National Center for Research Resources National Institutes of Health Summary of Technical Assistance Workshop for Institutional Development Awards (IDeA) October 20, 2000

Dr. Judith Vaitukaitis, Director, National Center for Research Resources (NCRR) introduced and welcomed Dr. Ruth Kirschstein, Principal Deputy Director, National Institutes of Health (NIH)

Dr. Kirschstein's Remarks -

Dr. Kirschstein described the challenges facing investigators in states eligible for the Institutional Development Award (IDeA) and explained how NCRR will expand its IDeA Program to meet those needs. A July 21, 2000, IDeA Workshop provided investigators in IDeA-eligible states an opportunity to shared with NIH the needs of their institutions to successfully build infrastructure and to recruit and retain outstanding and experienced investigators. NIH recognized that institutions in IDeA states vary in their levels of research capacity and development. In the past, the Institutes and Centers of NIH, working through NCRR, have been supportive of the IDeA Program, but it has not been until this Fiscal Year (FY) 2000 that significant funds became available for NIH to develop a new program to address these needs. The new program, the Biomedical Reseach Infrastructure Network (BRIN), complements the earlier and quite successful Centers of Biomedical Research Excellence (COBRE) Program. In FY 2000, NCRR made 19 COBRE awards (\$165.5 million over 5 years). Then the original COBRE Request for Application (RFA) was revised and reissued with an application receipt date of January 2001 for the next round of awards.

The BRIN RFA requires institutions to develop partnerships with other institutions of higher education wither within the state or within other IDeA states. Dr. Kirschstein outlined BRIN program goals:

- Develop the biomedical research infrastructure at institutions within IDeA-eligible states.
- Develop a competitive biomedical research base
- Bring together institutions within a state to establish networks
- Enhance research training
- Develop areas of potential research through staff development
- Develop and/or provide access to research resources
- Strengthen and/or develop pre and post award management of biomedical research grants

NIH is also aware that the diversity of the BRIN applications may necessitate more than three years of grant support. Dr. Kirschstein emphasized this unique opportunity to improve health and bridge the divide between basic and clinical sciences to acquire a unified understanding of health and disease. A cooperation among institutions will allow solutions to previously insurmountable problems. She stated that scientists' talents at all levels are needed to make the BRIN Program a success and that NIH is prepared to work with each institution and to provide advice as needed.

An Overview of NCRR and IDeA Program – Dr. Judith Vaitukaitis, Director, NCRR

Dr. Vaitukaitis discussed various NCRR programs but highlighted the IDeA Program from its inception in 1993. The IDeA Program was authorized by the NIH Revitalization Act of 1993 with a Congressional intent to enhance geographical distribution of research funds. She briefly provided the IDeA Program funding history and the potential increase of appropriations in FY 2001. Dr. Vaitukaitis outlined other NCRR programs and resources that may benefit developing institutions in IDeA states. Several NCRR programs provide support for infrastructure support. For example, the Research Facilities Improvement (RFI) Program provides funds for renovation or construction of research facilities. Applications from IDeA state institutions for RFI funding have done extremely well for each of the past two fiscal years; that cohort has had the highest success rate from the RFIP. The Animal Facilities Improvement Program provides funds to upgrade animal facilities. IDeA-state institutions have also competed extremely well for Shared Instrumentation Grant (SIG) Program funding. A shared instrumentation grant funds from \$100,000 to \$500,000 to help purchase advanced instrumentation, generally too expensive to be purchased with research project grant funding. NCRR's Comparative Medicine area supports several biorepositories and models for studies of human diseases or normal physiology. Models include genetic stocks of several species, ranging from the fruit fly, C. elegans to the mouse.

