

IDeA Program Principal Investigator Meeting

Lister Hill Auditorium, National Institutes of Health
September 24-25, 2019

SUMMARY of Presentations and Discussions

I. NIH INITIATIVES/PROGRAMS

Updates from NIGMS

Jon Lorsch, Ph.D., Director, NIGMS/NIH

National Institute of General Medical Sciences (NIGMS) Director Dr. Jon Lorsch welcomed the group to the inaugural Institutional Development Award (IDeA) Program Principal Investigator (PI) meeting and provided brief Institute updates relevant to the IDeA community:

Personnel

- Behrouz Davani, Ph.D., joined the NIGMS Division for Research Capacity Building as a Program Director
- Susan Gregurick, Ph.D., who led the NIGMS Division of Biophysics, Biomedical Technology, and Computational Biosciences has been hired as NIH Associate Director for Data Science and Director of the NIH Office of Data Science Strategy
- NIGMS is [seeking applicants](#) for two Branch Chief positions in the Division of Pharmacology, Physiology, and Biological Chemistry
- Four medical students from IDeA states were accepted to [NIH Medical Research Scholars](#), a research and mentoring program for future clinician-scientists

Events and Outreach

- NIGMS hosted “[The Research Organism \(RO\) Landscape: Choosing the Best Organism for Your Scientific Question](#)” September 12, 2019.
- NIGMS has established a partnership with *Scholastic* featuring the [Pathways](#) magazine and associated curricular materials about basic biomedical research. To date, this resource has reached an estimated 2.5 million high and middle school students and 19,000 teachers in all 50 states.

Programs and Evaluation

- The NIGMS Office of Program Planning, Analysis, and Evaluation published the results of two analyses: i) the NIGMS SBIR/STTR portfolio and [showed a relationship](#) between geographic distribution and commercialization success, toward actionable steps to improve overall program performance and ii) developed [a natural language-processing/machine learning algorithm](#) that accurately auto-assigns applications to program staff – saving time, increasing objectivity/standardization, and retaining institutional knowledge.
- The NIGMS Advisory Council’s Sepsis Working Group [conducted an analysis](#) of the Institute’s sepsis research portfolio. In response, NIGMS recently published two documents in the NIH Guide: i) [Notice of Information: NIGMS Priorities for Sepsis Research](#) and ii) [Request for Information \(RFI\): Strategies to Support Acquisition and Use of Biospecimens for Research on Sepsis in Humans](#).
- NIGMS re-issued its Maximizing Investigators’ Research Award (MIRA) funding announcement for established investigators with updates that allow renewals, expand eligibility windows, remove the detailed-budget requirement, enable conversion of other NIH grant mechanisms (Pioneer Award

and Transformative Research Award), and cluster application review for recently funded early-stage investigators (ESIs).

- The ESI MIRA program continues to be a popular choice for ESIs (including several in IDeA states), accounting for the majority of NIGMS-funded ESIs.
- Between 2016 and 2018, the ESI MIRA success rate averaged 31.4%.
- ESI MIRA applicants and awardees are younger (by about 1 year) than ESI R01 applicants and awardees.
- NIGMS launched its [Maximizing Opportunities for Scientific and Academic Independent Careers \(MOSAIC\)](#) program to promote successful transitions of postdocs from diverse backgrounds to independent faculty positions at research-intensive institutions.

Resources and Opportunities

- NIGMS offers several large-scale technology resources, including [synchrotron beamlines](#), Cryo-EM [centers](#), [service centers](#), a [tomography service-network hub](#), and a suite of [national and regional resources](#) (R24 mechanism).
- Opportunities for collaboration at the NIH Clinical Center include various training/educational opportunities, the NIH [Bench-to-Bedside](#) program, and [Opportunities for Collaborative Research at the NIH Clinical Center](#) (U01 mechanism).

How Can Science Help Solve the Opioid Crisis?

