National Institutes of Health – Association of Biomolecular Research Facilities

Workshop on Enhancing Efficiency of Research Core Facilities

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Workshop Report

Contents

Executive Summary

The National Institutes of Health (NIH) and the Association of Biomolecular Research Facilities (ABRF) hosted a workshop on March 28, 2015, in conjunction with the 2015 ABRF Annual Meeting in St. Louis, Missouri, to identify lessons learned and best practices for enhancing the efficiency of research core facilities. The purpose of the Workshop was to bring together NIH leaders, as well as ABRF members, institutional directors, and research teams, to discuss existing challenges and suggested practices to increase efficiency in core facilities. The NIH invests substantial resources in core research facilities that support research by providing advanced technologies and scientific and technical expertise as a shared resource.

During the workshop, the NIH characterized its support and policies affecting core facilities. Institutional leaders presented their experience and perspective on challenges and solutions to enhancing efficiency, including centralizing management, sharing, and co-locating core facilities. The Workshop was attended by 120 participants, including NIH leadership, National Science Foundation (NSF) staff, ABRF members, and institutional leaders such as core facility administrators and research deans.

The primary outcome of this meeting was a set of recommendations for the NIH and institutions to consider. Major recommendations for the NIH included: identifying opportunities to facilitate coordination between and among the Clinical and Translational Science Award program, Cancer Center Support Grants, and other funded core facilities; conveying to the scientific community that core resource sharing is encouraged (e.g., Funding Opportunity Announcements); enhancing cross-agency (e.g., NIH, NSF) coordination about core facility sharing and co-investment; and implementing the development of unique core identifiers for use in grant applications and reports to facilitate reporting and citations/ indexing. Participants recommended that institutions each develop a core strategic plan that can facilitate coordination among all core facilities; invest in specialized expertise in financial management; and develop and disseminate models for governance of research core facilities, including transparency in business practices, annual reviews, and recruitment of senior laboratory members.

The NIH and ABRF with other institutional leaders will use the information and challenges outlined from the workshop to develop the most appropriate actions and a plan for moving forward.

Introduction

On March 28, 2015, the National Institutes of Health (NIH) and the Association of Biomolecular Research Facilities (ABRF) hosted a workshop to identify lessons learned and best practices for enhancing the efficiency of research core facilities. Cores are shared resource facilities that provide investigators with access to sophisticated technologies and specialized instrumentation operated by expert staff that also provide consultation services. During the workshop, the NIH characterized its support and policies affecting core facilities. Institutional leaders presented their experience and perspective on obstacles and solutions to enhancing efficiency, including centralizing management, sharing, and co-locating core facilities. Participants and speakers engaged in discussions that addressed critical benefits and obstacles to enhancing the efficiency of cores and generated recommendations for consideration by the NIH and institutional leaders.

Welcome and Opening Remarks

William Hendrickson, Ph.D., Director, Research Resources Center, University of Illinois, Chicago, President, ABRF; James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH

Dr. William Hendrickson welcomed the participants to the first NIH-ABRF Workshop on Enhancing Efficiency of Research Core Facilities. The ABRF is an international organization that strives to advance core and research biotechnology laboratories through research, communication, and education. To achieve this mission, the ABRF partners with Federal agencies, such as the NIH and the National Institute for Standards and Technology (NIST), to conduct studies and develop standards. The Workshop attendees represented a mix of ABRF members, NIH leadership, and institutional leaders and core facility administrators.

Dr. James Anderson expressed appreciation to Dr. Hendrickson and the ABRF for partnering to address the pressing issue of research core facility efficiency. He emphasized that core facilities are fundamentally important for scientific research. Given the recent NIH budget limitations, it is important to determine how to conduct the best science with the available resources. The issue of how to enhance the efficiency of core facilities to support the best possible science would be addressed through the Workshop presentations and discussions. Dr. Anderson encouraged all of the Workshop attendees to participate in the discussion and asked the participants to be practical and provocative in their suggestions for improving the efficiency of research core facilities.

Overview of NIH Investment in and Policies Governing Core Facilities

Overview of NIH's Investments in Cores

Sally Rockey, Ph.D., Deputy Director for Extramural Research, NIH

Dr. Sally Rockey described the NIH support of core facilities as centralized research resources that provide access to instruments, technologies, expert consultation, and other services to basic, translational and clinical investigators. In addition, core facilities provide centralized oversight, which enhances efficiency and provides opportunities for reducing duplication by consolidating billing, purchasing, scheduling, and tracking services.

The NIH's investment in cores occurs through P30 and other grant mechanisms or funding through components of other awards—R01 grants can support core facilities. Tracking support of core facilities

can therefore be a complex process, making efforts to catalog information on programs and resources a challenge.

The NIH is interested in improving data on research core facilities and using those data to identify and promote successful research accomplishments supported by the cores. NIH Funding Opportunity Announcements (FOAs) outline project-specific core reporting requirements that are not necessarily congruent with each other, adding to the complexity of tracking cores. The NIH can now capture some structured data through electronic application and reporting through the Research Performance Progress Report (RPPR). The effort to collect standardized data and identify efficiencies will be further facilitated when all NIH activity codes transition to electronic submission effective on May 25, 2015.

Dr. Rockey reviewed the NIH's policy for cores, which allows for flexibility in including core resource sharing. She stated that a follow-up to the previous workshop on the Efficient Management and Utilization of Core Facilities (May 2009), the Office of Extramural Research issued a frequently asked questions (FAQ) document for NIH-Funded Core Facilities (http://grants.nih.gov/grants/policy/core_facilities_faqs.htm). The FAQs were developed with extensive input from NIH staff and the extramural community and cover such topics as the costing of NIH-funded core facilities and general core operating principles. Dr. Rockey also stated that the Office of Management and Budget (OMB) recently released Uniform Guidance regarding core facilities. Requirements are largely unchanged for the management and costing of cores. Items that may significantly impact cores include procurement, administrative/clerical costs, and fixed amount awards or sub-awards. For example, some central services and personnel integral to a project can be charged directly to the project with prior identification and written approval, rather than being recovered as an indirect cost. These adjustments allow for a broader and consistent treatment of costs, which is especially beneficial for smaller awards.

She asked participants to consider whether NIH policies could be revised to enhance effectiveness and efficiency of core facilities, if NIH-wide metrics would be useful (and if so, what the measures should be), how to facilitate communication about core facilities to identify available resources, and how NIH data could be used to improve core alignment and effectiveness. Dr. Rockey reiterated that the NIH would like to work in partnership with institutions to facilitate the goal of improving core facility efficiency.

Outcome of the American Recovery and Reinvestment Act (ARRA) Core Consolidation Supplement Program

James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH

Dr. Anderson presented results from the one-time program to encourage core consolidation activities using funds from the American Recovery and Reinvestment Act (ARRA) of 2009. The program was implemented by the NIH Administrative Supplements to Support Core Consolidation (NOT-RR-10-001) for the purpose of consolidating multiple cores into a single, more efficient combined core facility. Dr. Anderson indicated that NIH annual support of research cores is estimated conservatively at $900M, and that NIH is interested in finding ways to ensure cores are managed efficiently. Anecdotal evidence suggests that redundancy in core services exists within institutions and within and between NIH funding Institutes and Centers (ICs), but the level is challenging to document. He dispelled the urban myth that NIH policies discourage sharing: institutions are encouraged to examine their management of cores and local cultural factors that affect efficiency as well as share cores with other institutions to reach a greater efficiency and better science.

The aim of the Core Consolidation Supplement program was to reduce the number of similar core facilities at an institution, thereby enabling the pooling of resources to become better organized in a more

cost- and time-efficient structure. Supplements to 26 institutions ranging from $300,000 to $1.3M were awarded for mechanisms, including P30, UL1, G12, P60, PL1, and U42. Eighty applications were received and 12 NIH ICs participated, attesting to the interest in core consolidation. Awardees agreed to share best practices for core consolidation with the research community after these projects were completed.

To assess the extent to which the consolidation program has been achieving its goals, the NIH analyzed available information obtained in final progress reports from grantees who received administrative supplements to support core consolidation. Dr. Anderson highlighted the results of the study that were published recently in the ABRF's *Journal of Biomolecular Techniques* (http://www.ncbi.nlm.nih.gov/pubmed/25649473). Most awardees consolidated two cores into one, with several consolidating three to five cores into a single combined core. Notably, some of the combined core facilities were funded by different NIH ICs, and a project combining five core facilities from the National Institute of Environmental Health Sciences, U.S. Department of Energy, and U.S. Environmental Protection Agency demonstrated success in combing cores across different funding agencies. All research core facilities increased their number of users (up to three-fold), services (up to two-fold), or both. Efficiencies were observed in billing, purchasing, scheduling, and tracking, particularly in terms of increased speed and reduced costs. Dr. Anderson also showed that cost recovery to support core operations benefitted from the consolidation effort, in some cases several-fold.

Dr. Anderson acknowledged that despite the great success of the ARRA Core Consolidation Supplement program, it is unlikely that a similarly large bolus of funding will be available again for this type of consolidation effort. He encouraged the participants to consider how to promote core consolidation efforts at a lower cost to duplicate the results in a more financially constrained environment. He reiterated that the study showed that efficiencies resulted from consolidated billing, purchasing, and scheduling and tracking services; integration of information management and data systems; increased services and more core users through installation of advanced instrumentation and access to higher levels of management expertise; cross-training of staff; enhanced consultation and analyses of complex data; and standard operating procedures.

