

The Efficient Management and Utilization of Core Facilities

**Sponsored by the National Center for Research Resources
and
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Final Workshop Report

For More Information Contact:

Gregory Farber, Ph.D.
Deputy Director, Office of Extramural Activities
National Center for Research Resources
6701 Democracy Boulevard, MSC 4874
Bethesda, MD 20892-4874 (20817 for express mail)
Tel: 301 435 0778
E-Mail: farberg@mail.nih.gov

Louise E. Ramm, Ph.D.
Deputy Director, National Center for Research Resources
6701 Democracy Boulevard, MSC 4874
Bethesda, MD 20892-4874 (20817 for express mail)
Tel: 301 435 0879
E-Mail: ramml@mail.nih.gov

Sylvia L. Parsons
Program Analyst, Office of Science Policy
National Center for Research Resources
6701 Democracy Boulevard, MSC 4874
Bethesda, MD 20892-4874 (20817 for express mail)
Tel: 301 435 0860
E-Mail: parsonss@mail.nih.gov

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THE EFFICIENT MANAGEMENT AND UTILIZATION OF CORE FACILITIES

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Background

Medical research must keep pace with scientific opportunity despite challenging funding environments. Cost-efficiency is crucial, and sharing expensive “core” resources — often cutting-edge tools otherwise difficult to find or afford — is one way to achieve this goal. A core facility is a centralized, shared resource that provides scientific investigators with access to instruments; technologies; services; cellular, animal or human study support; and expert consultation.

Anecdotal reports of overlapping cores at institutions, the impact of federal policies, and questions of quality and access led NCRR to issue a request for information (RFI) (<http://grants.nih.gov/grants/guide/notice-files/NOT-RR-09-003.html>) earlier this year that solicited input from the extramural research community on its challenges and experiences with research cores. As part of this effort, a public meeting was also planned to explore issues that were raised in responses to the RFI.

Summary

The purpose of this conference was to discuss the state of existing NIH-funded research core facilities, identify common problems encountered during their operation and use, and raise options to maximize the use and efficiency of core facilities. The conference brought together some of the leading administrators, researchers and government officials in the area of state-of-the-art core facilities, giving them the opportunity to exchange ideas, share experiences, and think together about ways to more effectively and efficiently use these invaluable resources.

Sessions took place on access to core facilities, current policies that support or hinder the use of cores, cost-recovery challenges, improving the management of core facilities, and measuring and improving the quality of services.

The primary outcome of this meeting was a set of actions for NIH and the scientific community to consider. They focused on: 1) implementing standards; 2) supporting development and sustainability through planning grants and career training grants; 3) supporting both equipment and personnel in core grants; 4) promoting full utilization of core facilities; 5) supporting collaboration; and 6) supporting consistency and harmonization.

Day One: Tuesday, July 14, 2009

Welcome and Opening Remarks

Barbara Alving, M.D., Director, NCRR, welcomed all participants and guests to the conference. She explained that this meeting was planned to further address feedback from those who responded to NCRR's RFI and from recipients of Institutional Development Awards (IDeA), Clinical and Translational Science Awards, and other programs. Dr. Alving stressed that efficiency and synergy are critical in the current economic environment and that it is more important than ever that resources and responsibilities be shared. She then thanked the organizers of the meeting — Dr. Greg Farber, Dr. Louise Ramm and Sylvia Parsons — and the institutes and centers that contributed.

Mark O. Lively, III, Ph.D., Director, Molecular Genetics Program, Wake Forest University School of Medicine, and NCRR Council Member, told participants that this is an opportunity for NCRR to hear from the community. A survey described in a recent issue of the *Journal of Biomolecular Techniques* found that most challenges faced by scientific core facilities are related to funding.

Sally Rockey, Ph.D., Acting NIH Deputy Director for Extramural Research, described core facilities as a valued and critical part of extramural research that fosters strong partnerships with extramural researchers. The success of core facilities is currently based on the skills of those in leadership roles. She charged the participants to:

- Consider ways to expand the model of core facilities beyond instrumentation and hardware.
- Consider mechanisms that would provide support to all core facilities.
- Focus on how to improve institutional commitment to core facilities.
- Address the challenges faced by core facilities in the current economic situation.
- Identify ways to optimize the facilities' efficiency and effectiveness.
- Discuss ways to harmonize the operations of core facilities in order to reduce the complexity of NIH requirements as well as other federal, state and local requirements and to simplify financial and reporting obligations.

Dr. Rockey asked participants for creative solutions to the following questions:

- How do scientists get access to core facilities?
- Are the facilities impacted by institutional policies?
- What approaches constitute best practices and what are the impediments to these approaches?
- What should be the scope of core facilities — how many, regional or local, size and basic structure?
- How do we evaluate the program?

She concluded by pointing out the importance of identifying solutions at the grassroots level.

Session I: Finding Core Facilities and Access to Core Facilities

Question: How useful would a national registry of core facilities be? What is the present state of access to core facilities? Are core services available to outside researchers (outside the department or outside the institution)? Are regional cores useful?

Session Summary

This session stressed the importance of activities on the local, regional and national levels to improve networking among researchers and among facilities. Recommendations for establishing a national registry of core facilities were shared as were suggestions to improve the skills and expertise offered by core facilities.

Panelists and guests also shared a number of ideas that could help defray expenses for regional core facilities and at the same time promote their use, including the use of seed grants and vouchers and the employment of state funding and partnerships to cover the costs of salaries and service contracts.

Other recommendations regarding regional cores included:

- Institute Material Transfer Agreements (MTAs) to clarify ownership and ensure trust.
- Use tiered service to promote sharing and avoid duplication.
- Support employment at core facilities as a career track.
- Conduct external reviews of the use of core facilities to provide an incentive for the institution to encourage the use of cores.
- Address discrepancies between NIH policies and requirements for providing priority access.
- Improve accountability in Shared Instrumentation Grants (SIGs) by extending the funding cycle and requiring evaluations.

Presentations

Gregory K. Farber, Ph.D., Deputy Director for Extramural Activities, NCCR, moderated this session, starting with the following working definition of a core facility: “A centralized shared resource that provides access to instruments, technologies, and services, as well as expert consultation.” He reviewed the purpose of this meeting (see statement above) and expressed his thanks to those who made this meeting possible.

George Grills, Director of Operations of Core Facilities in the Life Sciences, Cornell University, described the Cornell University Life Sciences Core Laboratories Center and its outreach activities at the local, regional and national levels and then made a number of specific suggestions about how to improve efforts in networking and outreach.

The Cornell University Life Sciences Core Laboratories Center provides services for more than 100 institutions; however, 80% of the services are for Cornell researchers. The Center evaluates the needs of investigators, finds resources and funding, and has a process by which faculty can request new cores.

The Center also participates in a number of activities designed to reach potential core users and to network with other core facilities at the local level, including:

- Maintaining a Web site; listing on local, regional and national databases; posting on campus bulletin boards; holding workshops, seminars and symposia; participating in scientific meetings and user groups; and conducting user surveys.
- Hosting an annual Life Sciences Core Laboratories Center Exhibition, which features seminars, posters and other activities designed to inform researchers and others about the services offered by the Center.
- Encouraging faculty involvement through a Faculty Advisory Board for each core and for faculty members from across the university.

On a regional level, the Center at Cornell works with a number of important groups, including:

- The Academy for Medical Development and Collaboration, which provides many resources shared by member institutions in New York state.
- The Northeast Regional Life Sciences Core Directors (NERLSCD), which holds an annual meeting to allow core directors to network in the region.

At the national level, the Center is a member of the Association of Biomolecular Resource Facilities (ABRF), which hosts a directory of member facilities, research groups, an annual meeting, an electronic discussion group and more.

In response to the question of how to make it easier for potential users to find core facilities, Mr. Grills suggested that NIH offer funding opportunities to establish a national registry of life sciences core facilities that would leverage existing core registry resources. He also suggested a grant-funding program that would enable national networking of scientists and core resource facilities. Some existing core registry resources include:

- The ABRF Yellow Pages.
- The Vermont Genetics Network Core Facilities Database.
- VIVO, a semantic Web-based research discovery tool developed at Cornell University, which cross-links information about investigators, departments, graduate fields, research projects, core facilities and other research resources at the university.

To overcome other barriers, he suggested that funding institutions put policies into place for funding research grants that strongly encourage the sharing of core facilities both within and between institutions. These grants could include:

1. Matching grants for service contracts and salary costs.
2. Training grants for students and investigators to learn how to use core resources.
3. Research seed grants targeted for the use of core facility resources.

Tim Hunter, Manager of the University of Vermont's Vermont Cancer Center DNA Analysis Facility and the Vermont Genetics Network (VGN) Microarray Facility, explored a number of possibilities to help users find core facilities. He also identified several barriers to finding core facilities, including:

- Local barriers: No centralization, no single listing, no promotion or outreach.

- Regional or national barriers: No single comprehensive national repository exists with search capabilities.

Approaches that have helped researchers find out about core facilities include promotion, forums, networks and the use of other tools. Mr. Hunter identified the following specific forums where people can learn about core facilities: ABRF, NERLSCD, IDeA grantee meetings and specific technology forums. Other tools to find cores include:

- [Harvard Catalyst.](#)
- [University of California, San Francisco Cores Database](#)
- [Association of Biomolecular Resource Facilities Yellow Pages](#)
- [Vermont Genetics Network Core Facilities Database](#)
- [VIVO, a semantic Web-based research discovery tool, Cornell University](#)

On the local level, networking might occur via seminars, open houses, participation in the orientation of new PIs (principal investigators), high-visibility collaborations and demonstration projects. On the regional level, networking can occur through meetings as well as through the use of incentives and other efforts to promote the sharing of unique resources. At the national level, both meetings and a national registry would be effective strategies.

