



**National Center for
Research Resources**

NATIONAL INSTITUTES OF HEALTH

The Efficient Management and Utilization of Core Facilities

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Executive Summary

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Introduction

Core facilities funded by the National Institutes of Health (NIH) as well as other federal agencies, are increasing in number, complexity, and cost. In order to address the issues of cost efficiency and management, the National Center for Research Resources and the NIH Director's Office of Extramural Research convened a two-day conference in July 2009 to focus on the following areas: finding and accessing core facilities, addressing NIH policies as well as the Office of Management and Budget Circular A21, providing training opportunities for core directors, improving management of core facilities at the institutional level, and considering quality improvement in core facilities.

For the purposes of this conference, a core facility is defined as a centralized, shared resource that provides scientific investigators with access to instruments; technologies; services; cellular, animal or human study support; and expert consultation.

Finding and Accessing Core Facilities

Challenges:

- Absence of a central database to provide location of core facilities and cost of services
- Need for potential users to have information on:
 - Quality of services
 - Sample preparation, transport, and storage
 - Proper utilization of cores

Possible Solutions:

- Institute Material Transfer Agreements (MTAs) to clarify ownership and ensure trust
- Conduct external reviews of usage by funding agencies as an incentive to encourage use
- Provide funding for the development of a self-sustaining central database of core facilities
- Provide educational opportunities for potential users

Federal Government Policies and Requirements: NIH and OMB

NIH Policies:

Challenges:

- Restrictions by some NIH Institutes on use of their funded cores
- Requirements for creation of stand-alone centers
- Absence of:
 - Incentives to promote utilization
 - Standardized policies regarding funding for salary and services of core managers

- Standardized reporting requirements to NIH Institutes and Centers and to other agencies such as the National Science Foundation

Possible Solutions:

- Promote the following principles for cores by all funding institutions:
 - Full utilization
 - Collaboration and sharing of equipment
 - Consistency, harmonization and integration of operations
 - Consolidation or leveraging of resources
- Consider establishing a central body that would develop benchmarking, auditing and rating standards; guidance regarding user fees and cost recovery across NIH programs
- Include incentives for sharing, leveraging, and financial independence in funding announcements
- Address conflicting NIH policies
- Support interagency (NIH, NSF, Departments of Defense and Energy, etc.) cooperation so that cores serve all investigators and can improve cost recovery
- Promote uniform reporting requirements

Interpreting OMB Circular A21:

The Office of Management and Budget, an Executive Branch agency, regulates the management of all NIH grants and contracts. The regulations for core facilities are contained in Circular A21, “Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements with Educational Institutions.”

Challenges:

- Cores are not allowed to depreciate federally funded high-end equipment. The value of a high-tech instrument is essentially eliminated in three years. This places a burden on cores in terms of equipment costs
- Cores are not allowed to make a profit or develop a capital reserve. Without a sustainable fund, cores need regulatory relief or support through crisis management
- Lack of standardized interpretation of Circular A21 among institutions

Possible Solutions:

- Provide education and communication about the institutional interpretation of A-21 to faculty and staff
- Increase allowable rates for the cost of administration
- Allow the direct charge of purchases of capital equipment to the core operating fund
- Increase the maximum annual activity that is currently accepted as the definition of a specialized service center

Management of Cores

Managing cores places significant responsibility on the department, school or college, or institution level. There are multiple models for core management, all with advantages and drawbacks. Institutions need to consider for their core facilities if university-wide, centralized billing infrastructure or other university-wide infrastructure would increase the efficiency of a core.

Challenges:

- Deciding on centralized vs. de-centralized management
- Reorganizing duplicative core facilities within an institution or region
- Developing appropriate management systems for each newly-funded core
- Accessing software that can be utilized for core management

Possible Solutions:

- Develop institutional and regional “tiered” services to promote sharing and avoid duplication
- Promote and incentivize resource sharing, partnership and collaboration
- Develop measures for evaluation and accountability
- Support the creation of a comprehensive business plan
- Provide guidance to help with the costs of contracting service
- Share model systems that cores could use to optimize their management systems
- Provide funding for software development for core management

Training for Core Facility Directors

Highly qualified and well-trained core directors are essential for the efficiency and value of the core resource.

Challenges:

- Absence of:
 - A well-defined career path and funding for core directors or “resource scientists”
 - Well-defined training courses for core directors that could lead to certification
 - A designated institution/organization to provide certification of core directors

Possible Solutions:

- Fund the development of training courses that would include instruction for building capacity for translational research, fostering research by providing state-of-the-art technologies, and maximizing partnerships

- Provide education on standard business management skills to core directors. Courses could include information on writing a business plan; developing marketing strategies; and planning, purchasing, and managing an inventory
- Consider building on the following programs as models for training courses: the Howard Hughes program, “Partners in Scientific Management Training”; “Lab Manager Boot Camp: Be a Better Manager,” sponsored by the Laboratory Management Institute; the Association of Biomolecular Resource Facilities workshops; “Core Managers Workshop,” sponsored by the Great Lakes International Imaging and Flow Cytometry Association; and a forum sponsored by the Association of Lab Managers
- Develop training programs that would lead to certification by a recognized authority

Quality Improvement Activities in Cores

Challenges:

- Absence of an evaluation requirement and certification for funded core facilities
- Absence of metrics specific to each type of core to assess quality
- Potential need for additional staff to track and report metrics

Possible Solutions:

- Develop metrics to be used by funding agencies in assessing core quality and value. Metrics should include scientific outcomes, such as publications, cross-disciplinary research and partnerships
- Engage all stakeholders in efforts to improve quality
- Include quality improvement measures in criteria to be reviewed by study sections

Quality Improvement in Clinical Research Cores

There is a question whether Clinical Laboratory Improvement Amendments (CLIA) certification is useful. The College of American Pathologists (CAP) could play a role in certification of clinical research cores.

Challenges:

- No certification is required of cores that provide data utilized in clinical research cores
- Requirements of clinical research cores vary by funding institution
- Cores performing analyses with material from human subjects have increased complexity and costs

Possible Solutions:

- Consider CLIA certification (or other certification) of a core clinical research laboratory
- Develop institutional review board (IRB)–approved language at the time the protocol for human subjects is created to state if participants will be informed of results

- Consider the potential for clinical translation of a test at the outset of a project in order to avoid retesting if the laboratory is not CLIA certified

Summary: Next Steps

The NCRR, working with other NIH staff and representation from the extramural community, will use the information and challenges outlined from this meeting to develop the most appropriate actions and a plan for moving forward. Actions may include:

- Preparation of funding opportunity announcements to
 - Merge core resources, when appropriate
 - Develop course materials
 - Support a core resource directory
 - Support the development of core management software
- Discussions with OMB with representation that includes extramural grantees as well as NIH staff regarding A21 interpretation
- Continuation of dialogue with core resource stakeholders