Centers of Biomedical Research Excellence - COBRE

Programmatic Issues – Dr. Sidney McNairy, Associate Director for Research Infrastructure, NCRR

Dr. McNairy provided an overview of NCRR's Research Infrastructure (RI) area and several programs administered by RI:

- Research Centers in Minority Institutions (RCMI)
- RCMI Clinical Research Infrastructure Initiative (RCRII)
- Centers of Clinical Research Excellence (CCRE)
- Specialized Neurosciences Research Program (SNRP)
- Science Education Partnership Award (SEPA)
- Research Facilities Improvement Program (RFIP)
- Animal Facilities Improvement Program (AFIP)
- Institutional Development Awards Program (IDeA)

Dr. McNairy summarized current IDeA eligibility criteria as: 1) states with a less than 20 percent success rate for obtaining NIH grant awards; and 2) states with a higher success rates, but receiving less than \$70 million total NIH grant funding between 1995 and 1999. Dr. McNairy named the states that received FY 2000 COBRE awards. He discussed FY 2001 COBRE guidelines and application receipt dates and the number of applications each IDeA-eligible state is permitted to submit. For example, if the number of COBRE awards received by an IDeA state in FY 2000 was:

2 awards: then that state may not apply for a COBRE award; 1 award: then that state may submit one COBRE applications; 0 awards: then that state may submit two COBRE applications.

The COBRE research objectives are to augment and strengthen the institutional biomedical research capability, provide support for the development of a multi-disciplinary center, and develop a thematic science focus. Essential elements for the COBRE include a Principal Investigator/Magnet Investigator, core laboratory, new faculty recruits, and an advisory committee. The Principal Investigator (PI) must be an established biomedical researcher, have an active research laboratory, possess relevant peer-reviewed funded research, show institutional commitment, and be a capable mentor to junior faculty via support for 3 to 5 pilot projects. The new faculty recruits are eligible for up to \$100,000 per year for faculty start-up cost. The fundamental elements of a COBRE applications are:

- a clearly defined plan
- 5-year research plan
- description of and justification for proposed research projects
- description of the research training or career development goals
- description of available infrastructure that supports the proposed objectives
- advisory committee

Dr. McNairy concluded with a summary of frequently asked questions about the organization of the application and the possibilities of continued development of established investigators. Dr. McNairy's attached presentation provides additional details.

Review Considerations – Dr. Charles Hollingsworth, Director, Office of Review, NCRR Dr. Hollingsworth shared significant review criteria for applications submitted for COBRE funding.

- PI's qualifications
- Proposed research projects and the COBRE as a whole
- Plans for coordination and cooperation
- Investigators strengths
- Level of institutional commitment
- Need for proposed core facilities

The COBRE review criteria is also based on the merit of individual proposals and includes significance, approach, innovation, investigator, environment, and overall evaluation. The instructions and review criteria are included in the RFA. Dr. Hollingsworth encouraged potential applicants to:

- 1. Read the RFA
- 2. Re-read the RFA
- 3. Call if there are questions (301-435-0807)

Grants Management and COBRE - Irene Grissom, Grants Management Officer, NCRR Ms. Grissom provided an overview of application fundamentals for the IDeA Program. She said "project-specific assurances" relates to human subjects or vertebrate animals and "project-specific statements" relates to inventions or patents. Awards can be made without assurances, but they will have restrictions. Budget preparation and justification figures should include \$1.5 million in annual direct costs, excluding consortium facilities and administrative costs. These figures should be simple, complete, convincing, and accurate. Please contact the NCRR Office of Grants Management (301-435-0844) if you have questions about including general office supplies or other administrative/indirect costs in your application budget proposal. Facilities and administrative costs are awarded at negotiated institutional rates and have an escalation factor of 3 percent. In determining personnel salaries and fringe benefits, one should take into consideration the individual's type of appointment, level of effort on project, institutional base salary, benefits, and role in project. Other expenses that should be included in budget preparation are consultant fees, equipment, and supplies. Travel is approved only for project staff to attend annual meetings. This RFA does not allow alteration and renovation costs. Consortium agreements must include facilities and administrative costs, a detailed justification, and a budget statement signed by authorizing official of consortium institution. Once an award has been approved, an emailed notice of grant award is sent to the awarding institution. Accumulated balances from prior year funding can be unliquidated (purchase orders are not cleared) or unobligated (the money has not been spent). Prior approval is needed before balances can be carried forward. A carry-over request authorizes the use of unexpended funds from a previous budget period. It must be non-recurring, include a written request, and be for a special need or project. A financial status report is due annually within 90 days after the budget period ends. This report prompts any unuse of funds and allows a 15-month window for revisions. Ms. Grissom concluded by listing staff contacts and Internet sources of useful information. Ms. Grissom's attached presentation provides more detail.