Nora D. Volkow, M.D., Director, NIDA/NIH

Following a steady increase in opioid prescriptions over the past two decades, death rates from opioid overdoses continue to rise precipitously – a nearly 10% increase in one year alone (2016-2017). Currently, deaths from synthetic opioids (primarily fentanyl) outstrip deaths from heroin and prescription opioids. The NIH Helping to End Addiction Long-term (HEAL) initiative is a trans-NIH effort to improve prevention and treatment strategies for opioid misuse and addiction, as well as to enhance pain management. More than 20 research programs are led by 12 NIH Institutes and Centers (ICs) and interface routinely with experts across disciplines and sectors. [Ongoing research](#) is generating many new pain targets, revisiting existing targets, and testing numerous devices for pain management. Extended-release formulations of existing treatments (naltrexone and buprenorphine) are available and can improve medication adherence. Medications for opioid-use disorder have been shown to reduce opioid use and overdose deaths, criminal activity, and infectious-disease transmission, as well as increase social function and treatment retention. However, these medications are [dramatically underused](#). Various approaches are addressing the problem of opioid addiction by implementing medication-assisted treatment (MAT). These include [emergency department-initiated buprenorphine treatment](#) and [infectious-disease clinic-based administration of buprenorphine](#) to opioid-dependent HIV-positive individuals. The number of substance-abuse treatment facilities offering MAT has risen significantly in recent years, offering more venues for individuals to seek therapy. NIH-funded research is underway to identify novel approaches to addressing opioid-use disorder, including in populations of individuals who have been incarcerated. Other strategies include stimulation of brain regions that control the addiction cycle, vaccines and immunotherapies, and socially based addiction treatments. The National Drug Abuse Treatment Clinical Trials Network is conducting rural interventions and creating an opioid registry in a diverse healthcare-delivery system. The problem of neonatal abstinence syndrome is urgent in many IDeA states, and the HEAL-based [Healthy Brain and Child Development Study](#) is a large, multi-site longitudinal study to examine brain, cognitive, behavioral, and social and emotional development beginning prenatally and extending through childhood.

II. IDeA PROGRAM UPDATE

IDeA Program Overview

Ming Lei, Ph.D., Director, Division for Research Capacity Building, NIGMS/NIH

The goal of the IDeA program is to enhance geographical distribution of NIH research funds and strengthen research capacity in states that receive lower levels of NIH funding. Currently 23 states and Puerto Rico are IDeA-eligible. IDeA began in 2000 with funding of the first Center of Biomedical Research Excellence (COBRE) and was migrated in 2012 to NIGMS from the former National Center for Research Resources. IDeA has continued to earn steady Congressional support, which is just under 1% of the overall NIH allocation and has aligned proportionately with NIH budget changes over time. IDeA has five principal components, all of which have been renewed in 2019. In addition to the COBRE program (currently 130 awards), IDeA components include the IDeA Networks of Biomedical Research Excellence program (INBRE, 24 awards), the IDeA Infrastructure for Clinical and Translational Research program (IDeA-CTR, 11 awards), the IDeA Co-Funding program with other NIH ICs and NIH OD (about 35 awards per year), and the IDeA Regional Technology Transfer Accelerator Hubs (four awards, one in each IDeA region). NIGMS has several new vehicles for facilitating collaborations among and between IDeA-state investigators and students. These include the Collaborative Innovation Award for collaboration with the CTSA program, the i-MRSP (i-Medical Research Scholars Program for collaboration with the NIH Clinical Center), the IDeA Regional Technology Transfer Accelerator Hubs (which offer pilot projects), as well as various other NIGMS and NIH programs. Available inter-IDeA program collaborations include INBRE administrative supplements, *Business Fundamentals for IDeA Core Directors @NISBRE2020* (course at 2020 NISBRE meeting), and the September 2019 IDeA PI meeting.

New COBRE Phase 1 and 2 FOAs

Zuzana Justinova, M.D., Ph.D., Program Director, DRCB/NIGMS

NIGMS recently re-issued funding announcements (FOAs) for the COBRE program, with modifications that address: i) the definition of junior investigator, ii) changes in eligibility for pilot project leaders and research project leaders, and iii) changes to applications for rural health research. Current FOAs consider junior investigators, pilot project leaders, and research project leaders as distinct concepts. A junior investigator is considered an individual who does not have, or has not previously had, an external peer-reviewed, independent research project grant or similar. Previously, pilot project leaders were required to be junior investigators whereas in the current FOAs, faculty investigators of any rank may lead pilot projects, as long as junior investigators are given priority. The current FOAs require that research project leaders must hold a faculty appointment (or equivalent at a research institution) at the time the COBRE application is submitted, and the majority must be junior investigators. Institutions must demonstrate a clear commitment to support a multi-year faculty appointment for the proposed research project leader independent of the outcome of the COBRE grant application. COBRE PIs are encouraged to use the pilot project programs to develop promising candidates for future research project leader appointments. Notices clarifying eligibility requirements of institutions, PD/PIs, and research project leaders have been published: [NOT-GM-20-004](#) and [NOT-GM-20-005](#). Many IDeA states have substantial rural populations facing serious health issues such as substance-use disorders, obesity, and chronic lower respiratory diseases. Current COBRE FOAs specify the need for innovative, multidisciplinary approaches for improving rural health and reducing rural health disparities. Such research programs must establish a Community Engagement and Outreach core to engage primary care physicians of the Practice-Based Research Networks (PBRNs).