Mr. Hunter identified pricing and requirements for subsidies as challenges at the local level. At the regional and national levels, barriers include affordability (differential chargeback for external use), geography (should be local and easily accessible), Material Transfer Agreements (MTAs), intellectual property issues and administrative challenges (such as no mechanism for recovering external costs).

What is the solution? Mr. Hunter recommends:

- Making access to core facilities affordable for all levels of researchers (junior to senior).
- Providing salary support for core staff that is based on the need for the core, the base budget of those facilities, a business plan to recoup costs through fees for service and an evaluation plan.

In conclusion, there is a high level of interest in a national registry for core facilities. It may be best that inclusion be voluntary, with periodic updates and edits, and have the ability to filter data. There also need to be new approaches and open-door policies, pilot grants, centrally funded staff, standard MTAs and incentives to share.

Jonni S. Moore, Ph.D., Professor, Pathology and Laboratory Medicine; Director, Path BioResource; and Director, Abramson Cancer Center Flow Cytometry and Cell Sorting Shared Resource, University of Pennsylvania School of Medicine, opened her presentation with a proposal that the term “core facility” be changed to “resources laboratory” to reflect the importance of these facilities to science, service and educational missions. Similarly, “lab technician,” a term that does not denote a career path, should be revised to “resource scientist” to reflect the high skill level and advanced understanding of the science that is required by those who staff these facilities.

Dr. Moore then described strategies of both Path BioResource and the Abramson Cancer Center Flow Cytometry and Cell Sorting Shared Resource, the two facilities she directs at the University of Pennsylvania School of Medicine. Best practices at these facilities include:

- Recruiting and nurturing resource scientists with a high level of expertise.
- Centralizing resources to fund both instrumentation and staff.
- Educating PIs, along with the trainees and technical staff, in the science and technology of the resource lab.
- Getting the word out to increase accessibility of technology.

Specific educational activities include integrating education on technology into the academic curriculum, participating in the orientation of new faculty, collecting data on institutional technology, developing and hosting regional workshops, and providing educational support to local users. Using smart marketing approaches has also been a strength of this program.

Dr. Moore shared a number of helpful policies as well:

- Prohibit duplication of services.
- Require development of an active educational program.
- Define the role of the scientific director to include active consultation.
- Encourage participation of the staff in continuing education through national or regional organizations.
- Create an appropriate career path for resource staff.
- Support centralized and coordinated Web sites.
- Incorporate an orientation about the resource laboratory into the orientation of new faculty.

Dr. Moore proposes that these policies and practices be instituted in a regional shared resource laboratory to bring synergy, not competition, and to provide tiered services. Other specific recommendations for a regional center include:

- Discourage the duplication of facilities and encourage cooperation by policy and funding mechanisms to avoid excess instrumentation with a paucity of expertise.
- Develop a national registry for shared resource facilities that would be easily accessed through the NIH institute sites as well as NCRR.
- Support the renovation/construction of a centralized physical facility.
- Provide training grants in both technology and management of resource laboratories in academic settings.

Benefits of these regional cores would include:

- Lower cost for participating groups.
- Enticement for recruitment.
- Focus for funding and philanthropy.
- Focus for educational programs.
- Efficient use of federal funds to support more investigators.

Victoria Christian, Chief Operating Officer, Duke Translational Medicine Institute, described Duke's efforts to enable investigator access by establishing public-private partnerships, leveraging co-investment, and regionalizing key translational resources. She began by stating that cores face a challenge because of the obstacles, including:

- Cost.
- Attenuation of time, energy and attention.
- Allegiance to department of origin.
- Gaps in knowledge about available cores.
- The lack of a clear career path for those in laboratory resources.

Possible solutions to these obstacles include:

- Providing direct incentives to collaborate by raising money to support team science projects.
- Providing funding through pilot and other seed mechanisms to stimulate proposal development and promote inter-institutional and multidisciplinary science.
- Demonstrating the power of translational technologies and collaborative resources by communicating their impact in every possible way.

At Duke, facilitation of the resource cores is enhanced through:

- Assisting cores with workload.
- Building systems that enhance research (i.e., central sample preparation, facilitating biobanking, document control systems).
- Celebrating triumphs of team science in newsletters, research conferences, and seminars.
- Identifying external sources of investment.
- Providing vouchers for specialty core services to promote generation of preliminary data and working closely with core leadership to develop high-impact projects. This may be a more effective way to promote use of core resources than providing salary support to core personnel.

Ms. Christian supports the concept of regionalization, which, she said, has the potential to eliminate redundancy in research infrastructure and conserve investments by maintaining volume and efficiency. Potential side benefits could include more diversity in the collaborative landscape, more inter-institutional team science and a greater translational impact. Still, there are going to be obstacles, such as distrust of the collaborative process and fear that collaboration will add complexity. The best way to overcome these barriers, she suggested, is through well-designed, effectively managed demonstration projects that generate interesting data and demonstrate feasibility.

General Discussion

- The challenge of providing priority access to the centers while still being a viable resource for external researchers can be addressed by focusing on economies of scale and opportunities for collaboration.

- An important difficulty faced by the cores is the conflicting requirements to give priority to NIH grantees while also maintaining the lowest available cost for services. Participants discussed various solutions to this problem.
- Currently, NCRR's Shared Instrument Grants (SIGs) do not provide funding for staff and are only one-year awards; thus, core equipment may not be used to its fullest extent, and grantees face a crisis at the end of a funding period because of a lag before follow-up funding becomes available. Grantees would like these issues to be addressed by NIH. The National Science Foundation (NSF) and the state of New York have models that may be useful for supporting salary; it may be possible for NIH to work with state agencies to facilitate this type of funding.
- Without centralization, there is no assurance that an instrument is being shared (nor is oversight possible to see that it is). Centralization could allow the broad use of instruments. If some cores were regionalized, NIH could incentivize grantees to share instrumentation.
- Collaboration can lead to overuse of equipment, which can hamper a researcher's ability to conduct research. However, in this economy, more efficient use of equipment may trump agility.
- It may be preferable to establish primary, secondary and tertiary centers with specific areas of resources or expertise.
- Systems and memoranda of understanding are needed to assure the proper use of equipment.
- A centralized data center may be needed.
- The ability to provide vouchers for users raises a core's visibility and usage.
- Ownership and depreciation need to be considered; however, a grantee may not take depreciation of equipment that is purchased with federal funds.
- A national database needs to address changes in technology and requires a mechanism to automatically pull information from local databases.

Session II: NIH and Other Federal Government Policies and Requirements

Question: How do current NIH or federal policies (apart from OMB Circular A-21, "Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements with Educational Institutions") contribute to or inhibit the efficient and effective use of cores? What changes would improve core management?

Session Summary

This session allowed for a review of current NIH and other federal policies that affect the use of cores as well as recommendations for improving these policies. General principles that should be promoted, supported and possibly incentivized include:

- Full utilization.
- Collaboration and sharing of equipment.
- Consistency, harmonization and integration of operations.
- Consolidation or leveraging of resources.

Participants also asked that a central body consider developing (or supporting the development of):

- Benchmarking, audit and rating standards.
- Uniform guidance regarding user fees and cost recovery across NIH programs.
- Guidelines for interpreting federal policies and compliance.

Other funding mechanisms that would be useful include:

- Continued funding for facility construction and renovation and equipment.
- Planning grants and career training grants to support development and sustainability.
- Grant funding for both equipment and personnel.
- Generic funding opportunities so that the institution can request funding for what it needs to do.
- Seed grants to organizations that use core facilities and to junior faculty to fund pilot studies using core resources (but there is a need to watch the supply-and-demand aspects that could raise prices).

The following issues were also raised:

- The need for smooth operational funding that avoids leaving grantees without funding at the end of a cycle.
- Cores cannot bank funds in preparation for fluctuations in the price of services.
- The impact of subsidizing user fees on small core facilities that also provide consultation.
- The need for a mechanism to use local revenues to start up other types of technologies.
- An improved process to ensure full use of shared resources (SIGs).

Presentations

Mark Guyer, Ph.D., Director, Division of Extramural Research, National Human Genome Research Institute, moderated the second panel.

Valerie E. Scott, Senior Director of Scientific Services, The Jackson Laboratory, described The Jackson Laboratory, which was founded in 1929 and designated as a Cancer Center by the National Cancer Institute (NCI) in 1983. The Jackson Laboratory currently employs 1,340 people at campuses in Maine and California. She then described several challenging NIH policies and recommended policies that would help core facilities meet their mission to provide investigators access to comprehensive research support systems, including effectively managed, state-of-the-art facilities, technologies and dedicated expertise.

Policies and mechanisms that hamper the effectiveness of cores include:

- Limiting access to specific users.
- Requiring creation of stand-alone entities.
- Providing one-time support.
- Failing to emphasize best practices and standards.
- Accepting the status quo.
- Ignoring cost.

These policies can spawn redundancy, complicate fee structures, burden the collection of data on utilization, reduce space and operational efficiencies, and fail to fully leverage NIH's investment. On the other hand, policies that would encourage, reward and support the mission of core facilities would focus on the following:

- Best practices and operations through the adoption of standards and training.
- Effective operations with reporting requirements and meaningful review criteria.
- Regular assessment and accountability with meaningful descriptors of merit that address quality, ease of access, timeliness, cost-effectiveness, breadth of utilization and operational stability.

In reviewing applications, it was suggested that NIH develop descriptors of merit and criteria for evaluation on the role of the center in setting priorities, resource planning and oversight; the importance of services and technologies in relation to the scientific needs of the center; the qualifications of resource directors and technical staff; operational policies; and measures of cost-effectiveness. These might be modified or adopted for the collection of benchmarking data and could form the basis for an operational audit.