Dr. Anderson asked participants to share their thoughts on obstacles to sharing and centralized management, such as policies, culture, or lack of awareness; potential motivations and solutions to increase core facility efficiency; and the extent to which sharing can or cannot be achieved, and at what scale (e.g., inter-institutional, state-wide, or regional). What can be done to incentivize core efficiency? Dr. Rockey then emphasized the NIH leadership's interest in understanding how institution-wide core administrators track core facilities across their institutions, and she encouraged participants to share best practices concerning research core indexing and tracking efforts. Dr. Anderson elaborated that current NIH databases are not designed to easily report core system data. A recent manual exercise to identify core facilities across institutions was challenging, yet confirmed existing redundancy. Increased awareness of core research facilities across institutions is an important priority.

Selected Examples of NIH Approaches to Core Facilities

Update on the Clinical Translational Sciences Award (CTSA) Program

Todd Wilson, D.O., Medical Officer, Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), NIH

Dr. Todd Wilson presented an overview of the history and future directions of the National Center for Advancing Translational Sciences (NCATS) Clinical Translational Sciences Award (CTSA) Program. The CTSA is a national consortium of medical research hubs that work together to improve the way clinical translational research is conducted nationwide. It was established in 2006 with the intent to re-

engineer the translational research enterprise and provide training for clinical translational researchers. The Program currently has 62 sites that provide training for clinical translational researchers.

CTSAs offer many different resources, services, and other components across a spectrum of work in clinical translation, from the preclinical stage to dissemination. Dr. Wilson highlighted examples of cores supported in the past: translational genomics technologies, high-throughput screening capabilities, and clinical research units for which CTSA is well known. Many CTSAs have engaged business schools to develop business models to assist in developing cores, resources, and services. Also, CTSAs are asked to leverage the CTSA funding given and try to maximize its impact.

Dr. Wilson informed participants that the CTSA now builds metrics into its FOAs. To develop common metrics, NCATS developed a CTSA working group that includes staff, investigators, and an external consultant. Dr. Wilson stressed that a major goal is to minimize the administrative and data burden on CTSAs. To receive feedback on the implementation process, Domain Task Forces (DTFs) have been developed to include representatives from all 62 hub sites. DTFs serve as a link to the CTSAs with regard to assessing methods and processes, informatics, workforce development, collaboration/engagement, and integration across the lifespan.

The most recent CTSA FOA (RFA TR 14-009) responds to the concerns of the 2013 Institute of Medicine report. The U award (cooperative agreement) addresses several overarching topics (e.g., informatics, integration of health and research), required modules (e.g., workforce development, regulatory knowledge, special populations), optional modules in areas of institutional strength or opportunity, and network support (e.g., multi-site studies [IRB, contracting], recruitment [electronic health records (EHR), on-the ground recruitment support]). The K award addresses mentored career development, and the T award is a National Research Service Award training award.

Multi-site trials are necessary to move from discovery to the clinic. In the traditional CTSA model, trials were rebuilt each time. Other drawbacks included decentralized Institutional Review Board (IRB) review and contracting, splintered and complicated compensation, and overestimates of trial participant numbers. The new CTSA model incorporates prefabricated and funded clinical trial infrastructure with willing and veteran clinical sites, Master Trial Agreements in place, a central IRB (cIRB) with existing reliance agreements, an HR estimate of patient availability, and a means to introduce eligible and willing participants to investigators, which has improved recruitment times. The value of regional IRB reliance agreements—networks that collaborate on approving clinical trials—was evident following the Boston Marathon bombing, which has served as a unique case study. Doctors at the Massachusetts Eye and Ear Infirmary in Boston recognized the value in studying the blast-related ear injuries of the bombing victims. Because the Harvard University CTSA already had in place an IRB reliance network with seven area hospitals, rapid IRB approval was obtained to study a large number of ear injuries from the same blast and to observe patients as they healed. This case study highlights the value of standardization.

Dr. Wilson shared several of the pilot initiatives within the CTSA Program. One such pilot initiative, cIRB, has drafted reliance agreements that are currently under review and also is developing an open source information technology platform. A contracting initiative, in coordination with the National Patient-Centered Outcomes Research Institute, has drafted and executed master trial agreements for CTSA–industry interactions at two-thirds of CTSA sites. A subcontract template for NIH-funded studies also is under development. The goal of a third initiative is to implement the use of EHR at all 62 CTSA sites that can be accessed for patient recruitment purposes. The first wave of technology implementation has begun at 11 sites; sites for the second wave have been identified.

The CTSA Program's ultimate goal is to set up Trial Innovation Centers (TICs), Recruitment Innovation Centers (RICs), and Collaborative Innovation Awards (CIAs). TICs would customize clinical trial support

through central IRBs, master trial agreements, and streamlined communications and oversight within the organization. They would seek innovative approaches to increasing clinical trial efficiency and effectiveness. RICs would focus on improved recruitment and data-driven discovery. For example, they could use EHR to estimate the number of potential participants who meet the trial entry criteria within the CTSA network. CIAs would seek to: (1) develop a new technology, method, or approach that addresses a general roadblock in science or operations that limits the efficiency and effectiveness of translation; (2) demonstrate in one or more use cases whether the tool, method, or approach is effective in accelerating translation across multiple CTSA hubs; and (3) advance collaboration, building on existing strengths and resources of CTSA hubs. Dr. Wilson noted that the CTSA Program is not focused on clinical trials only. The Program serves as an incubator of ideas and community engagement and is evolving to transform clinical translational science. Significant funding has been delivered to local sites to develop resources and services.

NCI-Supported Cancer Centers and Core Facilities
Michael A. Marino, Ph.D., Program Director, Office of Cancer Centers, NCI, NIH

Dr. Michael Marino's presentation detailed the NCI's grants supporting Cancer Centers and core facilities. The Cancer Centers' mission is to foster excellence in research across a broad spectrum of scientific and medical concerns relevant to cancer and to extend the benefits of research to patients, their families, and the general public through clinical care, outreach, and education.

Dr. Marino distinguished the two types of NCI Cancer Centers: (1) Comprehensive Cancer Centers (41) must demonstrate reasonable depth and breadth of research activities in each of three major areas: basic laboratory; clinical; and prevention, control and population-based research, and must have substantial transdisciplinary research that bridges these scientific areas; and (2) Cancer Centers (27), which are primarily focused on basic laboratory; clinical; and prevention, cancer control, and population-based research; or some combination of these areas. Both types of Cancer Centers must demonstrate strength in six essential characteristics. Together, these characteristics maximize its scientific potential and produce a whole that is greater than the sum of its parts: a dedicated physical space; organizational capabilities that must be sufficient to maximize productivity and take advantage of institutional strengths; transdisciplinary collaboration and coordination; a critical mass of cancer-focused research; a strong institutional commitment; and, a Center Director with appropriate scientific and administrative qualifications and authority.

Dr. Marino presented the general policies for Cancer Center Support Grant (CCSG)-supported shared resources. No restrictions exist on the types of resources that can be covered, as long as it is justified. These resources may be Center- or institutionally managed. Users can be internal or external, but priority is given to Cancer Center members with peer-reviewed funded cancer research projects. Other researchers can use the facilities at the discretion of the Center Director. Usage of a facility should focus on shared resources serving multiple members, but there are some exceptions to this policy. With respect to budgets, CCSG supports "fixed" costs associated with key personnel and minimal supplies. These costs vary according to the number of users, type of resource, and other sources of support including chargebacks. For institutionally managed resources, the facility's budget should be proportional to its use by Cancer Center members. CCSG is not intended to support highly specialized projects specific to one or two investigators, shortfalls in other funding mechanisms, or services normally provided by the institution.

CCSG funding has remained fairly consistent over the last several years at around $260M, with the exception of a drop in 2013 to $244.8M due to budget cuts. The number of Centers, currently at 68, has increased approximately 1 per year. The percent of funding that is designated for supporting shared resources has remained fairly consistent at around 55 percent of direct costs, except for a slight decrease in 2013. In 2013, 688 cores were supported with an average of 10 cores per Cancer Center.

Dr. Marino stated that shared resources fall into one of seven categories: Laboratory Sciences, Laboratory Support, Epidemiology or Cancer Control, Clinical Research, Biostatistics, Informatics, or Miscellaneous. In 2011, the majority of core funds were distributed to shared resources in the Laboratory Science category (52%). Clinical Research resources accounted for 23 percent, while Bioinformatics resources were at 12 percent. The remaining categories accounted for 5 percent or less. In 2013, Laboratory Science continued to be the largest (50%), but the distribution of funds among the smaller categories increased considerably (Biostatistics: 15%; Clinical Research, 14%; Informatics, 9%; Miscellaneous, 7%; Epidemiology and Cancer Control, 4%; Laboratory Support, 1%). Dr. Marino noted that bioinformatics and informatics are key to conducting translational clinical research.