Update on IDeA-CTR

Rafael Gorospe, M.D., Ph.D., Medical Officer, DRCB/NIGMS

The IDeA-CTR program (currently 11 awards) is the youngest of NIGMS' IDeA programs and aims to support the development of infrastructure and human resources required to conduct clinical and translational research in IDeA-eligible states, as well as to foster and sustain collaboration and coordination of clinical and translational activities within and across IDeA institutions or organizations. A particular focus of IDeA-CTR is to address health concerns that affect the medically underserved and/or are prevalent among populations in IDeA states. IDeA-CTR sites are extremely diverse geographically – some are small (within a single state), while others span multiple states. The IDeA-CTR regional alliances have been productive, publishing research on a wide range of health concerns relevant to each's geographic locale. For example, the Northeast region reports on asthma and firearm violence; the Southeast region reports on health outcomes after bariatric surgery, healthcare seeking, and substance-use disorder; the Central region reports on rural preterm birth and social support to enhance physical activity; and the Western region reports on oral health and cancer. Several opportunities are available for IDeA-CTR awardees to collaborate and cross-leverage with existing NIH programs, such as the NIH Medical Research Scholars Program, the [CTSAs](#), and the [Environmental influences on Child Health Outcomes \(ECHO\)](#) program (e.g., via the IDeA States Pediatric Clinical Trials Network, or ISPCTN). The first receipt dates for the newly issued IDeA-CTR FOA will be in October 2020, with the first funded awards in July 2021.

Update on Regional Technology Transfer Accelerator Hubs for IDeA States

Krishan Arora, Ph.D., Program Director, DRCB/NIGMS

The federal/NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs support technological innovation through the investment of federal biomedical research funds that address the NIH mission component supporting application of knowledge to improve health. The [Regional Technology Transfer Accelerator Hubs for IDeA states](#) represent a new initiative in response to Congressional directive. Funded in FY 2018, one shared Accelerator in each IDeA region (four total) provides infrastructure toward building an entrepreneurial culture at IDeA institutions. The Hubs represent a collaboration between small businesses in any state and academic institutions in IDeA states. After the first year, all milestones for phase I of the Hubs have been achieved. Phase II will continue phase I activities and implement action plans. Activities will include strengthening infrastructure for Offices of Tech Transfer and Commercialization, entrepreneurial educational training and skills development, networking activities, linkages with state, local and other available resources, and support for innovative pilot projects. Outreach will be a key component for creating a viable and sustainable entrepreneurial ecosystem. NIGMS recently funded four administrative supplements to IDeA Regional Hubs to support pilot projects from entrepreneurial scientists at the IDeA Regional Hub partner institutions to gather data for feasibility and proof-of-concept studies that may have translational/commercialization potential.

Update on Human Subjects and Clinical Trials Policies

Sarah Dunsmore, Ph.D., Program Director, NIGMS

As part of the federal clinical research ecosystem, NIH has implemented two major areas of policy change: clinical stewardship reforms and the revised Common Rule for human subjects. Compliance with the new clinical stewardship reforms involves answering four questions: Does your study: i) involve one or more human subjects? ii) prospectively assign human subject(s) to intervention(s)? iii) evaluate

the effect of intervention(s) on the human subject(s)? and iv) have a health-related biomedical or behavioral outcome? “Yes” to all four indicates that the study is a clinical trial under the new policy. In addition to implementation of the Common Rule, other updates include the requirement for refreshing Good Clinical Practice Training every 3 years, less flexibility for misclassified clinical trial applications, and reporting flexibilities for basic experimental studies. [Key provisions of the revised Common Rule](#) include definitions of exempt and non-exempt human subjects research, single-IRB membership, functions, and review criteria, informed-consent changes and special considerations for vulnerable populations. Updates to the [Human Subjects System](#) (HSS) include a bar on paper/pdf submissions and expansion of [NIH inclusion policies](#) to cover women, minorities, and lifespan/age. NIH/NIGMS is currently drafting guidance for applicants using the HSS, but IDeA applicants proposing research with human subjects should plan ahead to comply with the changes by consulting with experts. Applicants should be clear about collaborations and regulatory responsibilities and should consider associating human subjects research with IDeA projects or cores.

Update on NAIPI and 2020 NISBRE

Douglas Wright, Ph.D., Kansas INBRE PI & NAIPI President

The [National Association of IDeA Principal Investigators](#) (NAIPI) is a nonprofit, 501c(3) organization that fosters interactions between the IDeA program and its constituencies. NAIPI aims to enhance the visibility of the IDeA program as well as develop a consensus on priorities and new directions. Leadership consists of a president, vice president, secretary, and treasurer (with external help from a contracted accountant); two NIGMS non-voting ex officio members, and a national, 20-member committee representing all regional IDeA divisions. NAIPI challenges include an increase in the number of IDeA programs, national data collection for evaluation purposes, and resources to facilitate IDeA interactions. The next National IDeA Symposium Biomedical Research Excellence (NISBRE) Conference will be held June 21-23, 2020 in Bethesda, Maryland, featuring plenary presentations, poster presentations, and workshops. IDeA participants representing all career stages are encouraged to attend, and four major awards will be announced (nominations currently encouraged).