Guidelines to support well-used, healthy, stable core operations include:

- Assure baseline support of critical operations.
- Stop cliff-edge, nonrenewable funding for core operations.
- Incentivize financial independence.
- Recognize and reward breadth of utilization.
- Recognize and reward achievement of economies.

Ms. Scott also pointed to the importance of encouraging and supporting facility staff, possibly with a mechanism like the K awards, and recommended the adoption of new platforms and technologies through core planning grants and support of efforts in validation and implementation.

In summary, the recommendations posed by Ms. Scott include:

- Provide unlimited access to federally funded facilities.
- Conduct integrated, not stand-alone, operations.
- Implement standards (benchmarking, audit, rating).
- Conduct management training.
- Provide smooth operational funding (weaning, not the cliff edge).
- Provide continued funding for:
 - Facility construction and renovation.
 - Equipment funding.
 - Evolution of the facility and its technical capabilities.

Her presentation concluded with a reminder that each core has its own particular strengths that should be maximized.

Scott A. Ness, Ph.D., Professor, Molecular Genetics and Microbiology; Director, Keck-UNM (University of New Mexico) Genomics Resource; and Associate Director, Shared

Facilities, UNM Cancer Center (UNMCC), University of New Mexico Health Sciences Center, delivered a presentation titled, “Shared Resources: In Competition with NIH?”

Dr. Ness reviewed the UNMCC’s scope and services for patients and researchers. Shared resources of the UNMCC include genomics, fluorescence microscopy, flow cytometry and drug discovery, tissue repository and tissue analysis, biostatistics, bioinformatics and computational biology, animal models and imaging, human imaging, and clinical protocol and data management. Approximately one-half of the user base of the genomics core (Keck-UNM Genomics Resource [KUGR]) is from the UNMCC.

To maximize service quality, the KUGR is interested in the best possible service for its users. Thus, the core provides consultation at the pre-experiment, sample analysis and data analysis phases of research. Because of the cost of this individualized service, the core has high fixed costs as well as expensive instrumentation with large annual maintenance fees, and it must pay for expertise in instrumentation and data analysis. The cost for salaries (82% of the operating budget) comes primarily from institutional support and limited user fees.

Some NIH policies present unique challenges to smaller core facilities but could be corrected by a change in policy. For example, the funding by NIH of resources at an institution that competes with institutionally funded resources might be addressed with a national database that could be used to review the impact of existing resources. Also, currently NIH-funded consortia undercut rates, but this might be fixed if NIH could provide bulk-purchased gene chips to PIs to run and analyze at local shared resources or fuse funds to subsidize the use of local facilities. Finally, NIH incentives that limit users and make non-Cancer Center users a liability could be remedied if achievements rather than users are counted to indicate the value of shared resources and if use by all users is encouraged rather than limited.

Despite the current challenges, local shared resources provide a valuable service — they provide expertise for designing and implementing experiments with advanced technologies. They also provide unique services such as expert data analysis and data storage, and they help to train users in new, developing technologies. They provide all of this while remaining accountable to local users.

Dr. Ness summarized his position as follows:

- Shared resources are more than equipment.
- Specialized techniques require highly skilled personnel for operation and data analysis.
- NIH policies must support both equipment and personnel.
- Policies that promote full utilization help support all aspects of the shared resources.

Tesheia Johnson, M.B.A., M.H.S., Chief Operating Officer, Yale Center for Clinical Investigation, shared “The Yale Experience” in the efficient and effective use of cores. The philosophy of the Yale Center for Clinical Investigation has been to assure benefit to a broad base of users and not to break a system that is working. Yale’s Clinical and Translational Science Award (CTSA) philosophy is also to leverage all NIH and institutional support by collaborating or in some cases combining cores from other large center grants. The program at Yale also strives to break down research silos and promote collaboration. Ms. Johnson explained that she

feels that leveraging and breaking down silos have allowed innovative research without prohibitive costs.

Yale has experienced a number of issues related to NIH or federal funding of its cores. The first issue is related to pilot funding and new technology. Yale has found that, although pilot data are required if a grant submission is going to be successful, most cores operate through a chargeback to researchers using the facility. For many of these researchers, sufficient support for pilot studies is difficult to obtain because the operational cost per unit is quite high.

A second issue is related to fees for new users and inflation rates for core user fees on existing grants. Johnson noted that as grants are cut or institutional support is reduced, rates must be increased, and then users can no longer afford the services of the cores. She noted that budgets have been flat for five years, which is a strain on everyone.

The third issue is the need to find sufficient funding every year for worn-out instrumentation. These costs can be quite high. For example, it is estimated that \$3.8 million is needed annually just to replace worn-out instrumentation in the Yale Keck Facility.

Three issues related to the efficient and effective use of cores were also described: reporting, ownership and user fees. In terms of reporting, the differing reporting requirements of NIH and its institutes require multiple requests from the core or its investigators of its usage and progress. Ownership and collaboration are also difficult to foster when, at renewal/review, centers are judged harshly for not being in control of a resource they cannot control. Finally, it is not clear how members from contributing grants/centers can receive a discount when all NIH projects are required to pay the same rate.

Ms. Johnson concluded with three recommendations:

- Reporting and evaluation requirements should be harmonized so that institutions can prepare a single report that details their accomplishments.
- The institutes should encourage consolidation or leverage resources in announcements and RFAs.
- There should be standard and clear guidance regarding user fees and cost recovery across NIH programs.

General Discussion

- Asked about breaking down silos at NIH, Dr. Farber explained that with 27 institutes and centers, coordination is difficult. Dr. Alving added that what might be needed are generic ways that institutions can request funding for what they want to do.
- Seed grants can be given to other organizations or to junior faculty to fund pilot studies using core resources.
- Because of the principles of subsidization, it is better to pump money into the cores, which will lower cost and increase demand, than to pump money into the users, which will increase cost and demand.

- Asked about the process for handling rate increases, Dr. Ness explained that price changes are implemented yearly and that at times the core must ask the chair of research for institutional support. This is not a great solution. Ms. Johnson said that Yale looks at user impact and grandfather in existing projects for a fixed duration to allow grant funding to catch up. Ness pointed out that cost recovery depends on use. The panel also noted that cores cannot bank funds, and they are sometimes faced with the dilemma of maintaining purchasing power by funding fewer grants.
- Subsidized user fees can impact cores because researchers will shop for the best price and quality, but cores cannot compete when the services are offered for free. Investigators go to one core to receive the resources for free but then go to another center and ask for consultation when the free service fails. Because of the institutional culture, there has traditionally been no charge for this consultation. This might be remedied if equipment is shared, if start-up packages for new investigators are leveraged, and if a campus “core czar” can be funded to consolidate core facilities in a way that would recognize all contributions. This is difficult from a grant perspective.
- Stony Brook University (New York) has had success in putting highly-specialized equipment in core facilities. Although there has been some tug-of-war around this, it has forced transparency.
- Privatization is a natural process, and there is a role for commercial competition. However, discomfort was expressed about international competition, which was considered unfair.
- It was suggested that NIH consider a mechanism to use local revenues to start up other types of technologies.
- NCRR may consider a change to the SIGs that go to groups of three investigators. However, NCRR needs to be sure that those investigators will use the instruments to capacity and, if not, it needs to know how they will make them useful to their users. A progress report may be required, but this would be an additional burden on the grantee.
- The discussion of how a core might encourage the interaction of core faculty prompted a suggestion that the core charge for biostatistical consultation and require it in some cases. This may require a culture change, with users now expected to pay for expertise as well as equipment.

Day Two: Wednesday, July 15, 2009

Session III: Cost Recovery

Question: Cost recovery has become a key component of managing core facilities. What are the best practices to negotiate OMB Circular A-21? What impact does complying with A-21 have on core facilities?

Session Summary

Background: The Office of Management and Budget (OMB) is an agency of the executive branch of the U.S. government that assists the President in overseeing the preparation of the federal budget and supervises its administration in executive branch agencies. One of OMB's responsibilities is establishing government-wide grants management policies and guidelines through circulars and common rules. These policies are adopted by each grant-making agency and inserted into its federal regulations. One of the OMB circulars, designated A-21, is titled "*Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements with Educational Institutions.*" The cost principles in A-21 provide the general accounting "rules" for colleges and universities. These principles define the costs that are allowable and allocable to the federal government.

In addressing the issues related to cost recovery and the requirements set forth by OMB A-21, panelists and participants identified the following challenges:

- Cores are not allowed to depreciate federally funded high-end equipment, and there is a problem in finding funds to replace this equipment.
- The value of a high-tech instrument is often gone in three years, not five.
- 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.

A number of recommendations and suggestions were also shared, including:

- Providing education and communication about the institutional interpretation of A-21 to faculty and staff.
- Ending the system of discounts offered to center members — there should be a rule of one service, one price. NIH policy should clearly reflect this.
- Developing a system of credit to address both compliance and program concerns by handing out scholarships.
- Increasing the maximum annual activity currently accepted as the definition of a specialized center.
- Increasing allowable rates for the cost of administration.
- Allowing the direct charging of capital equipment purchases to the core operating fund.
- Developing a consistent reporting system for users and rate payers.
- Improving cost recovery by increasing interagency cooperation (NIH, NSF).

Presentations

Joe Ellis, Director, Office of Policy for Extramural Research Administration, NIH Office of Extramural Research, moderated this session. He explained the cost-reimbursement mechanism used by most programs of NIH.

Kelvin Lee, Ph.D., Director, Delaware Biotechnology Institute, University of Delaware, focused on A-21 compliance and management of the core facility from the perspective of a core customer, faculty mentor, administrator and proteomics core facilitator.

In terms of A-21 compliance, Dr. Lee explained the relationship between the research and academic side of a university and the finance/administration side. Sponsors need to communicate with both groups. Because A-21 lays out the principles for determining costs applicable to

grants, contracts and other agreements with educational institutions, these parties are all involved in ensuring that compliance is met, although the expertise tends to reside with those on the administration side.