Cancer Centers have the same core mission—to cure cancer—but they vary in size and geographic setting. Each Center strives to tailor its study of cancer to its catchment area, which can range from an entire state to a single zip code. This tailoring is important to avoid establishing Centers that have a distinct specialty but that ignore the patients who visit the hospital. It is important for Centers to show that their research programs work within their catchment area. Dr. Marino noted that St. Jude Children's Research Hospital in Memphis, Tennessee, has a catchment area of the entire United States and has never refused a child referral.

Dr. Marino explained that the CCSG FOA (PAR-13-386) dictates what each Cancer Center needs to include in its application. Developmental funds can be allocated to the development of new shared resources when there is a recognized need that was not included in the original 5-year plan. The purpose of these funds is to increase access to state-of-the-art technologies or other specialized shared services through purchase of peer-reviewed shared services from other NCI-designated Cancer Centers.

Dr. Marino outlined the benefits and concerns relating to Center-to-Center core sharing. Aside from the obvious benefits of improved scientific research, these include access to state-of-the-art technology with expert staff and consultation services, the development of standard operating procedures (SOPs), a reduction in cost due to sharing rather than duplicating, equalization of the research field for all Centers (large and small), and increased collaborations or co-publications. Issues focus primarily on intellectual property concerns, such as non-royalty Academic License Agreements and invention sharing via a Memorandum of Agreement. Also, fees need to be negotiated, quality assurance of the Core facilities needs to be executed, and protection of patient information needs to be ensured.

Panel Discussion
Moderators: *James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH; William Hendrickson, Ph.D., Director, Research Resources Center, University of Illinois, Chicago, President, ABRF*
Panelists: *Sally Rockey, Ph.D., Deputy Director for Extramural Research, NIH; Todd Wilson, D.O., Medical Officer, Division of Clinical Innovation, NCATS, NIH; Michael A. Marino, Ph.D.; Joe Ellis, Senior Policy Advisor, Office of Extramural Research, NIH; Christopher Sanford, Ph.D., Program Director, Division of Biological Infrastructure, National Science Foundation (NSF)*

Dr. Anderson introduced the panel members and encouraged the meeting participants to ask specific questions about NIH policies and procedures. He invited the participants to offer their ideas regarding the NIH's potential role in increasing efficiency.

Referring to Dr. Anderson's presentation on the ARRA Core Consolidation Supplement program, a participant asked about the nature of the consolidation activities. Dr. Anderson clarified that projects typically combined similar technologies, for example in one case five different genomics technologies into a single core.

In response to a question from Northwestern University's Dr. Phil Hockberger about the fixed amount awards, Mr. Joe Ellis clarified that on an *ad hoc* basis, awardees can negotiate with the NIH to agree on a specific rate of reimbursement. Fixed amount awards do not require cost accounting, which helps achieve the goals of improving the quality and efficiency of the service and reducing the administrative burden for routine services.

- Dr. Rockey added that many core services likely would qualify for fixed amount awards, and she encouraged the participants to consider the award mechanism for their core facilities.

Dr. James Cherry, Frederick National Laboratory for Cancer Research (FNLCR), asked what the NIH's position is on allowing extramural investigators to partner with NIH intramural core laboratories.

- Mr. Ellis stated that the ability for extramural use of intramural facilities is being explored, and that currently there is a U01 program facilitating access to the NIH Clinical Center when there is a shared research objective between an intramural and an extramural investigator.
- Dr. Rockey clarified that the existing program with the Clinical Center awards grants to extramural investigators collaborating with an intramural investigator to use resources at the Clinical Center. Funding is distributed in three ways: to the extramural grantee in the form of a grant, to the intramural collaborator through his or her laboratory, and to the Clinical Center for the resources used.
- Dr. Cherry elaborated that FNLCR's two established partners, the University of Maryland and The Johns Hopkins University, are permitted to use their services.
- Dr. Anderson summarized the discussion by acknowledged that attendees were interested in finding ways that intramural and extramural investigators can share core resources.

Dr. Bradley Cairns, University of Utah, commented that Cancer Centers and CTSAs occasionally have overlapping core facility needs and wondered how these institutions might improve coordination or be incentivized by the NIH to do so. Dr. Cairns added that a major opportunity lies in biorepositories and the informatics that links them and that connecting independent resources has been a recent effort at the University of Utah. Dr. Cairns pointed out that institutions could include this as part of grant renewal criteria as emphasis.

- Dr. Marino agreed that coordination between CTSA and CCSG should be explored.

Dr. Lauren Becnel, Baylor College of Medicine, advocated for the implementation of core identifiers that could be used with grants and easily pulled through electronic processing of SF424 application forms. She explained that a single core is often identified in various ways on different applications.

- Dr. Rockey supported the idea, acknowledging that cores can be difficult to identify particularly in subprojects. The use of identifiers also would be helpful to clearly identify core facilities that are cited in or paid for by R01 grants.
- Dr. Anderson asked by whom core identifiers would be used and whether they could be used to nationally advertise the cores.
- Dr. Becnel replied that not only could the NIH staff use core identifiers, but also core customers would be able to unambiguously cite cores in publications and grants, which has been an ongoing challenge. A core research object identifier also could be utilized by indexing services.
- Dr. Rockey urged thoughtful development of the syntax for core identifiers to optimize indexing based on the resource available at each core.

Dr. Jean Schaffer, Washington University in St. Louis, commented on the administrative burden of trying to ensure compliance of all publications that arise from use of a core facility.

- Dr. Rockey recognized that core facilities would like to be credited when accomplishments and publications arise from their use. She stated that the NIH's public access policy has been

modified to relieve cores of the responsibility of ensuring compliance and that a notice had been disseminated 3 to 4 months ago. Dr. Rockey offered to distribute an additional notice to help core facilities with this issue.

Dr. Katia Sol-Church, Nemours/Alfred I. DuPont Hospital for Children, who is involved with the NIGMS Institutional Development Award (IDeA) Program, requested that NCATS materials regarding the formalization and standardization of the evaluation process be shared.

- Dr. Wilson agreed, recognizing that NCATS metrics and evaluation standards might be similar to others.

Dr. George Grills, Cornell University, expressed enthusiasm for the implementation of national core identifiers and added a recommendation that they be annotated to distinguish between a core and a core center. To assist with long-term tracking of the use of shared research resources, he suggested that R01 grant applications and progress reports include a section about the potential and actual use of cores. Dr. Grills inquired about an optimal method for creating databases and surveys of cores. He suggested that the NIH fund the development of a national core database, indicating that barriers to creating such a database include the initial investment and funding for annual surveys to update the data.

- Dr. Anderson acknowledged the need for strategic thinking about such a resource. Because some institutional cores are not ready or willing to be shared, a database comprising every core is not necessarily the goal.
- Dr. Grills offered the suggestion that each institution list its own cores and their availability in a national database, because it can be difficult for an investigator to know what shared resources are available even within his or her own institution. The ability to query a database for local, regional, and national resources would be useful.
- Mr. Ellis pointed out that the NIH does not support all cores and wondered whether the database should be developed by the NIH or perhaps by another group.
- Dr. Grills encouraged developing a database in a manner that resembles the development of Eagle-i— i.e., securing funding for the creation of a nucleus for the development of the database, which is the major cost. The community could then be tasked with determining the best mechanism for moving forward. Dr. Grills suggested that the NIH plus other funding agencies (e.g., NSF) encourage a collaboration with other organizations (e.g., ABRF, Eagle-i, Vermont Genetics Network) as a quick way to move forward.

Dr. Lawrence Marnett, Vanderbilt University Medical Center School of Medicine, further explored the idea of a database of cores. He referred to Dr. Wilson's slide about the CTSA catalogue of approximately 35 high-throughput sequencing facilities, which range from a single investigator with one robot to a highly sophisticated facility. Dr. Marnett noted that the quality of the cores could represent a second level of information. He suggested including a reference list of investigators who have used and been satisfied with each core.

- Dr. Hendrickson responded that a database user would likely move from the master list to a detailed Web page for each core. Rating cores, he noted, may not be appropriate, but a publication list might be one way to avoid being judgmental.
- Dr. Anderson added the caveat that the list would require upkeep.

Dr. Ronald Niece, Research Resources and Technologies, said that the ABRF Membership Committee, of which he is a member, awaits the database of core facilities for recruitment and information dissemination purposes. Many institutions with core facilities are not yet ABRF members.

Dr. Terry Magnuson, University of North Carolina at Chapel Hill, spoke of the struggles that his institution has faced in regard to charging internal versus external rates for core use.

- Dr. Hendrickson shared as an example the coordinated core system that three major Chicago universities have established at the President level. Their effort was successful in part because of an external survey presented to each of the university's top administrators that projected high efficiency and cost savings over time. Metrics showed that the costs coming into and out of each institution were approximately equal, and no institution was losing indirect costs.
- Mr. Ellis indicated that the NIH is not engaged in a discussion about this issue, but he agreed that the idea is excellent as a regional approach. He noted that no requirement in Federal cost principles or NIH policy instructs institutions on this issue.

Ms. Julie Auger, University of California at Davis, remarked that although many NSF-funded core facilities exist and span several disciplines, biomedical institutions are often unfamiliar with NSF programs. She wondered about the level of cross-agency integration regarding the sharing of facilities, user bases, and other resources and inquired about the policies dictating cross-agency cooperation.