Update from the EPSCoR/IDeA Foundation

Jessica Malow-Molesworth, Executive Director, EPSCoR/IDeA Foundation

In 1978, the U.S. National Science Board established the Experimental Program to Stimulate Competitive Research (EPSCoR), and later, in 1993, Congress authorized the IDeA program. Both EPSCoR and IDeA programs were created to ensure that all states receive federal funds for scientific research. Through coordinated and organized efforts, the EPSCoR/IDeA (a nonprofit 501c(3) organization established in 1995) advocates for federal research and development support for the two programs. Its key activities include hosting an annual conference (February), conducting agency and state outreach, data collection, communication of impact to legislators and other stakeholders, and coordination of IDeA stakeholder groups. As part of its advocacy, the Foundation seeks compelling success stories from IDeA program participants and works to coordinate messaging to enhance the visibility and impact of IDeA.

III. BUILDING STRONG AND SUSTAINABLE RESEARCH CAPACITY IN IDeA STATES

Mentoring Research Project Leaders

Alex Adams, M.D., Ph.D., COBRE PI, Montana State University

The Center for American Indian and Rural Health Equity (CAIRHE) at Montana State University works in research partnerships with communities to design and implement health interventions. The Center builds a critical mass of health-equity researchers, maintains efficacious and respectful community partnerships, and promotes interdisciplinary approaches to address health disparities in rural Montana. The CAIRHE investigator-mentoring structure features oversight and evaluation and has developed successful strategies for mentoring junior investigators toward becoming research project leaders. These include knowing and adhering to mission and vision; being passionate about a topic of study (aside from its fundability); building and sustaining mentoring teams (including at least one mentor with power); sticking to goals without becoming distracted by too many opportunities; acquiring good leadership training; choosing research partners wisely; employing effective time management (personal and professional); understanding the funding ecosystem; and enjoying wins when they occur.

Supporting and Mentoring Investigators at PUIs

Nigel Cooper, Ph.D., INBRE PI, University of Louisville Health Sciences Center

The INBRE program aims to develop research capacity and enhance the competitiveness of research investigators for federal funding. Providing undergraduate students with opportunities for quality research experiences in federally competitive research labs can help achieve this goal. The NIH R15 program (Academic Research Enhancement Awards, or AREA grants) is an effective vehicle for building the pipeline in IDeA states. AREA grants support biomedical research at institutions that have not received more than \$6 million in NIH research grants in 4 out of the last 7 years, including many primarily undergraduate institutions (PUIs). The Kentucky INBRE has developed a set of successful strategies for PUI investigators to attain R15 funding through various approaches to improve grantwriting skills. These include intensive grantwriting workshops; assembling and sharing successful proposals; offering consultation and intensive pre-submission review; providing access to state-of-the-art technologies for gathering pilot data (e.g., through core vouchers); bridging funding when needed; and requiring institutional release time from teaching. A difficult challenge has been the requirement for PUI faculty to publish one paper and one R15 submission each year. The INBRE team also conducts annual site visits to aid PUIs and their administrators in R15 preparation and submission. As a result of this coordinated and sustained effort, Kentucky has seen steady increases in a range of NIH awards, and several investigators have attained multiple R15 awards.

Leveraging Institutional Support for the Oklahoma COBRE in Structural Biology

Ann West, Ph.D., COBRE PI, University of Oklahoma

IDeA programs are intended to provide only partial support for investigators in IDeA states; additional funding streams and institutional financial commitment are required for success. One approach to actualizing leadership commitment is through negotiating for infrastructure/physical space. The University of Oklahoma acquired institutional funding to inhabit one floor of a newly constructed life-sciences research center to bolster efforts of the Oklahoma and regional structural-biology communities. Having a business plan in writing backed up with expected outcomes facilitated negotiations for this initial support. As a testament to this dedicated space and coordinated effort, three of four junior investigators earned R01 grants and five junior investigators received tenure. The group has had a solid track record of numerous projects, publications, and both external and internal funding. Through strong letters of support from the IDeA external advisory committee, additional junior investigators could be recruited with institutional start-up funds. Establishing a new M.S./Ph.D. sub-program in structural biology is helping to sustain the talent pipeline. Via both phases of the COBRE

award and additional external funding, the Oklahoma University, Norman COBRE has achieved an 18-fold return on investment from institutional funds.

Sustaining the footprint of IDeA investment after COBRE support

Charlie Wood, Ph.D., COBRE PI (completed), University of Nebraska Lincoln

Sustaining a vibrant research community after COBRE support requires strategic planning and action. Established in 2000, the Nebraska Center for Virology (NCV) built research capacity by attracting promising scientists and supporting research programs for junior investigators and cores. In addition to recruiting talent and non-tenure track research staff, COBRE leadership acquired institutional commitment for research space to co-localize NCV faculty; accessed competitive external funding; developed an international footprint and reputation; maximized use of cores; and collaborated with other IDeA programs. Establishment and growth of the NCV has changed the research landscape on the University of Nebraska campus, and the physical research center is unique in co-localizing faculty from five departments and two campuses. Ensuring continued success beyond COBRE funding required succession planning. This process has included hiring a new external director; maintaining funding and recruitment; bolstering interactions and alignment with institutional leadership and funding-agency missions; developing implementation research; and enhancing collaborations, in part through research clusters. Despite significant advanced planning and execution of these strategies, several factors impede progress including state-level fiscal constraints and administration staff turnover along with misalignment between NCV and institution/department priorities.