Although there is a level of institutional interpretation in all of the areas listed below, A-21 does include provisions for:

- Allowable and unallowable costs.
- Determination of costs/fees.
- Calculation of costs for facilities and administration (F&A).
- Specialized service facilities.
- Provisions for the same rate for the same service.
- General administrative costs.

Dr. Lee described a particular challenge faced by institutions that need to comply with A-21: the recovery of administrative costs. Centralization provides efficiency, minimizes risk and supports the mission, but it requires funding at the institutional level for administration. These costs are difficult to absorb centrally because A-21 does not allow the recovery of costs related to administration. Lee provided three suggestions for addressing this challenge:

- Allow the direct charge of core facility administration costs.
- Encourage the education of upper administration about the benefits and issues related to core facilities.
- Encourage communication about A-21 and the institutional interpretation of A-21 with relevant faculty and staff.

He concluded by encouraging the establishment of regional cores, which could provide a solution to many of the cost-recovery challenges faced by technology cores today.

John Manning, Ph.D., M.B.A., Associate Vice Chancellor for Health Affairs, Vanderbilt University Medical Center, provided an administrative perspective on cost recovery from the shared resources program at Vanderbilt University Medical Center.

At Vanderbilt, science is at the heart of every core laboratory, and cores provide a cost-effective way to conduct high-quality, state-of-the art research. Shared resources also promote new science and support young investigators while allowing for cutting-edge technology and high-end instrumentation as well as the expertise provided by highly trained staff.

Dr. Manning identified several issues that institutions like Vanderbilt face that impede cost recovery. First, A-21 requires that each federally funded investigator pay the same price for the same service. At the same time, programs often expect cores to offer discounted prices to center members who use NIH program-supported cores. This causes problems because there is a conflict between the requirement to charge the same price to all users and the providing of a discount to members. A center with more members is then required to subsidize fees to recover costs for nonmembers. Conflicts between compliance and expectations of the program can limit access to cores, result in multiple operating units and increase administrative burden.

Recommendations:

- Educate core managers and administrators in the development of consistent fees for services.
- End the system of discounts offered to center members (one service, one price).
- Develop a system of credits to address both compliance and programmatic concerns.

There are also challenges with grants management. Awards often specify costs for personnel, service contracts or the purchase of equipment, but core service fees may not be recognized as an allowable direct cost. However, a core may have the technical personnel and equipment to accomplish the project's goals more efficiently and with less expense.

Recommendations:

- Develop a consistent system to manage the recording of core charges and revenues.
- Educate grants managers and administrators.

The biggest challenge to grants management is still the reconciling of varying directives from the funding programs or agencies (e.g., NIH vs. NSF).

Cost-recovery issues that institutions still face include capped indirect costs, increasing institutional subsidies and requirements for designation as a specialized service center. Dr. Manning explained that NIH caps indirect costs, which means that core activity increases overall administrative costs, and highly functioning cores increase the institutional subsidy for research. However, increasing the institutional subsidy of research/core facilities makes a core less attractive to nonmember users. Every year, more cores meet the working definition of a specialized service center (more than \$1 million of activity each year), but service fees to recover full cost are prohibitive, and it will become increasingly difficult to subsidize users.

To sustain core facilities in this climate is challenging and requires dedicated oversight of a core's development, operations and fund balances. It also requires tolerating a surplus in the fund balance. Outreach, training opportunities and education within core facilities can also help. Dr. Manning stated his belief that in the current climate, institutional subsidy is a necessity. Successful core facilities must do more than subsist if they are going to allow the development of resources for scientific and technical growth. They must develop new techniques, offer cutting-edge equipment and provide expertise. Dr. Manning made a number of suggestions for NIH:

- Issue a guide to operating core facilities in compliance with A-21.
- Support interagency cooperation so that cores serve all investigators (NIH, NSF, Department of Defense, Department of Energy, etc.).
- 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 (e.g., to \$3 million).
- Encourage program officers and peer review committees to recognize that the best cores serve multiple programs.

- Promote diversity of use and technology.
- Increase the NIH cap on the administrative cost portion of indirect cost rates.

Gilbert Tran, Office of Federal Financial Management, OMB, provided the federal perspective in a presentation titled, “The Garden of Grants: An OMB Update.” Mr. Tran reminded participants that OMB needs to make sure that money is being well spent.

Mr. Tran described the pyramid of grant requirements. These requirements start with congressional appropriation and authorization (which dictates such items as salary caps). OMB circulars that guide operations in the government are then formulated, based on the statutes. Next in line are agency program regulations, guidance, policy manuals, and terms and conditions.

OMB circulars fall into three categories: cost principles (which include A-21 for colleges and universities), administrative requirements (which cover both government and everyone else) and audit requirements (with which everyone must comply).

The A-21 circular provides guidelines used to determine whether a cost can or cannot be reimbursed based on what is fair and reasonable to charge the government. It covers the areas of cost allowability, direct and indirect costs, and allocation of indirect costs. Mr. Tran explained that if a specific item is not covered in the circular, the guideline to follow is whether it is “reasonable, allocable and allowable” (RAA).

He concluded by asking for more detail on areas that had already been touched on in the meeting or in written responses to the Request for Information (RFI), specifically the minimum requirements for specialized service centers and the issue related to charges for administrative costs.

General Discussion

- The basic rule of A-21 is that an institution cannot charge the government more than it charges other users.
- A-21 does allow depreciation, but depreciation cannot be claimed for any part of equipment that was purchased using federal funds.
- Replacement costs cannot be bundled into a user fee; replacement costs are the responsibility of the institution. Similarly, a reserve cannot be set up with federal funds.
- Currently, a core grant cannot be used to subsidize user fees, which is a real concern for cores, as institutions generally cannot afford to cover subsidies.
- While scholarships have been used in place of subsidies, it is not clear that these are in compliance with A-21.
- A fee structure can be based on the whole center so that one core can support another if costs can be tracked from the main core to the sub-core. The key is to assure allocable costs. The audit is looking to see that a cost is not charged twice.
- It is a myth that external users need to be charged the overhead rate. In fact, all users may be charged the discounted rate. However, the institution is then required to cover overhead costs.
- Replacement costs need to be covered by the institution except in specialized centers, where depreciation may be calculated into the rate.

Session IV: Management of Cores

Question: Management of cores can place significant responsibility at the department, school or college, or institution level. What are the advantages and disadvantages of each of these management models? Does a university-wide, centralized billing infrastructure or other university-wide infrastructure increase the efficiency of a core? Should there be guidelines or standards for the size of cores? In cases where the consolidation of cores is necessary, are there good models for taking this action?

Session Summary

This session focused on a variety of models that are now in use at core facilities and on business concepts that can help cores make management decisions. The overarching message was that no one model will be right for all cores.

Business concepts that can be used to help make tough decisions and to manage cores effectively include data interrogation to identify problems; analysis of demand curves; supply/service reduction; risks and rewards of outsourcing; and considerations for termination versus platform integration. In terms of a management structure that would support core directors and the core facility, the following roles were identified:

- Program director in the administration: serves as an advocate for core facilities.
- Financial analyst: assists in reporting, billing and rendering advice.
- Administrative specialist: supports the centralized Web site and marketing.
- Financial support and subsidy: assist with the submission of grants.

When determining the best management model for a core (centralized, decentralized, center based, institution based, partnership/collaboration, etc.), the following parameters need to be considered:

- The potential for improved quality of service.
- The needs of the investigator community and the potential for collaboration.
- Scope of the available core's services.
- Resources available for needed instruments and facilities.
- Potential for cost savings.
- Benefits of flexible funding sources.
- Potential to reduce burden.
- Staffing considerations.
- Needs for long-term maintenance.
- Potential for Web-based reporting/accounting.
- Risks/benefits of centralized billing.

Key ideas were presented for ways that NCRR/NIH could support core business practices:

- Promote and incentivize resource sharing, partnership and collaboration.
- Provide software support for core management.
- 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.

Presentations

Robert Carter, Ph.D., Deputy Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases, moderated this panel.

Richard Hichwa, Ph.D., Associate Vice President for Research, University of Iowa, explained the driving forces for resource sharing, barriers to sharing, and what NCRR can do to encourage interinstitutional and intra-institutional sharing. He also stressed the importance of sustainability as well as of “sunsetting” a resource that is no longer needed.

Resource sharing is an institutionally provided service, activity or function that is required by a number of investigators, which can in principle be sustained by external funding or user fees for the conduct of research. The driving forces for creating resource sharing include external funding, a PI consortium, strategic recruitment (sustainability is key), existing resource consolidation/facility redesign, an institutional focus (grand initiatives) and funding consequences such as a Clinical and Translational Science Award. Similarly, there are valid reasons for closing a shared resource, including the departure of PIs or faculty users, unsustainable funding, evolving or eclipsed technology, changes in institutional governance, and competition between internal and external resources. These decisions are made by the institution.

Cores serve a variety of functions and need to balance their revenue with their expenses, just like any viable business venture. Common functions include data acquisition, data analysis, education and training, biostatistics, dissemination, marketing, system maintenance, development, and planning for obsolescence. Revenue can come from grants or recharge fees. Expenses include director supplies, equipment maintenance and service, travel, reports, outreach, and dissemination. Dr. Hichwa noted that it is important to realize that no core is self-sufficient.

Why are resources not shared more? These are some of the barriers:

- Perception that the resource is too difficult to use, far away or complicated.
- “Not invented here” syndrome.
- Lack of clarity about how to handle schemes for interinstitutional charges.
- Issues of regulatory compliance.
- Concern about timeliness.
- Perception that there is no incentive to cooperate.
- Time, costs and access.
- Intellectual property (IP) protection issues.
- Lack of incentives to share.