- Dr. Christopher Sanford, NSF, mentioned that his role at the Workshop was to determine how the NSF can facilitate rather than duplicate efforts.
- Ms. Auger advocated for enhanced cross-agency coordination and an open dialogue about the benefits of sharing and co-investment in resources.
- Dr. Rockey mentioned that a Federal-wide working group, Research Business Models (co-chaired by NSF and the NIH and composed of 14 agencies that all fund research), has been evaluating guidance from the OMB to ensure that Federal-wide policy facilitates instrument-sharing. The group has disseminated notices clarifying permissions regarding sharing.
- Ms. Auger added that her question speaks to the cultural change that needs to occur within institutions and funding agencies beyond putting mechanisms into place.
- Dr. Rockey commented that the NIH first needs to communicate rules and regulations very clearly to universities to avoid misinterpretation. To this end, she requested that meeting participants inform her of specific concerns, beyond the shifting of culture, that hinder the sharing of facilities.
- Dr. Anderson remarked that at a recent meeting with NSF leadership, points of contact in different fields were established to be able to more effectively communicate and facilitate sharing.

Dr. Andy Chitty, Oregon Health and Science University, called attention to the funding structure for core consolidation. To reduce costs to the NIH and to incite universities to think carefully about their strategic policies regarding cores and consolidation, he recommended that a certain fraction of the funds be matched by universities.

- Dr. Anderson responded that no grant supplement follow-up exists to the ARRA Program, although he is interested in the factors that might have driven efficiency.

Challenges, Solutions, and Best Practices for Centralized Core Management and Overcoming Policy, Administrative, and Practical Challenges to Enhancing Efficiency of Core Facilities

Strategy, Governance, and Effectiveness of Shared Resources (Cores)

Bradley Cairns, Ph.D., Professor and Chair, Department of Oncological Sciences Investigator, Howard Hughes Medical Institute; Senior Director of Basic Science, Huntsman Cancer Institute, University of Utah School of Medicine

Dr. Cairns described his experience overseeing a set of shared resources at the Huntsman Cancer Institute (Cancer Center) at the University of Utah. He explained that the governance structure of the University of

Utah's core facilities includes two broad oversight committees: one for the School of Medicine and the other for the Main Campus. Within the School of Medicine, cores are managed by either the School of Medicine or the Cancer Center. Both systems report to the Senior Vice President, who then reports to the University President. Dr. Cairns elaborated that all cores within the School of Medicine strive to have the same governance structures. Each has a faculty steering committee and a Chair, who works closely with the core's directors and staff. In addition, all cores are open to all faculty and laboratories. The cores have an open queue for resources, one-tier pricing, a transparent budget, professional directors, extensive surveys and benchmarking, and a unified website (http://www.cores.utah.edu). The School of Medicine's cores have been structured to have clear and coordinated centralized governance.

Dr. Cairns contrasted the governance of the School of Medicine's cores with that of the Main Campus' cores. The Main Campus cores are organized and governed in a more distributed way, either by individual schools or departments. These cores report to the Senior Vice President of Research and have various models of oversight. Their policies include variable pricing, a variable queue, and closed budgets, and they lack a central website. The Vice President, however, is interested in transitioning to a centralized model similar to that of the School of Medicine and has engaged a Central Committee that includes core facility representatives from both the School of Medicine and the Main Campus. The catalyst for this shift, Dr. Cairns noted, was a strategic plan that resulted from the review of the shared resources. The Central Committee serves in both advisory and financial oversight roles and uses an RFA that encourages cores and laboratories to compete for equipment. Dr. Cairns added that a larger amount of funding is distributed to core facilities, whereas individual laboratories have to show either extreme effectiveness or a sharing format to receive funding. Overall, the University of Utah's centralized core facilities have proven more effective than the decentralized facilities.

Dr. Cairns stated that centralized facilities generally are more efficient and effective than decentralized facilities; the decision to centralize has to consider both faculty and institutional priorities. Faculty prioritizes cutting-edge equipment, high-quality services, high capacity and fast turnaround, and low costs. Institutions, however, must consider the funding necessary to achieve discovery, the coordination required between core facilities, and the reporting requirements of the institution. As a result, the return on investment for each core facility needs to be thoroughly examined. User proximity to cores, for example, can be a serious challenge to consolidation. Dr. Cairns recognized that not all facilities need to be centralized and that institutions will need to consider the services that are absolutely essential for group investigators in a particular entity.

Dr. Cairns explained that implementation of centralized facilities at the University of Utah was successful in large part due to effective administrators in the 1990s who recognized the importance of consolidation and coordination. Having established a system for core facilities prior to core proliferation allowed for a smoother introduction of new cores. A major challenge to centralizing core facilities, however, is building trust and transparency among the faculty. Particularly important is assuring the faculty of continued access to the facilities, high-quality services, and reasonable or one-tier pricing. He suggested that faculty define and manage the services and that an annual survey and central review of each core be used to assess ongoing success.

Sharing of facilities and services could be encouraged through a number of effective incentives. Dr. Cairns noted that institutions could offer central costs that cover equipment, technicians, and service contracts. Central costs also can cover informatics (e.g., Laboratory Information Management Systems [LIMS]) as well as billing and reporting services. To determine what can and should be centralized, Dr. Cairns suggested that each service undergo a careful assessment of current and future costs, including personnel and the costs of space, in both centralized and distributed scenarios. Commercial options and upcoming technologies also should be considered.

Dr. Cairns elaborated on several costs to catalyzing greater efficiency. These include a financial outlay of money that needs to be balanced against the long-term financial benefits determined in the cost model. In addition to financial concerns are a loss of autonomy among research groups, which often are proud of their stewardship and accomplishments. Dr. Cairns added that faculty steering committees have become very important to ensure continued heavy involvement by the faculty. Proximity issues also are of concern, as is the communication burden required to inform the community about the services and price models. The latter concerns can be facilitated by an effective website.

To encourage efficiency in facility use and organization within institutions, Dr. Cairns recommended that NCI and the other institutes and centers at the NIH articulate in their proposals that sharing is encouraged. Toward this end, he suggested that the NIH could return to the individual scoring of cores in CCSG rather than bundling them. Dr. Cairns also returned to a point that Dr. Marino made earlier, namely, that some Cancer Centers offer special access or pricing for Cancer Center members. This policy has caused fragmentation and friction at some institutions when coordinating use of the facility with non-Cancer Center members. Dr. Cairns noted that the University of Utah has elected to make the availability of the facility uniform to the entire School of Medicine. Dr. Cairns suggested that the NIH promote core consolidation by providing funds that enable consolidation. Also, the NIH can help ensure that new equipment is not contributing to the "silo" perspective by incorporating into their RFAs eligibility criteria that align with centralization.

Dr. Cairns asserted that obstacles to success in centralizing facilities lie more with institutions than with the NIH. Leadership at institutions need to consider governance, policies, and communications and how best to align incentives with their goals. Dr. Cairns noted that an Institutional Core Strategic Plan is very effective in helping with coordination among all entities. Some institutions, however, need guidance on how to do this well and could benefit from use of a model. The CCSGs at many institutions could provide a useful model for centralizing facilities. Often CCSG cores are very effective scientifically and efficient operationally, and they have the types of reporting mechanisms and organizational capacity that are required. Institutions seeking to centralize facilities need to have similar capabilities, not only to receive a CCSG grant but also to be effective in providing patient care, precision oncology, and research. Yet these services require an incredible amount of coordination and integration of shared resources. Providing comprehensive patient care requires coordinated use of, for example, EHR, biospecimen tracking, LIMS systems, genomics data, and integrative software. Therefore, it is essential that considerable centralization and consolidation occurs to have shared resources be compatible. Significant opportunities exist for adapting centralization or coordination modules throughout and across institutions.

Central Coordination of Core Facility Management: Challenges, Solutions, and Best Practices
Julie Auger, Associate Director, Campus Core Facilities Program, University of California at Davis

Ms. Auger has been working in the coordination of core facilities since the mid-1980s at the University of Chicago, the University of California at San Francisco (UCSF), and the University of California at Davis (UC Davis). At the University of Chicago, she created the Office of Shared Research Facilities to coordinate central infrastructure and administrative support for core facilities. The initiative was incentivized by an investment from the university to the Biological Sciences Division (BSD) over a period of 6 years and was implemented at a time when there were very few centralized models in place.

In 2008, UCSF underwent a process of identifying and examining the operations of their core facilities. These efforts resulted in the creation of the Research Resource Program in 2010 to oversee approximately 80 cores. Ms. Auger said that she was recruited to help UCSF establish the administrative office for centralization. Ms. Auger shared that she recently relocated to UC Davis, where she spent 2 years examining its shared research infrastructure. About 170 cores were identified that span all colleges and professional schools and include the biological, physical, veterinary, and social sciences.

Ms. Auger explained that centralization is a systematic set of tools that institutions employ to support and enhance the operations of shared research facilities. Centralization integrates processes for effective review, as well as transparency of available resources at institutions and across regions. In addition, centralization results in effective information-gathering and sharing for informed decisions that strive to maximize research dollars. It is not sun-setting programs or laying off of personnel.