Thematic Synthesis of Discussion

The twin goals of the IDeA program are to broaden distribution of NIH research funds in states that receive disproportionately low NIH funding and to strengthen research capacity in those states. The large and disparate geographic distribution of the 23 IDeA states and Puerto Rico translates into a significant diversity of science and health topics under study, and through IDeA, NIH has an enormous opportunity to broaden the scope of NIH-funded research. Yet, with this opportunity comes challenges for coordinating research and research training environments that are typically under-resourced compared to those environments in non-IdEA states.

Mentoring

- Mentoring should be specifically tailored to an individual's needs and workstyle, in the form of a healthy, bidirectional relationship.
- Effective mentoring teams are multilevel, consisting of peers, scientific advisors, sponsors for career advancement, as well as individuals who can help a mentee solve problem-related science, and psychosocial challenges that arise in the context of biomedical inquiry.
- Mentoring resources:
 - [Center for Improved Mentored Experiences in Research](#)
 - [National Research Mentoring Network](#)

Faculty retention

- Inclusive environments help junior investigators feel wanted and respected.
 - If an individual feels part of such a successful team, it is harder for she or he to leave.
- The dynamic nature of the IDeA program poses opportunities to build career ladders for investigators to move up within the team environment to assume new roles and responsibilities prior to formal academic promotion.

- Recruitment and retention efforts should appreciate dual-career and family-based challenges such as acclimating children into local schools and other personal and community-related issues.

Business practices

- Sustainability is one of the paramount goals of IDeA programs and securing research funding is a key to achieving sustainability. Successful practices to incentivize grant submissions:
 - “R” and “K” clubs and protected time help junior investigators write specific aims.
 - INBREs can provide resources, communications channels, and documentation for lead institutions to help partner institutions apply for and secure funding.
 - INBRE supplements can be used to help establish and train partner business offices for effective and efficient grants management and technology-transfer practices.
- Align program goals with institutional strategic priorities to secure institutional support:
 - IDeA programs should strive where possible to articulate clear expectations and financial commitments from their institution(s).
 - Prioritizing research plans that align with institutional (and state) missions can optimize chances for continued support beyond NIH funding.
 - Stretching the value of core services outside of the IDeA environment can help fulfill this goal and also contribute important data to show program value.
- Collecting data and using metrics to measure success is important to institutional leadership and can create a compelling case for return on investment and lead the way for continued support.

Challenges

- In contrast to well-resourced institutions, IDeA state faculty juggle many obligations including heavy teaching loads that can steal time from doing research.
- Stark state budgets amid steadily rising biomedical research costs create an unsustainable environment in which to grow and expand without cutting corners – and turnover of institutional and state administration makes it easier for promises of financial support to be forgotten.
- Structural program requirements, such as program cores in states with multiple IDeA programs, can inadvertently create redundancy in services and resources.
- Creating and sustaining a healthy culture is not simple nor is it unique to IDeA-funded institutions.
 - Difficulties building and sustaining relationships across departments and with institutional leadership is a common feature of many academic environments across the nation.

IV. RESOURCES AND RESOURCE SHARING

Building a Sustainable Research Core with a Strong User Base

Qian Chen, Ph.D., COBRE PI, Rhode Island Hospital

The lifespan of a COBRE award across three phases hinges on developing a strong scientific vision and continually growing a community of talent. Achieving this success is advanced through a multidisciplinary approach involving different types of investigators that complement each other and that commit and contribute to solving a larger scientific problem. Maintaining flexibility in arranging research projects and cores can ease the transition between phases, toward maximizing growth potential and ultimate independence. Leveraging expertise and core facilities (e.g., through two price tiers for services) can earn revenue from the local academic and commercial environments. Building such relationships tailored to local science and health needs works toward independence following the COBRE-funding period.

