIONS

This guideline is under the authority of the Associate Dean for Research.