Centralization of facilities has advantages for both cores and institutions. Ms. Auger reviewed the benefits for cores, including increased awareness of core operations and services among the community, providing support for needs assessments regarding the latest scientific and technological advancements, and financial stability and planning ability, particularly related to efficient billing and recovery. Centralization of facilities promotes among faculty the ability to focus on science, not on administrative tasks. Additional benefits include a focus on education for staff and clients, increased investment from funding agencies, increased attention to deferred maintenance, and efficiencies of scale for specialized support. Ms. Auger explained that the benefits of centralization for institutions include increased strategic investment opportunities, increased faculty satisfaction regarding service and access (i.e., recruitment and retention benefits), the ability to leverage group buying power, increased revenue recovery from external sources, reduced audit risk (i.e., elimination of inequitable charge practices), and reduction of deficit spending by shared research facilities.

Institutions establishing a central or coordinated core management program should incorporate support for central specialized business functions. These include educational experiences beyond an institution's curriculum or technical training abilities, as well as the ability to conduct research and development that enables the development of next-generation applications or technologies. Centralization also can support the recruitment, retention, and continuing education of core scientists and ensure that they have the skill sets relevant to the research community's needs.

Ms. Auger explained several keys to success that allowed the University of Chicago and UCSF to be successful in implementing a centralized facility program. These included having core directors retain autonomy over facets at which they excel (e.g., scientific and technology decisions, personnel management, research and development). Central administrators served as partners to ensure that core directors were receiving the information necessary to make those decisions and supported cores in areas in which they were not as proficient (e.g., business skills).

When beginning to consider how to centralize facilities, Ms. Auger recommends tackling the challenges faced by core directors. These often include the need for communication and visibility tools (e.g., search engines, websites, sponsored technology seminars), grant writing support (e.g., instrumentation grants, center grants), equipment management (e.g., service contracts/maintenance, inventory), and mechanisms for researcher training and education to create a nimble user base. Institutional challenges include the need for change while keeping institutional integrity, the need to reduce deficit spending by cores and researchers, the limited process for evaluation of *ad hoc* subsidy requests, improvement to risk management (e.g., financial audit, biosafety, intellectual property protection), faster discoveries resulting in increased external support of research activities, as well as a content, successful, and engaged research community.

Ms. Auger suggested several best practices that institutions can implement to facilitate the centralization process. Investing in and developing requirements for continuing education of core scientists will accelerate researchers' abilities to adapt to changing technologies and applications. Ms. Auger also recommended investing in specialized expertise in financial management (e.g., in rate setting, monthly financial reporting, spending decisions) and in making better use of tools (e.g., electronic usage tracking, online scheduling and service requests, automated monthly billing). She suggested balancing rechargeable

activities with subsidization of research and development, as well as training and education. Ms. Auger highlighted that a consistent definition of a "core" is needed and that standardized guidance regarding regulatory issues (e.g., audit compliance, Unrelated Business Income Tax), biosafety, and work with external clients (e.g., business contracts, intellectual property consideration) is necessary. Finally, appropriate incentives need to be developed at each stage.

Value-Based Structures: Centralization and Decentralization
David M. Dilts, Ph.D., M.B.A., Professor of Management, Oregon Health and Science University

Dr. David Dilts, a management scientist serving as the Director of Evaluation for the Oregon Clinical and Translational Research Institute and Professor of Management at the Oregon Health and Science University, shared with the audience the two primary research questions that drive his work: understanding how diverse systems can be integrated for better performance and how to transfer lessons learned between domains. He observed that although all organizations consider their internal problems to be unique, in fact they all struggle with similar issues. A cultural shift is needed to achieve change. Dr. Dilts cited the example of the U.S. automotive industry's goal in the late 1980s of increasing production rates by imitating the Japanese production line's "andon cord" mechanism for alerting management to problems. When a similar cord was implemented in the United States, workers refused to use it. Analogously, Dr. Dilts advised the NIH not to simply implement a new mechanism or policy, but rather to initiate a cultural change.

Dr. Dilts explained several major differences between centralization and decentralization. Centralization is beneficial when technology is very expensive or specialized, as it will level peaks and valleys of demand, centralize control, and, typically increase efficiency. Decentralization is valuable when technology is relatively expensive, as it will facilitate responsiveness to immediate needs, localize control, and usually increase effectiveness. He added that whereas efficiency is defined as "doing things right," effectiveness is defined as "doing the right things." When deciding whether to choose centralization or decentralization, Dr. Dilts noted that centralization adds economies of scale ("bigger is better"), whereas decentralization adds economies of scope ("bigger is worse"). Often, when a project is delayed and additional individuals are added to the project, it becomes further delayed.

Dr. Dilts explained that a more centralized structure results in greater variability of the quality of the managers; i.e., highly capable managers have greater beneficial effects, and highly incapable managers placed in the same position have greater deleterious effects. He recommended choosing management of the central core wisely and emphasized that centralization can have an effect on innovation. Centralization is preferred when users have similar demands, when "market fluctuations" are large, and in the short term. In contrast, decentralization performs better when users have dissimilar demands, when "market fluctuations" are small, and in the long term. Dr. Dilts reiterated that the nature of the needs of the users, size of fluctuations, and the time horizon are important.

Dr. Dilts emphasized that any centralized system, including core facilities, must be built with sufficient technical and management capacity to satisfy its users. He added that the critical dimensions of performance must align between leadership and cores and that the organizational structure must support the customer's value needs.

Dr. Dilts advised meeting participants to consider multiple factors when deciding whether to centralize facilities. These include understanding: what incentivizes their facility's users (what is of most value to them); that users may not have value-added technical expertise; the customer needs and the timing of their needs; and that volume does not equal better. He also recommended being aware of "work-arounds" and "shadow systems," which are evidence of a poor broader system. Dr. Dilts reiterated that management, outreach, education, and understanding are the keys to success.

Panel Discussion
Moderators: *James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH; Julie Auger, Associate Director, Campus Core Facilities Program, UC Davis*
Panelists: *Bradley Cairns, Ph.D., Professor and Chair, Department of Oncological Sciences Investigator, Howard Hughes Medical Institute; Senior Director of Basic Science, Huntsman Cancer Institute, University of Utah School of Medicine; Julie Auger, Associate Director, Campus Core Facilities Program, UC Davis; David Dilts, Ph.D., M.B.A., Professor of Management, Oregon Health and Science University; Terry Magnuson, Ph.D., Sara Graham Kenan Professor, Chair, Department of Genetics, Vice Dean for Research, School of Medicine, University of North Carolina at Chapel Hill*

Dr. Nancy Fisher, University of North Carolina (UNC) at Chapel Hill, inquired about how to manage "shadow cores"—facilities supported by an external funding source that are located within individual investigators' own laboratories.

- Dr. Cairns stated that the University of Utah has not contended with this issue, noting that outstanding cores are required to hire exceptional faculty. If an investigator requires an instrument, the university will acquire it, house it in the core, and cover its service contract. Ms. Auger added that universities should recognize when a technology (e.g., a centrifuge) becomes commoditized. Such bench-top technologies should not threaten core facilities, as core facilities should be centers of innovation and specialized expertise.

A participant asked whether faculty steering committees for core facilities act as career development committees for core directors.

- Dr. Cairns replied that career development typically takes place at the Chair and Vice President levels. Faculty steering committees do occasionally discuss career development, but their main purpose is to define services (e.g., policies, pricing structure).

Dr. Howard Edenberg, Indiana University School of Medicine, expressed concern about how to appropriately measure the effectiveness of a core, specifically how to justify the return on investment and how to describe a core's impact on investigators' chances of being awarded funding. He emphasized the difficulty in capturing the value of core facility directors' expertise and dispensing of advice, a benefit not available when a task is outsourced to an external company.

- Dr. Cairns acknowledged the challenge of measuring impact and suggested communicating with peer institutions about best practices. He underscored the need for an administration that is aware of the output of the core (e.g., the papers published, the extent to which the data from the core is important in the publication, how the core is giving faculty an advantage at the institution). Dr. Cairns added that the NCI tries to determine the core's impact more precisely through an in-depth review of publications.
- Ms. Auger suggested using indirect measures to assess the core's benefit to investigators. For example, growing use of a central shared research facility by Federally funded investigators indicates that their funding for use of core facilities is increasing. Research scientists do not often think about return on investment, so determining appropriate metrics remains a challenge.
- Dr. Dilts stated that repeat business indicates that the core's services are highly valued. Dr. Cairns added, however, that some core facilities might receive a significant amount of business—but not much impact— because of their inexpensive or highly subsidized cost structure.
- Dr. Magnuson noted that although centralization of core facilities has many advantages, they cost money, need subsidies, and have deficits. Department chairs and center directors are highly resistant to losing authority over their facilities. UNC is taking small steps toward this end—

through changes in billing, collection, reports, and also by continuous analysis of core usage and flow of funds.

Dr. Anderson asked Dr. Cairns how to incentivize faculty to trust that centralization will not harm their careers.

- Dr. Cairns, using an example from the University of Utah, stated that an institution can transition equipment from a large and successful laboratory into a core facility by promoting a senior laboratory member to become the core's director. The director is provided with a staff to train, which gives the investigator confidence that the work will continue to be of high quality despite the increase in capacity. The institution provides funding for space and equipment, which often results in initial excess capacity on the front end but saves time in the long run.