Aligning IDeA Core Resources to Better Serve Regional and National Users

Alan Tackett, Ph.D., COBRE PI and INBRE Core Director, University of Arkansas for Medical Sciences

IDeA states face various levels of challenges in using, sharing, and sustaining core resources. These range from insufficient state-level staffing, to overlap of different core purposes and funding, to regional duplication of instrumentation and other resources. NIGMS recently issued a [FOA](#) to provide an economy of scale for increased access to state-of-the-art services for a substantial regional or national user base. One example is the [IDeA National Resource for Quantitative Proteomics](#) – the goal of which is regional consolidation (facilitated through a Memorandum of Understanding) between Arkansas and Oklahoma to create a quantitative proteomics resource with economy of scale to be a service provider for the entire IDeA network. The entity has a tripartite mission structure addressing sample analysis (discovery or targeted), outreach (vouchers and partnerships), and education (workshops, symposia, and [online resources](#)). INBRE-sponsored core voucher programs and partnerships across Arkansas and Oklahoma have increased accessibility of resources and provided peer-evaluated funds for PUI faculty and students. The impact of this consolidation effort has been significant, increasing the quantity of IDeA states served from 11% in 2016 to 100% in 2019.

IDeA Capacity Building and Institutionalization: From INBRE Bioinformatics Core to Data Science Institute

Cathy Wu, Ph.D., INBRE Program Coordinator, University of Delaware

IDeA cores contain valuable resources that can be leveraged and expanded to form a state-wide or regional resource. One example is Delaware's [Data Science Institute](#), which grew out of the state's INBRE-funded core, the Center for Bioinformatics and Computational Biology. Increasing collaborations with scientifically aligned endeavors and organizations nucleated this team-science ecosystem in Delaware. Beyond the INBRE core, bioinformatics entities include the Bioinformatics Network of Delaware and the Northeast Bioinformatics Collaborative, the latter of which is undertaking a skate genome project that features collaborative and integrated use of specialized resources and expertise. Through cross-institutional multi-core collaboration, the Delaware INBRE linked core services investigators (and their publications and grants), which has garnered enthusiasm and participation from seven academic institutions and is now offering various graduate programs in bioinformatics. The Institute aims to address state needs and priorities needed for sustained support, including from industry – a major player in the region.

NIGMS National and Regional Resources

Peter Preusch, Ph.D., Program Director, NIGMS

NIGMS recently issued a [FOA for support of national or regional \(multi-state\) resources](#), aiming to provide access to state-of-the-art resources on a service basis to a substantial user base at multiple institutions. The intent is to achieve significant economies of scale by expanding/upgrading existing resources that are mature to the extent that no additional technology development is necessary. Resource capabilities can encompass a wide range, including instruments, equipment, and facilities; computational hardware and software; research materials, tools, expertise, and repositories; and biospecimen banks relevant to the NIGMS mission. Stand-alone databases, data repositories, and knowledge bases will not be supported by this funding, as those are within the mission of NIH's Office of Data Science Strategy. Although COBRE and INBRE programs are eligible for this funding, they must broaden their mission to serve a national or regional user base, and resource capabilities must pertain to the NIGMS mission. To that end, resources for clinically oriented or translational research must be

within one of the NIGMS areas of clinical research focus: anesthesia and pain, trauma and burn injury, wound healing, sepsis and septic shock, clinical pharmacology, or medical genetics. The first awards will be funded in July 2020.

Thematic Synthesis of Discussion

By design, the IDeA program aims to fill gaps in NIH research funding at institutions who have less of it compared to those institutions in more populous and research-intensive areas, such as major metropolitan regions that also attract the private sector and its concomitant investments. The disperse nature of IDeA programs across the United States makes it more difficult for institutions to share IDeA resources, but various strategies and tools are helping to overcome these hurdles and achieve economies of scale for accessing federal research investments. Importantly, solidifying long-term institutional support for not only space but for permanent staff and support of cores is essential for sustainability – and also for everyday availability and function of scientific resources valuable to many users.

Core management

- The need for a keyword-searchable IDeA program resource database
- More effective tracking of core usage vs. capacity
- Utilizing management systems such as iLab to maximize core usage
- Reporting actual costs on service invoice to enhance PI awareness/appreciation
- Offering business training to core personnel to increase efficiency

Encourage core consolidation

- Co-location of cores within a campus can create a one-stop-shop model and promote interactions and collaborations.
- Regionalizing resources, such as through the newly established [NIGMS R24 awards program](#), should create economies of scale that both reduce cost as well as increase visibility and availability of valuable scientific resources that are in high demand.
- Availability of resources can also be broadened through virtual platforms and resources that can be accessible anywhere.

Accountability and institutional commitment

- Researchers who routinely use biobanks, bioinformatics expertise, instrumentation, and other core offerings readily appreciate the value of these tools of research.
 - Measuring this value is essential for calculating return on investment – a critical institutional metric and bargaining tool for sustained support.
 - Cores should collect both qualitative and quantitative data continuously from baseline use to post-core use.
 - Core use should be detailed on institutional grant-application routing paperwork. Frequent progress reports (~ every 3 months) can document successes and challenges.