Institutions also have concerns about participating in shared resources. They are concerned, foremost, about the long-term support they would be required to provide (personnel, funding, space, etc.). There are also concerns about the need for budget management; accountability

measures; data storage, sharing and ownership; and issues related to inheriting cores from investigators, departments or colleges.

Possible remedies:

- Encourage (but not necessarily require) inter-institutional and intra-institutional sharing of cores in new RFAs. Whenever possible, explicitly promote and leverage cross-NIH entities in the process.
- Solicit meaningful evaluation criteria for core operation and function and share as a white paper.
- Require a true business plan for sustainability of the core when a shared resource will be established as part of sponsored research.
- Create incentives that make integration and interinstitutional sharing too good to pass up.

William Hendrickson, Ph.D., Director, Research Resources Center (RRC), University of Illinois at Chicago (UIC), described the Chicago Biomedical Consortium (CBC) and shared elements of its central management system, including the UIC RRC intranet, which handles many of the management functions for the CBC. He concluded by sharing challenges that the CBC faces in running its shared resources program with this system.

The CBC was established to curb competition and encourage collaboration among the core facilities at the University of Chicago, Northwestern University and UIC. Combining the resources at these major institutions has brought together faculty to write grants as well as to pool their expertise on determining what types of facilities are needed. The first task of the CBC was a Joint Proteomics Facility with joint oversight, local support, a large user base, resources for courses and workshops. It faced a major challenge in setting up a workable billing and accounting system and had to overcome issues related to ownership, relationships with previous cores and liability. Since then, the CBC has established a very successful intranet site that manages facility employee services, central billing and data management, submissions, tracking, and the scheduling of open-source instruments.

Having lived through the experiences of the CBC, Dr. Hendrickson stressed the importance of having an academic director to help reduce conflicts and an unbalanced burden, a facility director in addition to professional staff, and a central board to help set priorities. He also provided a set of guidelines for centralized management, including:

- Broad input and resources for new instruments and facilities.
- A grant process that focuses on the availability of core facilities to be shared.
- Flexible funding sources.
- Ensuring long-term maintenance/space.
- Provision of robust Web-based reporting and accounting.
- Online central billing and data systems.
- Centralized, online submission of samples.

Programs instituting the consortium model may face a number of challenges. Geography is one, and another is competing interests, which, combined with conflicting grant requirements, can lead to redundant cores, a suboptimal user base and idle instruments. Finally, there is a lack of

inexpensive central management systems (may need an open- source, central listing). Dr. Hendrickson made suggestions for addressing these challenges, including:

- Using the NSF Major Research Instrumentation Program system as a model for addressing competing interests.
- Identifying an open-source, central listing that can be adapted to serve as an integrated management system.

Glen Itzkowitz, M.A., Assistant Dean for Scientific Operations, Stony Brook University Medical Center, shared business principles that are relevant to decision making in a technology core in a presentation titled, “Technology/Platform Life Cycles.” The areas that need to be evaluated in this process include data interrogation, demand curves, supply/service reduction, outsourcing and termination versus integration.

Data interrogation includes both qualitative and quantitative data and consideration of user feedback (acknowledgments in publications, user surveys, data on usage), which will speak to the integrity of the administration and the reputation of the facility.

Developing a demand curve is part of a business plan. Stressing that every facility needs a business plan, Dr. Itzkowitz strongly recommended that this be developed and reviewed by someone who knows how to write a business plan and that it be monitored by advisory committees. The business plan will address strategies for:

- Spurring demand (e.g., providing vouchers, supporting pilot and feasibility studies, setting hours aside for new projects, fostering junior faculty, moving senior faculty to new platforms).
- Fostering next-generation methods and platforms.
- Using persuasion to create a wave of excitement.
- Meeting the market (the four Ps: product, placement, price and promotion).
- Flexibility (demand is a moving target).

Every business plan should also consider the pros and cons of reducing services based on utilization data, the shifting needs of research enterprises and a cost-benefits analysis.

Outsourcing has both risks and rewards that need to be considered. The pros may be the conservation of resources, reassignment of liability and improved financial performance. On the other hand, the institution needs to consider that with outsourcing, it will lose control of the sample queue, pricing and its pool of technical sophistication. To help make decisions about outsourcing, Dr. Itzkowitz recommended using a process called “gap mapping” or “gap analysis” every year.

Finally, a resource core should be evaluated with respect to termination or integration with other cores. Integration requires a plausible rationale. For example, would integration expand a service line or product line? Economies of scale and scope as well as financial systems need to be considered. An advisor’s perspective on this is critical. If it is determined that integration is not recommended, then termination needs to be considered. Core directors need to remember that “in business, nothing is forever” and that the utilization data or political realities may indeed indicate

that a core needs to be closed. In fact, termination of a service is part of responsible business planning at initiation of a new core.

Dr. Itzkowitz concluded with other recommendations:

- Communicate goals and objectives throughout the life cycle.
- Make sure service lines coincide with the organization's mission and vision.
- Understand the cycle of a business venture.
- Model outcomes frequently ("what ifs").
- Do not be afraid to make decisions.

Robert S. Sherwin, M.D., Director, Yale Center for Clinical Investigation, shared his experience with various management models for cores at Yale in a presentation titled, "Management of Cores: Centralized vs. Decentralized Models."

While some cores at the Yale Center for Clinical Investigation are laboratory based, many are either center based (managed by a department or a center and providing services to its membership) or institutionally based (managed by a school/institution providing services to any faculty member). Partnerships are the newest model and can be managed by the institution or the center. Sherwin looked at examples of each of these models and discussed the advantages and rationale for each.

Some cores at Yale are center based but not centralized. The Diabetes Endocrinology Research Center (DERC), for example, has two such cores, one that focuses on islet generation and one that focuses on constructs for mice with diabetes mellitus. These cores were not centralized because they have limited scope, the Center and its users can support the cost to operate and maintain the cores, and no cost savings or operational efficiency would be gained by centralizing.

DERC also has two centralized cores, one for cell biology and the other a transgenic core. These cores were centralized because of the need for special expertise outside of the diabetes area, the higher cost to operate and maintain the cores, and the high cost of the equipment.

The DERC/CTSA Translational Core, which promotes patient-based diabetes research, was centralized at the center level and is one example of how CTSA and centers can interact. This centralization was because of the broad-based benefit for investigators at the DERC and CTSA and the ability of the two center grants to share costs. Operational efficiencies were also gained by establishing and centralizing this core.

The CTSA-Categorical Center Partnerships in Biostatistics Core is another instance of a CTSA and a center working together. In this instance, a much richer environment for the biostatistical community was established by the partnership. Other advantages of an institutional/CTSA partnership include the broad-based benefit for diverse investigators, cost sharing, operational efficiency through centralization and benefits gained by integrating into the CTSA structure. Efforts by the CTSA program to increase core utilization include a newsletter, a Web site and scheduling programs, a core pilots program, and expanded capacity at other partner cores.

Dr. Sherwin shared a current evaluation to determine whether the “former GCRC” Core Laboratory should be merged with the Department of Laboratory Medicine’s research services and become an institutionally based core. He reviewed the process for making this decision and the points that will be considered; these considerations include the potential for improved quality of service, the needs of the investigator community, potential cost savings and the scope of the core’s services.

Both the DERC-CTSA Translational Diabetes Core and the CTSA-Cancer Center Partnership at Yale offer opportunities for interactions between CTSA’s and centers. This is possible because of the research infrastructure and the opportunities for training and credentialing for new investigators and research nursing staff, both of which are supported by CTSA, DERC and the Juvenile Diabetes Research Foundation Center. There are also opportunities for joint funding of pilot grants and joint support of cores. In the case of the CTSA-Cancer Center partnership, the management structure of clinical trials has also been merged.

The key question when determining the best management structure, concluded Dr. Sherwin, is whether there is benefit to the members of that center.

General Discussion

- There was great concern about the inability to carry over funds or to make a profit, both of which make it difficult for cores to do long-range planning.
- Open-source management tools are available and can be adapted. NCI’s caBIG (cancer Biomedical Informatics Grid) uses a system that may help cores.
- Stony Brook University controls all of its business systems independently. It uses this for billing and for projecting demand. This is also one advantage of centralizing.
- To become more efficient in merging, it was recommended that money be spent on contracting for services. Participants would appreciate guidance from NCRR to help them with costly service contracts.

Session V: Training for Core Facility Directors

Question: What is currently being done to train core directors and administrators who are responsible for cores? Are there good courses or other models for training core directors? Should general guidelines or some sort of certification for training be developed?

Session Summary

Business education adds value to managing a core facility and is highly recommended for middle and upper levels of management.

While there does not appear to be a current training course that is open to all core directors and administrators or that would meet all their training needs, there are opportunities to participate in workshops and seminars at annual meetings, and there are online and committee-based forums for networking where challenges and solutions can be shared.

There are also models that could be used as a basis for developing multiple modules for such a course. For example, for business-related tasks, there is easy-to-learn software as well as workshops and seminars, many of which may already be available at core institutions. It was also recommended that core directors engage in networking in order to share best business practices and available resources.

During this session, a proposal for a business training course for core directors was described. Objectives for such a course would focus on:

- Building capacity for translational research (including obtaining currency in cutting-edge technologies and applications).
- Fostering research by providing state-of-the-art technologies.
- Strengthening the workforce through education and mentoring.
- Maximizing partnership.

It was suggested that this course be practical, have a hands-on component (lectures and applied assignments) as well as an online component, be tailored to the needs of the core and include certification. It would cover principles of accounting, marketing, operations management, critical decision making and personnel management.

Suggestions for addressing the need for training included:

- Partnering with the Association of Biomolecular Resource Facilities (ABRF) or working with a large research lab to develop the course.
- Establishing a “centralized clearinghouse” for all information about running a core, including information on workshops, seminars, new technologies and applications.