Dr. Christopher Gilpin, Purdue University, expressed concern that startup funds for new investigators at the University of Utah are used to purchase new equipment housed in a core facility, and the investigators also are charged to use the facility.

- Dr. Cairns clarified that the startup funds are structured such that equipment costs and operational costs are separate. Faculty typically have similar operational costs, whereas their equipment costs can vary significantly depending on the type of work, whether the equipment already is present in a shared facility, and the equipment has the capacity required by the investigator.
- Ms. Auger recommended emphasizing that maintenance and personnel costs are covered. Most faculty appreciate receiving all of the benefits of having the technology available to them and avoiding the majority of the costs associated with it. In addition, all investigators who use the technology pay the same set rate; however, the investigator requiring it in his or her startup package may have a separate subsidy that comes from his or her operational component or is a separate allocation from the department.

Dr. Gilpin asked about the management structure of two similar but geographically dispersed facilities within an institution.

- Ms. Auger recommended that an overarching structure be implemented more frequently. She clarified that centralization does not imply that all facilities must reside at a single location but entails having a centralized approach to governance. This approach gives the community confidence that the same attention and service is available at all facilities. This is particularly important for facilities involving live cells or animals and less so for facilities with molecular technologies.

Dr. Justine Karungi, University of Kansas Medical Center, inquired about rate setting for centralized services that are not directly linked to a specific core (e.g., administrative contracts, service contracts).

- Ms. Auger replied that subsidized costs are be included in the cost rate. When administrative costs are included in recharge rates, which is allowable for specialized shared services, the administrative allocation becomes much smaller when multiple cores share the administrative services rather than when an individual facility covers the cost. This is not cost-shifting, Ms. Auger clarified, but cost-sharing because the administrative cost is an allowable expense that is appropriate on a recharge rate. Because the expense is shared, rates decrease.

Dr. Anderson expressed appreciation for Dr. Cairn's view that not only the NIH bears responsibility for improving the process of centralizing facilities, but also institutions do as well. Institutions need to be aware, deliberate, and informed about when they want to share facilities and how they centralize. Dr. Anderson asked for feedback from the meeting participants about how the NIH can help with the centralization process.

- Dr. Cairns proposed that the NIH, through CTSA and CCSG, incentivize core sharing and associated informatics programs either by making funds available for supporting informatics programs or by establishing separate RFAs. He suggested that this could be added to the review criteria as a bonus.
- Dr. Hockberger added that it would be helpful to take time to think about these ideas after the meeting and offer feedback in a more formal way. He also requested that the slides be made available. Ms. Auger suggested several ways in which the NIH can be helpful. First, it can provide the needed infrastructure for inventorying. Second, it should provide additional infrastructure when core facilities are adapting new technologies that do not have a very large initial user base. Third, more creative ways are needed to get new, cutting-edge technologies into the hands of investigators. An effective way is in shared research facilities, where there are experts who can focus on it. However, issues arise when core facilities are forced to break even; providing subsidies is a better solution.
- A participant added that it would be useful to have the ability to track grants that are using cores and the publications that come out of the cores. The participant suggested that PubMed add a field that allowed searching by core ID or grant as a simple way to track scientific impact.
- Dr. Fisher shared that core managers at smaller universities are not able to compete for shared instrumentation grants because they do not have the justification and sufficient number of users. They might manage to find equipment, but other items such as biosafety hoods to satisfy new guidelines are a hurdle. Therefore, she suggested having solicitations for issues regarding biosafety for which smaller institutions could compete for without the large justification need.

Sharing and Co-Locating Cores

Resource Sharing in Biomedical Research—Advancing the Institutional Research Mission Through the Cores

Sheenah Mische, Ph.D., Senior Director for Collaborative Science Cores, New York University

Dr. Sheenah Mische presented on her experience in consolidating and directing core facilities at New York University (NYU). She explained that centralization at NYU Langone Medical Center (NYULMC) grew organically out of the need for access to technology and expertise. An ARRA grant that NYU received was critical in facilitating the consolidation of two cores as well as a significant renovation and became the driver for organized centralization. In addition, the Office of Collaborative Science (OCS) was formed in 2009. Dr. Mische stated that the OCS is a collaborative model of interdisciplinary science and administration that is aligned with the institutional mission of enhancing collaboration, strategic planning, and investment. Its mission is to catalyze transformative changes in translational research through collaborative science, state-of-the-art infrastructure, and cutting-edge education. Dr. Mische said that in practice the OCS circumvents obstacles and delays in obtaining access to technologies that are needed for funded research projects. The OCS oversees 26 cores under a single administrative umbrella.

Dr. Mische outlined several of the challenges the OCS encountered when navigating a large, highly decentralized institution with 40 individual facilities. Contrasting departmental cultures, a sense of ownership, inconsistent historical data, an evolving organizational structure, and developing trust were all important factors. She also mentioned the lack of a shared vision and goals, which promoted independence and ownership; no incentive for teamwork and collaboration; and overlapping or competing priorities. Dr. Mische shared that the biggest challenge was securing funding for shared instrumentation. The university's evolution toward translational research had required core resources, cross-disciplinary approaches, and team science, but questions arose about how best to capitalize on existing shared resources.

Dr. Mische remarked that the OCS embarked on the process of consolidation by considering first the definition of a "core." A core is a centralized resource for expertise and technology that: (1) provides expertise or services that are not commercially available or are prohibitively expensive, (2) facilitates collaboration between researchers, (3) has institution-wide availability, (4) reduces duplication of instrumentation and expertise, and (5) reduces overall institution costs. The OCS sought to balance these benefits of centralization with the limited funds and space available, given its location in New York City. The requirements for shared resource cores are extensive: the need(s) for the core must be identified, alternatives must be considered, funding for expertise must be secured, a business plan must be established, space must be identified, and members for the Scientific Advisory Board must be selected. Nevertheless, the NYULMC was committed to its goal of centralizing core facilities.

Dr. Mische explained that NYULMC took the mandate for organizational change beyond facility centralization. She emphasized seven critical components used to drive collaboration and build cross-disciplinary competencies. First, strong and consistent institutional support are needed to invest in access to expertise and establish institutional knowledge management. A strong oversight committee must be built to ensure the alignment, productivity, and financial solvency of cores. Active faculty advisory committees must be created to leverage teams of influential investigators to support individual cores, evaluate instrumentation and staffing needs, and to assist with extramural grant funding activities. Data and analytics must be used to help in understanding the core's users, tracking grants, and evaluating the performance of each core prior to decision making. A central billing system should be implemented to create a single administrative group to handle billing and financial reporting for each core. Expertise should be hired, particularly scientists who are educators and innovators, to advance research and connect the scientific community in new ways. Finally, teamwork and collaboration must be fostered by bringing together core directors and scientists not just within the core but among all of the cores.

Dr. Mische recommended that institutions build partnerships of resource sharing and investment to benefit the entire community. At NYU, the OCS fostered partnerships between the NYULMC Cancer Institute, the NYULMC Clinical and Translational Science Institute, and other NYULMC Institutes and Departments. Beyond NYU lie opportunities to provide the NYULMC community access to technology and expertise not available internally, and core consolidation provides an institutional platform for extramural collaborative opportunities. NYULMC has undertaken city-side efforts to share technologies with the New York Structural Biology Center, the New York Genome Center, and pharmaceutical and biotechnology partners. Dr. Mische added that partnering identifies clear responsibilities and drives conversation around core facilities.

Dr. Mische shifted to a discussion of the attributes of Core scientists. NYU made it a point to hire expertise, educators, and innovators as core directors who offer comprehensive services from experimental design to data interpretation and who develop integrated project-centric, cross-disciplinary teams. Core directors are unique because they carry scientific, business, and leadership attributes. What distinguishes them from the average investigator is their collaboration and teamwork competencies and their overall quality of desiring to assist others. They not only must be creative scientists but also collaborative, business-savvy, and approachable. Having business and financial acumen, being capable of managing vision and purpose, and being entrepreneurial are key assets. Given the high level of importance of expertise related to the success of a core, a university that invests in its core professionals, and recognizes and rewards this quality, speaks to its success in research. Dr. Mische recommended establishing a leadership development program to foster teamwork and collaboration. NYU developed a human resources program similar to their scientist development program.

Dr. Mische emphasized the importance of retaining talent. She recommended having core directors as full-time, non-tenure track positions for those faculty members in any department whose primary career is

in research but who devote a portion of their efforts to education and service. They also should be named as co-principal investigators on grants. Institutions need to develop clear criteria for promotion. Dr. Mische pointed out that all metrics for success early in a scientist's career are against collaboration. For example, at NYU, criteria factored into performance reviews include a strong collaborative nature (e.g., the number of grants supported in the core), contributions to the academic mission, publications and acknowledgements, and the investigator's number of grants. Moreover, a standard faculty review question concerns whether the scientist has demonstrated independence. Dr. Mische recommended developing metrics to reward collaboration instead.