NIH actions

- IDeA FOA language should be explicit about sharing resources across institutions as well as across state lines.
- Including IDeA-specific language in FOAs outside the IDeA program can position IDeA investigators well for competitive submissions. Examples:
 - [NIGMS R24 awards program](#)
 - [NIGMS IDeA administrative supplements](#)

V. COLLABORATING FOR SYNERGY AND NEW OPPORTUNITIES

SC INBRE's Approach to Facilitating Collaborations Among IDeA-supported Investigators

Edie Goldsmith, Ph.D., INBRE PI, University of South Carolina

NIGMS issued a one-year administrative supplement to foster collaboration between INBRE investigators and COBRE/IDeA-CTR investigators. The South Carolina IDeA environment – with one INBRE and three COBREs with distinct scientific foci – serves as a case study. Efforts underway include an annual career-development workshop and scientific symposium, a seminar exchange program and weekly newsletter, cross-mentoring activities, and various informal opportunities for interaction. The COBRE-INBRE collaboration has used creative strategies to bring people together as well as outside their “comfort zones.” These include assigned seating (according to scientific commonality) at meetings and workshops to encourage relationship building. One outgrowth is a COBRE-INBRE interdisciplinary research project joining two PIs with distinct scientific interests that have intersected to create new research questions about cellular signaling in tissue fibrosis. The joint effort leverages the IDeA investment by involving undergraduate students from each investigator’s institution (one a PUI and one a research-intensive institution).

Building Bridges and Sharing Resources Across IDeA Programs

Brian Bothner, Ph.D., INBRE PI, Montana State University

Connecting IDeA programs is especially challenging in the Western United States where states and programs are hundreds of miles apart. Using INBRE to lay the foundation, Montana has made good progress toward collaboration among programs that have different mission statements and goals. These efforts include i) a COBRE program that aims to reduce health disparities in Native and rural communities in Montana through community-based participatory research (CBPR) considerate of and consistent with cultural beliefs; ii) a CTR program that works with Tribal communities in Montana and Alaska to reduce health disparities, foster research for healthier communities, and create equitable research collaborations; and iii) a SEPA program that equips teachers with the knowledge, skills, and dispositions to provide high-quality bacteriophage-based research opportunities for students. Montana’s INBRE leverages investments by sharing cores and resources, including a trans-state vehicle “HERB” (the health enhancement research bus) that travels to communities creating a place to meet with communities, gather data, and foster interactions between researchers and community members serving as research associates. One successful strategy has been to present a unified message and central points of contact community interactions. Three SEPA awards (one pending) expose high-school students to summer research in a college setting, toward interesting a cohort of diverse talent in the possibility of pursuing a STEM career.

Engaging PBRN to Address Rural Health Challenges

Sally Hodder, M.D., IDeA-CTR PI, West Virginia University

The West Virginia Practice Based Research Network (WVPBRN) conducts research relevant to health problems of West Virginians, translate research results into practical tools for improving their health, and disseminate research results to policy makers and rural community members. Of 107 individual clinical sites, 81 are Federally Qualified Health Centers that serve vulnerable populations. As part of underserved Appalachia, West Virginia has a significantly higher mortality rate compared to many other states. Together with the West Virginia Clinical and Translational Science Institute, the WVPBRN developed *Design Studio*, a virtual interactive resource that aims to improve quality of community

research project design among rural primary care providers with limited research and study-design experience. Other virtual educational opportunities include Project ECHO, a hub-and-spoke knowledge-sharing network led by expert teams through multi-point videoconferencing based upon a successful approach in New Mexico. West Virginian health providers communicate preferences for areas of focus for ECHO – such as hepatitis C, which resonate with local need and participation interest. An annual retreat invites all members to participate in setting the year’s research agenda and also serves as an opportunity to network and share success stories. Recent areas of focus for the WVPBRN include diabetic retinopathy and pain education – these and other research efforts have translated into substantial impact in the state, including 77 practice and policy changes that affect the health and well-being of West Virginians.

Collaboration Opportunities for CTSA and IDeA Investigators

Mike Kurilla, M.D., Director, Division of Clinical Innovation, NCATS/NIH

The National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards (CTSA) program, NIH’s largest, comprises a national network of medical research institutions, their partners and collaborators working together to speed translation of research discoveries into improved patient care by tackling system-wide problems in clinical and translational research that no single team can overcome. It was established in 2006 as an updated version of NIH’s former General Clinical Research Centers program when the National Center for Research Resources was dissolved and replaced with NCATS. Goals of the CTSA program address training, engaging patient and communities, innovating translational research processes, and advancing the use of cutting-edge informatics. One example of a consortium-wide capacity-building activity is the [Development, Implementation and Assessment of Novel Training in Domain-based Competencies](#) (DIAMOND) program, a sustainable, collaborative discovery learning space for clinical research professionals. Of interest to IDeA states with rural populations is the [Rural Health Research Support Network](#), a collaboration of CTSAs that is a regional and national core facility that supports community-based research. It aims to deliver rapid-response, best-practice methodology to perform translational research in rural, underserved, multi-ethnic populations. IDeA states are encouraged to interact with CTSAs as well as consider applying for the recently issued [Collaborative Innovation Award](#) between CTSAs and CTRs.