Presentations

Carole Heilman, Ph.D., Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, moderated this session.

Steve Bobin, Administrative Coordinator for Shared Resources, Molecular Biology and Proteomics Core Facility, Dartmouth College, delivered a presentation titled, “Core Facilities and Business Management,” which focused on what core administrators and directors need to know about business management. His overall conclusion was that:

- Management principles applicable to core facilities can be cherry-picked from any business curriculum.
- There is easy-to-learn software for most business-related tasks.
- Upper levels of management must be similarly educated for the system to work.

Mr. Bobin said that the most important elements of business management for core facility administrators and directors are:

- Writing a business plan.
- Marketing (pricing, promotion, advertising, outreach and SWOT [strengths, weaknesses, opportunities and threats] analysis).
- Operations management (planning, purchasing, inventory and value stream).

These skills will be somewhat different for upper and middle management and for core personnel. Bobin explained that upper management needs to have a rudimentary understanding of science as well as business planning, accounting, regulations, economics, and financial analysis, and it must have decision-making abilities as well. Middle management must understand the science and a whole host of management skills, including business planning, fund accounting, cost accounting, regulations, managerial accounting, marketing, economics, operations management, financial analysis, decision making and personnel management. For core personnel, the primary concern is science, but they will also have to be actively participating in administrative issues and what is needed to “keep their job.” This includes economics, fund accounting, financial analysis and decision making.

Mr. Bobin concluded that a business education adds value to managing a core facility. He suggested starting with available software that can be used to develop a course on most business-related tasks, including the preparation of a business plan.

Michelle Detwiler, M.S., Association of Biomolecular Resource Facilities, and President, Roswell Park Cancer Institute, delivered a presentation titled, “Resources for Training and Education of Core Facility Directors and Managers.” She described a range of available training and networking opportunities for core directors and also encouraged these directors to stay active in scientific societies and current with cutting-edge technologies and applications.

Training may take the form of formal laboratory management training, workshops, seminars, meetings or user groups. Primary resources include:

- Scientific societies and meetings.
- Academic and institutional entities.
- Commercial providers.
- In-house and empirical solutions.

Ms. Detwiler then described seven specific opportunities that are available currently or that could serve as models for a training course to be developed:

1. “Partners in Scientific Management Training” funds grants to come up with instructional guidelines for courses in scientific management. This organization is funded by the Howard Hughes Medical Institute and the Burroughs Wellcome Fund. The guidelines were used to formulate a course that covered leadership and management styles, time and resource management, funding and budgeting, mentoring, and collaborations.
2. “Lab Manager Boot Camp: Be a Better Lab Manager” includes sessions on educational management using improvisational theater to explore problems and solutions to common lab situations. This is sponsored by the Laboratory Management Institute and was presented at Pittcon 2009.
3. “Managing Performance and Productivity in the Laboratory Today” is a workshop that will be held at the 2010 ABRF Annual Conference.
4. “Core Managers Workshop” is an annual pre-meeting held in conjunction with the Great Lakes International Imaging and Flow Cytometry Association.
5. The Association of Lab Managers hosts a forum for sharing solutions and ideas.
6. A listserv, conferences, scientific research groups and committees are hosted by ABRF.

7. A networking meeting is hosted by the Northeast Regional Life Sciences Core Directors (NERLSCD).

Conclusions from this presentation:

- Resources and tools are available for training and education of the core facility director.
- Resources do not always specifically address the unique issues that face core facilities.
- There is clearly a need for a “centralized clearinghouse” for information on core facilities.

Katia Sol-Church, Ph.D., Director, Biomolecular Core Lab, Center for Pediatric Research, Nemours/Alfred I. duPont Hospital for Children, described a proposal for a course she calls, “Business Skills for Core Center Directors.” She also stressed, however, that most core directors can learn these skills on the job by networking through societies and associations. The goal of any management training for core directors needs to focus on the skills for managing the business side of a services lab and the provision of long-range planning to be sure the lab is successful and sustainable.

The training course that Dr. Sol-Church proposed would be both practical and hands-on, would be tailored to the needs of core facility managers/directors, and would include lectures and applied assignments (e.g., case studies, problem-based learning and peer-to-peer discussions).

The objectives for the course would focus on:

- Building capacity for translational research.
- Fostering research by providing state-of-the-art technologies.
- Strengthening the workforce through education and mentoring.
- Maximizing partnerships.

Dr. Sol-Church envisioned a course with both live modules and an online component. Modules would include 15-minute lectures, small-group discussions/exercises, and a take-home message from each participant (what tools and ideas will you use to improve my core/center’s effectiveness?). Module topics would include accounting, marketing, operations management, critical decision making and personnel management.

The online component would include highlights from each module, as well as a portal that would include links to video clips and other multimedia resources.

Dr. Sol-Church concluded by emphasizing that core success is all about people. She suggested that this course could be developed through a public-private partnership.

Beth Habecker, Ph.D., Associate Professor of Physiology and Pharmacology, Oregon Health & Science University (OHSU), described the evolution and structure of research cores at OHSU. She explained that core laboratories at OHSU developed from the grass roots with little central coordination or support, but eventually they all requested institutional support. Currently, there are a wide variety of “cores” across the campus with varied missions, funding and levels of administrative support. Although there was no uniform way for the institution to evaluate the effectiveness of the cores or their value to the research mission, there were still common challenges:

- Assistance with:
 - Business models
 - Financial business aspects
 - Marketing and promotion
 - Coordination to avoid duplication of effort

To address these challenges, core directors started meeting once a month and, among other recommendations, they decided that administrative help was clearly needed. A University Shared Resources (USR) administration was formed, which included:

- A program director (faculty, half-time), who works with core directors on long-term planning, is an advocate and assists with grants for shared instrumentation.
- A financial analyst, who helps develop business plans, reviews budgets, provides billing services, and tracks declarations of PIs that are planned for use on grant submissions.
- An administration specialist, who organizes meetings, coordinates communications, tracks grant information, and assists with Web sites for cores.

A Core Oversight Committee (COC) was also established to help establish accountability and to make assessments and determinations about when to add or close down a core. The COC assists the USR program director and provides financial support for:

- Pre-award consulting.
- Capital (items below threshold for major instrumentation grants).
- Financial subsidy (supplemental funding).

Central Financial Services reviews and gives final approval to cost-based rate calculations for service centers and monitors to ensure compliance with all internal and external regulations that affect service centers.

Dr. Habecker reminded participants that most core directors are scientists and faculty members and can use some help with the business side of running a core lab.

General Discussion

- Another existing training program for core directors is offered through the International Society for the Advancement of Cytometry (ISAC). It is only available to members, but it includes elements that would be useful to all cores.
- Training should also include a module on intellectual property.
- Core directors were advised to take courses in a business school, which can also be done online.
- Most core directors are onboard with an evaluation if it means they may receive funds to solve immediate problems. A process for evaluating cores with a timeline is recommended — and if the core is no longer needed or is too expensive, there should be a clear plan to close it out.
- The small business model does not fit all cores or the NIH mission because a business model works toward a profit. However, it is still important to know how to operate in a complex environment and to have the skills to survive a “dry season.”

- A sea change is necessary in academia to make it acceptable to charge for consultation or to use a model that accounts for and supports the value of consultation. A model focused on partnerships may help.

The following specific ideas were raised during the discussion:

- A certification requirement for the core facilities should be instituted to help with recruitment.
- Funding should be provided to support training for core directors, as well as for Ph.D. programs to incorporate these skills into existing programs.

Session VIa: Quality Improvement

Question: How should the quality of a core facility be evaluated? Should there be standard metrics? When are certification systems useful? What role should user comments have in core evaluation?

Session Summary

This session focused on the evaluation of cores and the role of certification in improving the quality of core facilities. In addition to identifying critical measures of quality, participants shared their ideas for how NIH can support quality improvement efforts at the institutional level.

General principles and caveats were shared by the panelists:

- Need to be careful not to add extra time and work to cores. Avoid low-value activities: rules/regulations, paperwork and compliance.
- The bottom line for quality is the ability of researchers to compete for funding at the federal level (focus on scientific outcomes, such as publications, cross-disciplinary research and partnerships).
- Need to engage all stakeholders in efforts to improve quality.
- Need transparency and willingness to change.
- It is possible to improve cost, quality and access — these are interrelated.
- Tie quality improvement measures to grant review and funding.

One panelist proposed that cost, quality and access can all be improved — and that these are interrelated aspects of core operations. Several management principles can be engaged to improve these operations: subsidizing of core services (not subsidizing the user); providing incentives to consolidate cores, to coordinate services and for specific types of research, such as translational research; and using business principles to determine whether cores can or should be centralized.

The components of quality improvement include oversight, feedback, accountability and measurement. User surveys were also recommended in order to inform planning. Accountability starts with institutional support; annual reviews of productivity; and the use of integrated electronic systems for scheduling, billing and reporting. Tools to measure quality should be designed to keep pace with scientific innovation and should be used to validate the quality of

service, data and equipment. It was further suggested that the best assurance of quality is a well-trained staff and that training should be included in any quality improvement strategy.

Presentations

Linda Weiss, Ph.D., Director, Office of Cancer Centers, National Cancer Institute, moderated this session. She posed two areas to focus discussion:

- How can we ensure that core facilities are achieving quality results?
- Given rapid changes in the science and technology, are we achieving quality today and in the future?

Maria Person, Ph.D., Director, Analytical Instrumentation Facility Core, University of Texas at Austin, gave a presentation titled, “Quality Improvement, Standard Metrics, and Certification.” She considered metrics that could measure elements that are critical to a core’s reputation with potential users. She also described several existing certification efforts that could be used to model a national certification program for cores. In her presentation, she stressed three principles:

- Evaluations that could burden a core and have low value should be avoided.
- All stakeholders should be involved in developing evaluation metrics and certification standards.
- Transparency and willingness to change are critical.