Dr. Mische pointed out that NYU's core model is an evolving entity that strives to drive translational research between the clinical and research sides, to develop integrated project-centric and cross-disciplinary teams, to provide nucleation for collaboration, and to offer comprehensive services from experimental design to data interpretation. Institutional support is critical in getting a centralized, shared resource off the ground, and continued institutional support allows for further expansion of the requirements for additional cores. Dr. Mische has seen a tremendous increase in collaborative projects at NYU initiated through the cores. Nevertheless, she recognized that many challenges exist, including the need for a change in culture regarding teamwork and community behavior. For instance, a shift in NIH funding from R01 to multi-investigator grants is needed to drive team science. Funding for cores (including "non-billable" core activities) can be difficult, and metrics for return on investment are needed to balance service, scholarship, and collaboration by core scientists.

Sharing and Co-Locating Cores

David Gorenstein, Ph.D., Associate Dean for Research, School of Medicine; Chair, Department of Nanomedicine and Biomedical Engineering, University of Texas (UT) Health System

Dr. David Gorenstein's vision is to create a network of state-of-the art Core Laboratories and Centers to accelerate basic, translational, and clinical research. The challenge is that a large number of tools have been thrust upon researchers. As a result, these Core Laboratories and Centers need to integrate new tools of molecular medicine (e.g., proteomics, genomics, metabolomics, systems biology, bioinformatics, biomedical informatics), as well as tools for "personalized" medicine and team-based science.

Dr. Gorenstein expressed enthusiasm that the UT system has a state-wide network of more than 100 cores—the University of Texas Core Lab Sharing Initiative—exists across four CTSAs. A Memorandum of Understanding between all 16 UT campuses states that standard rates apply for all standard services regardless of investigator institution, and there are no additional charges for indirect costs, which is remarkable. The UT system has provided financial support for iLabs, a superb core-management software, to be used across all campuses, and gives funds for pilot experiments to try to bring researchers together. A central website is maintained by the UT system to find core services.

Dr. Gorenstein noted the importance of increasing cross-institutional cooperation in shared resources. Constrained research funding increases the importance of efficient operations, new technologies are increasingly powerful, but also increasingly expensive, expertise required to operate some advanced technologies optimally is in short supply, some technologies can be operated more efficiently or in greater quality at high volumes, institutions have existing strengths in different technologies, and funding agencies are encouraging cross-institutional collaboration. Wherever possible, institutions should cooperate in the operation and funding of shared resource facilities.

The iLabs system at UT consists of a network landing page and a series of institutional landing pages. It includes a detailed list of cores across systems and allows for searching across all cores, reporting

enhancements to identify available capacity utilized and awareness. Future features might include WebEx/video capabilities, FedEx-like sample tracking, a Yelp-like rating for cores, and training videos.

Challenges to increasing cross-institutional core sharing are many. In a broad sense, a researcher must understand the availability of their own cores and all of the cores across 16 institutions. Managing access, privileges, and pricing across institutions is difficult with multiple usernames and processes as well as complex billing systems across institutions. Second, some technologies are not well-suited to remote usage, and building trust and communication between individuals who do not know each other can be difficult. Complex financial issues, such as partner pricing, allocation of indirect funds, and cost sharing, also are a hurdle. In addition, non-financial concerns pose a challenge, including resource location, access rights, and investment prioritization. Finally, some individuals or departments can be reluctant to give up autonomy or control. External resources may be perceived as inconvenient or unreliable. Challenges exist within systems/technology, scientific/practical, inter-institution coordination, and intra-institution coordination/politics.

The UT model for core sharing, a federation of independent research cores, is one of several existing models for core sharing. Others include centralized or hub/nodes core facility networks shared by institutions, a Gulf Coast Consortia (GCC)-type multi-institutional organization with centralized staffing, bilateral partnerships, or a GCC partnership with a core lab consortium. The model brings together the strengths of its seven-member institutions to build interdisciplinary collaborative research teams and training programs in the biological sciences at their intersection with the computational, chemical, mathematical, and physical sciences.

Another model for core sharing is the UT Proteomics Network, which consists of 15 sites. The Network improves access to existing core services across the state; adopts leading technologies, applications, and expertise on all campuses; assures high standards and quality; and enhances education for trainees and new investigators. Approaches to success include having a centrally coordinated network with in-house pricing agreements, common management platform (iLabs) and staff, funding for instrumentation and operations, a budget that emphasizes top-down technologies and staff for mass cytometry instruments and informatics, and shared best practices and a course curriculum. Dr. Gorenstein noted that communication is critical to promoting the network internally. He recommended budgeting for multiple in-person meetings for core directors and staff, having seminars and campus visits by specialty experts, hosting events, and coordinating email ListServs across institutions.

Vanderbilt Research Core Facilities
John Manning, Jr., Ph.D., Chief Administrative Officer, Vanderbilt University Medical Center; Senior Associate Dean for Operations and Administration, Vanderbilt University

Dr. John Manning's presentation reflected on Vanderbilt's ongoing centralization process that began nearly 17 years ago. All cores are driven by a scientific need and require the research community to achieve success. The cores are overseen by a set of faculty advisory committees at multiple levels. Faculty, however, are far more effective in determining overall direction of the program than they are in their implementation and operation of the cores. Overall, cores provide a cost-effective way to conduct state-of-the-art research, promote cutting-edge science, and mentor young investigators.

Vanderbilt has an ongoing commitment to cutting-edge technologies and high-end instrumentation in the shared resource environment. The institution supports more than 90 core laboratories that cover a range of technologies (e.g., genomics and DNA technology, proteomics and structural biology, computing and informatics, animal care). Thirty-five of the cores are considered Institutional Shared Resources and are integrated into research efforts across the campus. Collectively the cores expend $40 to $45M each year,

the majority of which comes from the NIH. Since 2008, Vanderbilt has committed more than $7M to matching 45 Federal shared-instrumentation grants awarded to principal investigators at Vanderbilt. Other investments in the cores total approximately $4M each year. Dr. Manning noted that costs for new cores are structured such that services are inexpensive in the first year and slowly increase over time to achieve a balance by the third year.

Dr. Manning explained that cores are a key part of the research enterprise and are managed through a shared governance model. All core facilities report to the Associate Vice Chancellors for Research. Each core has an advisory committee that consists of a Core Scientific Director (a faculty member), a Core Manager or Operations Director (a professional scientist who is not tenure-track), Core Research Technicians, and Senior Technical Specialists. Dr. Manning added that an Institutional Shared Resource Oversight Committee (ISROC) provides global input to the Associate Vice Chancellors for Research and recommendations. The collaborative synergy at Vanderbilt creates a supportive environment for core facilities.

Dr. Manning asserted that coordinated, centralized oversight ensures best practices. Vanderbilt's consistent recharge policy across all cores is designed to ensure compliance with the OMB Uniform Guidance and conscientiousness regarding allowable costs. The recharge policy also includes specific guidance on managing center memberships, external users, and Federal policies. Vanderbilt also strives to enact policies of institution-wide access that are consistent with Federal requirements. For billing and management, use of the Core Ordering and Enterprise Reporting System (CORES), which is migrating to the iLabs system, ensures appropriate cost recovery. General financial oversight and support of cores is facilitated by Office of Research. Other best practices include offering professional development for core technical staff, as well as separate core professional career tracks, which are powerful tools for retaining valuable expertise, fostering a sense of community, and maintaining continuity of core service quality. Finally, a culture of collaboration ensures that major research centers are engaged with and can take ownership of their cores. Ongoing relationships, integration, and alignment of missions is key to centralizing core operations, billing, and oversight.

Dr. Manning explained Vanderbilt's strategic spending of institutional dollars. The institution does not intervene in investigators' decisions regarding their R01 budget; however, it will not allocate funds for laboratory equipment that will reside in a faculty member's laboratory. Also, matching funds are given to new grants, and competitive internal development and equipment programs for cores are supported. Vanderbilt has a standardized approach to the S10 program and supports the Centers in developing and maintaining shared resources.

Dr. Manning shared that cost management principles have evolved over the 17 years of Vanderbilt's centralization program. Vanderbilt tolerates a fund balance surplus that is equivalent to no more than 3 months' operating expenses. The institution also encourages outreach, training opportunities, and education of both staff within core facilities and faculty. Dr. Manning said that in the current economic climate, an institutional subsidy is a necessity. The institution also offers partial indirect cost recovery for external academic institutions that use Vanderbilt's facilities, which Dr. Manning acknowledged is a source of contention. The institution also has dedicated administrative support.

Cost recovery solutions at Vanderbilt include developing a consistent system to manage recoding core charges and revenues (i.e., CORES, although the institution is transitioning to the iLabs system) and educating grant managers and administrators in regular outreach to core users and rate-payers.

Dr. Manning explained that Vanderbilt coordinates S10 program applications by requiring internal proposals that are reviewed prior to submission to the NIH. ISROC holds a "study section" to critique and

rank proposals. Higher priority projects are those that will place equipment in cores rather than faculty laboratories, which ensures financial, operational efficiency, and broad scientific impact.

Dr. Manning shared that before consolidation, administrative support was decentralized and involved more than 30 non-specialist individuals. Consolidation streamlined the group into a team of 6 experienced core administrators. The result was an expansion of support for best practices and improved consistency across all cores.