An Introduction of the Clinical and Translational Science Community

Frederick Meyers, M.D., President, Association for Clinical and Translation Sciences

The [Association for Clinical and Translational Science](#) (ACTS) supports research, education, advocacy, and mentoring for clinical and translational science. It works with Congress to support annual funding for NIH other health-related agencies and aims to maximize benefit from the CTSA program for enhancement of translational research infrastructure and education, training, and career development. ACTS is eager to interact with the IDeA community on clinical and translational issues of mutual interest. ACTS advocacy aims to be nimble enough to support community-based initiatives and welcomes an IDeA voice in its discussions and planning.

An Introduction of the IDeA States Pediatric Clinical Trials Network (ISPCTN)

Matt Gillman, M.D., Director, ECHO, NIH

The mission of NIH’s Environmental influences on Child Health Outcomes (ECHO) program is simple and straightforward: to enhance the health of children for generations to come. Aside from NIGMS’ suite of programs, ECHO is the only other NIH program with IDeA programming, in the form of the IDeA States

Pediatric Clinical Trials Network (ISPCTN) that consists of 17 clinical sites and a data coordination center. Grown out of a merging of programmatic interests between NIGMS and the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the ISPCTN provides medically underserved and rural populations access to state-of-the-art clinical trials and builds national pediatric research capacity. It is a relatively new entity and does not have a disease focus, although one example of a current trial is ACT NOW (Advancing Clinical Trials for Neonatal Opioid Withdrawal Syndrome), which aims to derive standards of care for NOWS treatment based on available evidence. A general goal for ISPCTN is to improve general and study-specific skills for health providers/researchers who lack these skills but are poised to conduct community-based research in areas of high medical need. Several IDeA states (via a range of IDeA programs) have partnered with the ISPCTN to expand pediatric clinical research capacity nationwide and to advance the health and well-being of children across the country.

Thematic Synthesis of Discussion

Redundancy among IDeA programs and their required cores is common and a reflection of programmatic infrastructure requirements. Many IDeA programs object to the NIH rule that investigators cannot be funded by more than one IDeA program. However, this rule is a consequence of NIH's view of the IDeA program's main capacity-building role of recruiting new faculty to fill workforce gaps in states with disproportionately low NIH funding. Collaboration takes time (and resources), and it is hard to do amid the demands of research. As already noted, [NIGMS administrative supplements to enhance collaboration](#) have been very helpful to facilitate interactions. Finding common ground appears to be the biggest hallmark for any successful alliance, and gathering people (e.g., via annual statewide conferences) helps to align individuals and programs that are separated by large geographical distances – arguably the largest barrier to cohesion among the vast IDeA-program network.

- IDeA communities contain many examples of best practices and innovations, and NIH as a funding agency cannot connect all the dots.
 - States should proactively search for common ground and collaborative opportunities.
 - Some have hired “resource navigator” staff for this purpose.
 - Tapping into existing, well-resourced programs, such as the CTSAs or the IDeA States Pediatric Clinical Trials Network (ISPCTN) offer important leveraging opportunities for IDeA-funded programs to acquire support outside IDeA funding.
- The IDeA program, at various levels, might be considered a textbook example of team science, which has emerged over the past decade as a scholarly area of pursuit.
 - NIGMS might develop opportunities for IDeA programs to learn about the [science of team science](#), through workshops or webinars.
- Clearer/stronger FOA instructions from NIH codifying how collaborative relationships will be valued during the grant renewal process, particularly for COBREs, may incentivize improved communication.
 - In many cases, INBRE is in the best position to coordinate such state-level communications platforms. Examples:
 - The Nevada INBRE hosted an annual meeting that led to development of a joint translational grant program between INBRE and CTR.
 - One novel state-wide collaborative effort in Montana is the HERB (a [health enhancement research bus](#)), in which INBREs can team up with COBREs to facilitate outreach.

CONCLUDING THOUGHTS

The juxtaposition of common goals and state-level identity create a unique set of opportunities and challenges for the IDeA program – which leverages both aspects for success. Many collaboration challenges – created or worsened by geographic distance – can be met with creative strategies to connect. Moreover, beyond collaboration for the sake of increasing efficiency and reducing redundancy, interactions between IDeA programs and states also serves another important purpose: to celebrate successes that reflect the needs of local constituencies.

It is also true that various realities of the federal biomedical research ecosystem – in addition to severe state fiscal challenges – are beyond NIH’s control in mitigating some of the persistent challenges to funding biomedical research. Representative issues include administrative and legal requirements for contracts and subcontracts, difficulty attracting (and compensating) clinician scientists, sparse populations with a rapidly shifting demographic landscape, and NIH’s limited ability to manage institutional accountability. Stakeholder organizations such as NAIPI and the EPSCoR-IdEA Foundation are well-positioned to take on some of these challenges.