Examples of standard metrics that would be useful to core facilities include:

- Reputation among potential user base — including access, turnaround, technical expertise, equipment, consultation and institutional support for the core.
- Facilitating scientific research — including publications and use of the core.

Dr. Person described three scientific societies that have developed standard or benchmark samples that could be useful for certification: ABRF provides annual test samples sent to facility cores with results reported at its annual meeting. The Human Proteome Organization training and test sample of 20 proteins shows that feedback can improve performance. Finally, MicroArray Quality Control develops standard operating procedures for microarrays. These could be used as models for the certification of core facilities.

Roles for NCRR in supporting these activities could include:

1. Developing or providing a clearinghouse for user surveys and other evaluation tools.
2. Funding the community-based development of standard samples (e.g., ABRF) for certification.
3. Supplying and evaluating test samples.
4. Providing feedback or training to improve performance.
5. Incentivizing publication or participation: require certification or survey data for SIG or other NIH grants.

Keith Joiner, M.D., M.P.H., Director, Health Research Alliance Arizona, University of Arizona, shared a number of business principles that can be applied to improving quality, access

and cost in core facilities. His premise was that for large integrated biomedical core facilities, all three parameters (quality, access and cost) can improve in parallel.

The first management principle he discussed was the concept of supply and demand. He described how measurements of demand and supply can be used to determine optimal price and output. A critical difference with core facilities is subsidization. He explained how either the core (supply) or the user (demand) can be subsidized, but if the user is subsidized, demand and cost both increase, while a subsidy to the core can actually lower prices, especially if the subsidy leads to consolidation of services. For example, the University of Arizona found that it had better success setting aside funds for core equipment and services, to be allocated by a committee, than with recruitment, retention and support packages to faculty (users).

Another useful principle is that of incentives. If cores have an incentive to consolidate, there will be substantial increases in quality and cost savings. At the University of Arizona, incentives for consolidation included access to a Web-based scheduling tool, a uniform fee structure and institutional support of core lab space.

Finally, the general principles from queuing theory hold for core facilities. Queuing models will show that a larger facility (with more machines) can realize a smaller average waiting time and achieve greater usage of equipment than can a smaller facility. This may not be intuitive but is borne out by examples and mathematics.

Dr. Joiner suggested several steps that NIH might take that would improve quality, access and cost in technology cores:

- Provide incentives for institutions to consolidate cores:
 - Stipulations on equipment grants.
 - Incentives for coordination across institutions.
- Take the lead in determining which cores can and/or should be centralized:
 - Funding/organizational structure at NIH to support central core services.
 - Ensure all institutions have access to centralized cores.

He concluded that it is important to get comprehensive data on the program which can then be used to model which cores can be best consolidated in an institution and which can be designated for regional consolidation.

Paula B. Turpen, Ph.D., Director, Research Resources, Office of the Vice Chancellor for Research, University of Nebraska Medical Center, echoed several other presenters when she posed the caveat that NIH needs to be careful not to add extra time and work to cores unnecessarily. She explained that the bottom line for quality is the ability of researchers to compete for funding at the federal level. She described how oversight, feedback and accountability can be used to ensure and improve the quality of core facilities.

Oversight at the University of Nebraska's Research Resources is led by an Office of Research Resources and each core's Internal Advisory Committee. The Director of Research Resources also chairs a campus-wide Research Resources Board that considers a broad range of research

issues, including core facilities. The Internal Advisory Committee deals with rate-setting and planning for growth.

Feedback can be gathered by assessing whether core facilities are a research infrastructure priority in the institution and by a survey of users. Dr. Turpen described such a survey conducted by the University of Nebraska Medical Center (UNMC) that asked funded faculty at the university to rank services. Core facilities were in the top three ranked services whether filtered for clinical activity or for no clinical activity. The first time the survey was conducted, however, it was clear that many researchers did not know about the services that were available to them. Using this feedback, the cores increased their marketing and noted a distinct improvement in awareness the next time the survey was conducted.

Accountability is perhaps the most important component of quality for core facilities. Accountability can be evaluated by reviewing data on annual productivity (income/expenses, number of users, user funding, user publications and intellectual property). Having institutional support is a key indicator as well, and it can be important to have a reward/incentive for meeting productivity goals. At UNMC, accountability of core facilities is tracked with an electronic system. This system benefits: 1. Users, who can apply for services online; 2. Core personnel, by automating billing; and, 3. Administrators, by generating real-time reports about the use of services and equipment.

General Discussion

- A database can be set up to add tag lines to invoices to track articles that are submitted and/or published as a result of research that uses core facilities. A strong quality assurance (QA) system will be apparent in publications of such research, which will describe how the quality of data was assessed.
- Core personnel should do QA checks on their equipment daily or several times a day to be sure data are valid. However, since research cores provide custom services, unlike hospital cores which perform routine clinical tests, results cannot be correlated. Therefore, it was suggested that the best QA is education — a standard curriculum can be developed that every user is required to complete.
- Evaluations can be for internal purposes (e.g., to make critical decisions) or external purposes (promotion, grant applications, etc.). In either case, it is recommended that an experienced evaluator be brought in to design the evaluation. Similarly, quality needs to be assessed by biostatisticians rather than by those who use a standard protocol, because expectations for quality are always in flux with changes in technology.
- Quality control can be part of the user fee.
- Outcome measures need to indicate progress or lack of progress in meeting specific goals (e.g., number of users, grants, submissions for publication, use for multi-investigator or translational research).
- To assure quality at Purdue University, the core personnel prepare a complete analysis of any samples that are tested by graduate students and send the report to the PI to ensure accuracy.
- It is difficult to get data to inform predictions of demand for a particular core, especially for smaller cores.

The following specific suggestions were raised during the discussion:

- NCRHR could fund benchmarking experiments or optimization experiments.
- Grantees would like to access data from other grants to make comparisons.
- A universal metric would be useful in comparing cores with similar functions (e.g., number of users, number of times an instrument is used, and length of time on an instrument).

Session VIb: Quality Improvement Clinical Research Cores

Question: Are national quality controls useful when dealing with human subjects? Is Clinical Laboratory Improvement Amendments (CLIA) certification feasible or useful? What is the role of the College of American Pathologists (CAP)?

Session Summary

Background: The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the United States through CLIA. The objective of the CLIA program is to ensure quality laboratory testing, and clinical laboratories must be properly certified to receive Medicare or Medicaid payments. CMS also approves accrediting organizations, such as CAP. CAP allows for validation of the methods used in research assays, which includes verification of analytic accuracy, precision, sensitivity, specificity and reportable range. Interfering substances, linearity, and calibration are also considered. The quality of the control material is also important, and CAP inspection considers periodic monitoring of control statistics, frequency and number of control runs, actions taken when controls are not in the acceptable range and the use of a patient sample to test for lot-to-lot variation.

CLIA certification (or other certification) of a core clinical research laboratory can be an important component of research on human subjects because it allows patients to be informed about testing results, assists in the transition of a research test to a clinical test and ensures good lab practices. Although expense and administrative burden dissuade some laboratories from accreditation, these guidelines help to ensure the translation of research into clinical applications. Alternatives to CLIA certification include selling or licensing the research test to industry and partnering with a commercial external “face.” Overarching recommendations made during this session included:

- Designing institutional review board (IRB)–approved language at the time the protocol is created to be used in the informed consent and any letters to subjects; it was suggested that core directors provide clinical researchers with boilerplate language.
- Considering 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. The Collaboration, Education and Test Translation (CETT) Program (<http://rarediseases.info.nih.gov/cettprogram/default.aspx>), overseen by the NIH Office of Rare Diseases, provides funding for translation and expert review of scientific merit.

Presentations

Anthony Hayward, M.D., Ph.D., Director, Division for Clinical Research Resources, National Center for Research Resources, moderated this session. He explained the purpose of the session, noting that NCRR is interested in receiving feedback from directors of clinical research cores about concerns related to quality assurance.

Peggy Emmett, M.A., Manager, Core Laboratory, Colorado Pediatric Clinical Translational Research Center, University of Colorado Denver, addressed common complaints about laboratory accreditation. She explained that while some may argue that they already perform good lab practices, the accreditation process ensures that this is the case. Responding to concerns that the cost of accreditation is too great, Ms. Emmett argued that the cost of quality results should be built into the pricing. Lastly, the administrative effort may be considered to be too high, but it is also a standard part of good laboratory practices. Ms. Emmett noted that most errors occur in the pre- and post-analytical phases, arguing the importance of precise documentation. She also noted that industry seeks out accredited laboratories to perform its research work. Core directors owe it to their users to supply the same level of high-quality products being sought by industry.

Andy Faucett, M.S., G.C.G., Director, Genomics and Public Health Program, Department of Human Genetics, Emory University, addressed the issue of whether CLIA certification is feasible or useful. He concluded that translation of a research test to a clinical test is important, and CLIA improves this translation.

There are legal, ethical and practical implications when considering sharing research results. Legally, CLIA is required to release results to subjects. Researchers face an ethical dilemma, including a feeling of duty toward participants and having knowledge that they cannot share results with the participant. Practical issues arise because research laboratories are not prepared to meet the needs of a patient community; these needs include fast turnaround times, a larger workload, insurance, and the fact that their results cannot be used by a clinical laboratory and must be repeated.

The solutions to these problems include having a research plan that includes translation of the product. A translation plan should also be in place, and this plan could be required as part of grant application, review and funding. Networking to build collaborations will also improve clinical research. Mr. Faucett argued that these considerations are the duty of both the researcher and the core director.