Vanderbilt made investments in infrastructure by leveraging ARRA funding. Eight separate cores became three consolidated shared resources: the Vanderbilt Technologies for Advanced Genomics, the VANTAGE Analysis and Research Design, and the Translational Pathology Shared Resource. Other facilities, such as the Cell Imaging Shared Resource, are supported by multiple Centers (i.e., Cancer, Diabetes, Digestive Disease, Kennedy Center, and Vision). Vanderbilt also is unique in that it does not force all confocal microscopy equipment into one facility. Dr. Manning noted, however, that one management structure oversees them.

Dr. Manning lamented that S10 reporting requirements have dramatically increased over the last several years. The amount of paperwork has nearly eliminated Vanderbilt's desire to allow external institutions to use its cores because following up with external users to track their data has proven extremely challenging. Dr. Manning acknowledged that some level of oversight is needed, but he asserted that pursuing these users for 5 years following their use of a core facility is an extraordinary administrative activity, especially when the intent of such monitoring is unclear.

Dr. Manning detailed another challenge of centralization: cost recovery issues. He stated that conflicts between compliance and program expectations can limit core access, result in the creation of multiple operating units, and increase administrative burden. He noted that the most significant challenge has been reconciling varying funding program or agency directives (e.g., NIH versus NSF, non-Federal versus Federal). The NIH's caps on indirect costs are problematic because core activity increases overall administrative costs. Also, an increasing institutional subsidy of research/core facilities makes Vanderbilt's cores less attractive to non-Vanderbilt users. Dr. Manning asserted that minimal administrative costs must be recovered.

Dr. Manning proposed several solutions to the challenges involved in managing core facilities. A change in the OMB Uniform Guidance (especially with regard to specialized service centers) is needed, but it is neither easy to achieve nor under the NIH's control. An increase in the NIH cap on indirect costs would be helpful, as highly functioning cores increase the institutional subsidy for research, and the need to recover makes cores unattractive to non-Vanderbilt users. Inter-agency cooperation is essential. Cores need the flexibility to serve all Federally funded investigators—not only the NIH, but also NSF, DOD, DOE, and others. Cores should be allowed to build capital equipment purchase costs into service rates, especially given that depreciation of equipment is not sufficient to maintain core technology. Finally, program officers should be encouraged to recognize that the best cores serve multiple programs. Diversity of use and technology results in excellent shared resources. Dr. Manning emphasized that core facilities excel at providing service and access to technology.

Panel Discussion

Moderators: *Michael Chang, Ph.D., Deputy Director, Office of Research Infrastructure Programs(ORIP), Division of Program Coordination, Planning, and Strategic Initiatives, NIH; William Hendrickson, Ph.D., Director, Research Resources Center, University of Illinois, Chicago, President, ABRF*
Panelists: *Sheenah Mische, Ph.D., Senior Director for Collaborative Science Cores, NYU; David Gorenstein, Ph.D., Associate Dean for Research, School of Medicine, Chair, Department of Nanomedicine and Biomedical Engineering, UT Health System; John Manning, Jr., Ph.D., Chief*

Administrative Officer, Vanderbilt University Medical Center; Senior Associate Dean for Operations and Administration, Vanderbilt University

Dr. Hendrickson reflected on the great discussion. Ms. Auger opined that core facility reporting requirements, especially utilization records, is fairly straightforward. She commended ORIP for forcing recognition of and accountability for the technology that is funded through the S10 program, though she recognized that tracking publications and scientific benefit is a challenge.

- Dr. Manning stated that trying to get investigators to track scientific publications has become an onerous process. He also expressed concern that some of the reporting requirements around usage might be inhibiting exploratory science and the development of new technologies by cores, but admitted that raw usage statistics can be generated easily.
- Dr. Fisher stated that NIH-funded investigators who are using the cores have been peer-reviewed previously, which means that they had to be productive on their previous work to be awarded an R01 grant. The cycle of using facilities and reporting publications seems redundant.
- Dr. Katherine Hale, UT MD Anderson Cancer Center, posed a question about whether the S10 application reviewers would prefer to see a list of 10 publications or a highlight description of three impactful publications.
- Dr. Michael Chang, NIH, recognized Dr. Hale's emphasis on quality versus quantity.

Dr. Gorenstein expressed his opinion that giving congressional testimony against overregulation might be useful, citing his experience receiving questions about how to eliminate the regulations that stifle research while giving congressional testimony 15 years ago.

- Dr. Manning responded that regulations must validate that the funds are being used appropriately and correctly, especially when the dollars come from taxpayers and the public trust must not be lost.

Dr. Jeffrey Weiss, Northwestern University Feinberg School of Medicine, shifted discussion to the practice of encouraging core directors to list percentage effort on investigator grants. He expressed concern that this practice might epitomize the law of diminishing returns and result in unrealizable time apportionment for core directors.

- Dr. Gorenstein replied that reaching 100 percent of a staff member's time justifies the need to recruit another staff member. Dr. Mische stated that effort by individual staff members differs for each grant and never approaches 50 percent.

Dr. Yan Wang, University of Maryland, asked Dr. Gorenstein about networking core facilities and allocating costs of a new instrument to a specific institute. How would a smaller institution compete for funds for a new instrument?

- Dr. Gorenstein responded that funding within the UT system is competitive, and different institutions can aggregate efforts. The Vice Chancellor selects the proposal with the best idea/instrument package, regardless of the institute's size. There is an opportunity for multiple campuses to combine in different ways.

Dr. Heather Richards, The Ohio State University Comprehensive Cancer Center, asked the panelists how they overcame the disparate requirements (e.g., usage and subsidies) when they consolidated CCSGs and CTSAs.

- Dr. Manning noted that the P30 requirements across ICs are beginning to converge into metrics of usage, publications, and demonstration that the funds are contributing to high-impact research.

Next Steps and Closing Remarks

James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives, NIH; William Hendrickson, Ph.D., Director, Research Resources Center, University of Illinois, Chicago, President, ABRF

On behalf of the NIH, Dr. Anderson thanked the speakers for sharing their insights. He expressed appreciation to the participants for voicing their ideas and concerns, adding that concerns can only be addressed if they are heard. Dr. Anderson indicated that the NIH would prepare as a public report a list of concerns and recommendations for enhancing core efficiency that were generated by Workshop participants. A video of the Workshop also would be made available.

Dr. Anderson informed participants that the NIH leadership would consider the participants' ideas and the feasibility of implementing them. Although some institutions have made substantial progress in the last 10 to 15 years, results are uneven due to the different types of solutions implemented. Additionally, many institutions have yet to embark on the centralization process and that some of the meeting's presentations could act as primers for how to improve and consolidate core research facilities.

Dr. Hendrickson expressed his appreciation to Dr. Anderson for initiating the idea for the Workshop on Enhancing Efficiency of Research Core Facilities. He hoped that such a meeting will occur annually or biennially and offered to be involved in this effort.

Dr. Anderson wished the meeting participants safe travels and adjourned the meeting.

Workshop Recommendations

NIH

Extramural Policy

- Convey that sharing is encouraged (FOAs) and also provide incentives to encourage sharing of facilities and services, e.g., through funding institutional support of equipment, technicians, and service contracts.
- Identify opportunities to facilitate coordination between and among CTSAs, cancer center support grants, and other funded core facilities.
- Enhance cross-agency (e.g., NIH, NSF) coordination about core facility sharing and co-investment.
- Implement a system of unique core identifiers for use in grant applications and reports to facilitate reporting and citations/indexing.
- Develop guidance about internal versus external rates for use of core facilities.
- Allow core facilities to build capital equipment purchase costs into service rates, especially given that depreciation of equipment is not sufficient to maintain core technology.
- Issue specific solicitations to encourage smaller institutions to compete for core facility equipment, such as biosafety upgrades.
- Issue clarification of NIH policy regarding reporting publications resulting from core facilities, ensuring a balance between accountability and evaluation with administrative burden.

Intramural/Extramural Policy

- Identify mechanisms through which intramural and extramural investigators can share core resources, e.g., PAR-13-029.

Funding

- Provide the support for creating the infrastructure for a national database of core facilities.
- Provide funds for core consolidation grants similar to the ARRA Core Consolidation Supplements.

Extramural Institutions

- Develop an institutional core strategic plan, which can be very effective in facilitating coordination among all core facilities. Share best practices on strategic plan development.
- Develop and disseminate best practices regarding centralization of core facilities.
- Develop an inventory of services at core facilities, including identification of need and a business plan. These individual inventories could feed into a national database of core facilities, if developed.
- Invest in specialized expertise in financial management (e.g., in rate setting, monthly financial reporting, spending decisions) and in making better use of tools (electronic usage tracking, online scheduling and service requests, automated monthly billing).
- Develop and disseminate models for governance of research core facilities, including transparency in business practices, annual reviews, and recruiting senior laboratory members as core directors.
- Consider implementing career development activities for core facility staff.
- Consider which core facility services may qualify for fixed amount awards to reduce administrative and reporting burden.
- Develop guidance about internal versus external rates for the use of core facilities.

Collaborative Activities

- Develop and disseminate examples of formalization, standardization, and use of evaluation metrics for core facilities.

Federal (OMB) Policy

- Increase the NIH cap on indirect costs to enable institutions to partially recover increased costs associated with core activity.
- Engage OMB to request a change in OMB Uniform Guidance (2 CFR 200), especially regarding specialized service facilities (2 CFR 200.468).

NIH-ABRF Workshop on Enhancing Efficiency of Research Core Facilities
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