Several misconceptions about clinical translation exist. Clinical laboratories are interested in this type of research, and translation can be cost-effective because insurers can pay for testing. The researcher can benefit from clinical translation because publication of additional testing on subjects can be facilitated, collaborators can expand their database and gain access to a larger patient population, and participants can be informed about the results. Misconceptions about clinical translation were reviewed in several articles in *Genetics in Medicine*, volume 10, number 5, May 2008.

Mr. Faucett reviewed a working solution for clinical translation: the CETT Program, which provides financial support for translation and collaboration (but not for testing or research) and expert review of the scientific merit of the potential clinical test. It also provides a pathway for researchers to assist with interpretation and gain access to new data. Patient advocacy is also considered, because all results are available to the subject, and genetic counseling and education are provided. The program has been successful; as of July 2009, new genetic tests for 64 rare diseases (including 89 genes) have been developed. Mr. Faucett concluded that there is an ethical duty to make results available to patients through CLIA, CETT or a combination of the two.

Daniel Mirel, Ph.D., The Broad Institute, focused his presentation on high-throughput research versus CLIA certification. The Broad Institute Center for Genotyping and Analysis (CGA) is the first national center for high-throughput genotyping dedicated solely to large-scale analysis of single nucleotide polymorphisms (SNPs). Since 2005, this center has been providing competitively priced fee-for-service genotyping and project management to researchers in the United States and other countries. NCCR-subsidized genotyping has been available to accepted applications.

CGA chose not to undergo CLIA accreditation; among the barriers to CLIA certification is the lack of interest in competition with industry. Because CGA is a specialized-service facility, it is considered a nonprofit organization, and it was not designed to compete with industry. In addition, the Massachusetts Institute of Technology, a partner with CGA, is not a medical institution and is not familiar with the regulatory and legal considerations associated with clinical medicine. Lastly, none of the research being performed at CGA would be likely to result in any tests for clinical translation, and therefore CLIA accreditation did not seem necessary. Dr. Mirel reviewed alternatives to CLIA certification of the CGA itself, including selling or licensing genetic tests to industry or partnering with a commercial external “face” to interact with clinicians.

Genome-wide SNP testing can uncover a variety of genomic anomalies, including aneuploidy, microdeletions and SNPs with known risk alleles. The ability to detect these alterations leads to the questions of what genomic changes are clinically relevant and who makes that determination. The study investigator and her or his IRB should consider these points at the outset and have a plan for how and when patients may be informed. Dr. Mirel acknowledged that any research finding would have to be confirmed in a CLIA-certified laboratory and would require medical interpretation and the counseling of subjects.

General Discussion

- It can be a challenge to run a core facility that performs both clinical and research tests. In some cases, multiple levels of standards might need to be met, which creates a burden for the laboratory. The panel agreed that working with researchers with very different goals is a challenge.
- Choosing one accrediting body, such as CAP, simplifies the administrative burden. One attendee acknowledged that CLIA certification attracted business from international clinical trials and that it is well worth the expense.

- The group discussed retesting subjects who have undergone non-CLIA certified testing and how patients are informed. Some believed that telling the patient or physician anything, including that they may require additional testing, is against regulations. It was clarified that a carefully designed IRB-approved letter that is completed at the beginning of the study would allow basic information to be given to the patient without breaking regulatory guidelines. The informed consent would have to be very clear about what information subjects can expect. It may also be possible to retest a sample in a CLIA-certified laboratory and then allow the physician or subject to be informed of the result. Dr. Faucett noted that unanticipated results may be found and that CLIA allows the laboratory to handle matters as they arise.
- Dr. Hayward commented that public perception of the process is also important and that people should be educated to be part of the health care system. Dr. Faucett stressed that some information could be dire for the family of the participant and that the ethics related to study results must be considered thoroughly. A suggestion was made that core facilities could provide boilerplate language to researchers for informed consent documents and protocols that relays the details related to releasing research results. Clinical validation is always warranted.

Dr. Hayward thanked the participants for their contributions and requested that attendees provide feedback to NCRR on the meeting.

Concluding Comments and 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
- Continuation of dialogue with core resource stakeholders

AGENDA

Tuesday, July 14, 2009

1:00 p.m.–1:30 p.m. Welcome and Opening Remarks

Dr. Barbara Alving, Director, National Center for Research Resources Dr. Mark O. Lively, III, Director, Molecular Genetics Program, Wake Forest University School of Medicine and NCRR Advisory Council Member Dr. Sally Rockey, Acting NIH Deputy Director, Office of Extramural Research, NIH

1:30 p.m.–2:15 p.m. Session I: Finding Core Facilities and Access to Core Facilities

How useful would a national registry of core facilities be? What is the present state of access to core facilities? Are core services available to outside researchers (outside could be outside the department or outside the institution)? Are regional cores useful?

Moderator

Greg Farber, National Center for Research Resources

Speakers

1) *George Grills, Director of Operations of Core Facilities, Cornell University* 2) *Tim Hunter, Manager of two cores, University of Vermont* 3) *Jonni S. Moore, Director of Pathology Bio-resource Facility, University of Pennsylvania* 4) *Victoria Christian, Chief Operating Officer, Duke Translational Research Institute*

2:15 p.m.–2:45 p.m. General Discussion for Session I

2:45 p.m.–3:00 p.m. Break

3:00 p.m.–3:45 p.m. Session II: NIH and Other Federal Government Policies and Requirements

How do current NIH or federal policies (apart from OMB Circular A21) contribute to or inhibit the efficient and effective use of cores? What changes would improve core management?

Moderator

Mark Guyer, National Human Genome Research Institute

Speakers

1) *Valerie Scott, Senior Director of Scientific Services, Jackson Laboratories* 2) *Scott Ness, Director Keck-UNM Genomics Resource, University of New Mexico* 3) *Tesheia Johnson, Chief Operating Officer, Yale Center for Clinical Investigation*

3:45 p.m. – 4:30 p.m. General Discussion for Session II

Wednesday, July 15, 2009

8:30 a.m.–9:15 a.m. Session III: Cost Recovery

Cost recovery has become a key component in managing core facilities. What are the best practices to negotiate OMB Circular A21? What impact does complying with A21 have on core facilities?

Moderator

Joe Ellis, Office of Extramural Research Administration, NIH

Speakers

1) *Gil Tran, Office of Federal Financial Management, Office of Management and Budget* 2) *John Manning, Associate Vice Chancellor for Health Affairs, Vanderbilt University Medical Center* 3) *Kelvin Lee, Director, Delaware Biotechnology Institute, University of Delaware*

9:15 a.m.–9:45 a.m. General Discussion for Session III

9:45 a.m.–10:00 a.m. Break

10:00 a.m. – 10:45 a.m. Session IV: Management of Cores

Management of cores can place significant responsibility at the department, school or college, or institution level. What are the advantages and disadvantages to each of these management models? Does a university-wide centralized billing infrastructure or other university-wide infrastructure increase core efficiency? Should there be guidelines or standards for size of cores? In cases where core consolidation is necessary, are there good models for taking this action?

Moderator

Robert Carter, National Institute of Arthritis and Musculoskeletal and Skin Diseases

Speakers

1) *Richard Hichwa, Associate Vice President for Research, University of Iowa* 2) *William Hendrickson, Director of Research Resources Center, University of Illinois at Chicago* 3) *Glen Itzkowitz, Assistant Dean for Scientific Operations, Stony Brook University* 4) *Robert S. Sherwin, Principal Investigator, Yale Center for Clinical Investigation*

10:45 a.m.–11:15 a.m. General Discussion for Session IV

11:15 a.m.–12:00 p.m. Session V: Training for Core Facility Directors

What is currently being done to train core directors and administrators who are responsible for cores? Are there good courses or other models for training core directors? Should general guidelines or some sort of certification for training be developed?

Moderator

Carol Heilman, National Institute of Allergy and Infectious Diseases

Speakers

- 1) *Steve Bobin, Manager, Molecular Biology and Proteomics Core Facility, Dartmouth College*
- 2) *Michelle Detwiler, Association of Biomolecular Resource Facilities President, Roswell Park Cancer Institute*
- 3) *Katia Sol-Church, Director, Biomolecular Core Lab, Center for Pediatric Research, Nemours A.I. duPont Hospital for Children*
- 4) *Beth Habecker, Associate Professor of Physiology and Pharmacology, Oregon Health and Science University*

12:00 p.m.–12:30 General Discussion of Session V

12:30 p.m.–1:30 p.m. Lunch Break

1:30 p.m.–2:15 p.m. Session VIa: Quality Improvement

How should the quality of a core facility be evaluated? Should there be standard metrics? When are certification systems useful? What role should user comments have in core evaluation?

Moderator

Linda Weiss, National Cancer Institute

Speakers

- 1) *Maria Person, Director, Analytical Instrumentation Facility Core, University of Texas at Austin*
- 2) *Keith Joiner, Director, Health Research Alliance Arizona, University of Arizona*
- 3) *Paula Turpen, Director, Research Resources, Office of the Vice Chancellor for Research, University of Nebraska*

2:15 p.m.–2:45 p.m. General Discussion Session Via

1:30 p.m.–2:15 p.m. Session VIb: Quality Improvement (Clinical Research Cores)

Are national quality controls useful when dealing with human subjects? Is CLIA certification feasible or useful? What is the role of CAP?

Moderator

Anthony Hayward, National Center for Research Resources

Speakers

- 1) *Peggy Emmett, Manager, Core Laboratory, Colorado Pediatric Clinical Translational Research Center, University of Colorado at Denver*
- 2) *Andy Fawcett, Director, Genomics & Public Health Program Department of Human Genetics, Emory University*

3) *Daniel Mirel, The Broad Institute*

2:15 p.m.–2:45 p.m. General Discussion for Session VIb

2:45 p.m. –3:00 p.m. Concluding Comments and Next Steps