Biomedical Research Infrastructure Network - BRIN

Programmatic Issues – Dr. W. Fred Taylor, Health Scientist Administrator, NCRR Dr. Taylor introduced the new Biomedical Research Infrastructure Network (BRIN) RFA. The BRIN program will develop a competitive biomedical research base by bringing together institutions within the state to establish networks, provide competitive funding to state-based networks, upgrade existing laboratories, provide the opportunity to apply for funding through the NCRR Research Facilities Improvement Program, equip laboratories with modern equipment, and recruit new faculty. The lead institution is to be a graduate/medical school or research institute. BRIN will provide support to build research capacity that will develop a partnership among institutions within a network. There will be a limit of two applications per state and the total cost for both applications is not to exceed \$2 million. Collaborations to enhance the next generation of researchers will be fostered by 1) addressing this approach at undergraduate and graduate levels through state-wide networks (this includes junior colleges), 2) recruiting outstanding faculty to mentor promising students, 3) recruiting junior faculty to graduate schools, 4) providing special courses and workshops to enhance career development of students and junior faculty, and 5) providing support to students to facilitate their pursuit of

careers in biomedical research. It is hoped that the BRIN will develop areas of potential research through staff development and access to research resources. Steering committees will be developed to determine the scope and number of shared research facilities to be included in the network. Administrative and Bioinformatics cores are mandatory. The Administrative core will serve as a clearinghouse for national and regional resources relevant to investigator needs. The Administrative core will be directed by the PI to provide logistical support for the network and serve as a clearinghouse for research activities. Hopefully, BRIN will strengthen research management within institutions by proposing that each network include an evaluation plan to assess effectiveness of the approach, set benchmarks for the network, modify the plan if necessary, and provide training for institutional officials to develop and administer an Office of Sponsored Programs. Officials may apply to the NIH Extramural Associates management fellows program. A Bioinformatics core will promote informatics training, education, and understanding of approaches and methods for data management and/or data sharing. At least one other core facility, such as a Training and Mentoring, Science Research, or Centralized Research must be included. A Science Research core may be included so that promising young investigators may gain hands-on training in the latest technologies. This grant program also requires a BRIN Plan which is to be completed within the first 6 to 8 months of the award. The remainder of the award period will be used to implement the plan. More than three years may be required to fully develop some networks and the plan may need to be modified due to unanticipated difficulties. Grant funds to implement the BRIN Plan may be restricted until NCRR program staff approves the plan. BRIN Plan criteria are as follows:

- Evidence of institutional commitment
- Viable recruitment plans for both established an promising investigators
- Relationship between elective cores and proposed thematic research
- Adequacy of research space and justification of proposed renovations
- Availability of research tools and instrumentation
- Availability of established investigators for mentoring
- Adequacy of operating principles and proposed committees

A coordinating committee will be established and membership will be selected collegially by representatives of eligible institutions within a state. This committee will assist institutions in selecting partners for a proposed BRIN, approve participation of institutions from other IDeA states as a research partner in a BRIN application, and be responsible for selecting BRIN applications to be submitted by an IDeA state. The established EPSCoR Committee may be used if appropriate expertise exists on the committee or can be added. The BRIN applicant may partner with other IDeA states, and budget requests will be adjusted pro rata toward participating states' ceiling for funding. There are two mandatory committees that must be incorporated into the application. The PI will act as the chairperson of the steering committee to establish policies and operating procedures of both itself and the BRIN. It will meet three times in the first year and twice a year thereafter. At least three permanent members and ad hoc members will make up an external advisory committee that will advise on scientific, administrative, and other matters. They will meet twice annually and provide meeting minutes to NIH staff. There will be two national meetings for BRIN, regional meetings will be driven by

the needs of the awardees. In conclusion Dr. Taylor provided a BRIN time line and application deadlines which are detailed in his attached presentation.

Review Considerations - Dr. Charles Hollingsworth, Director, Office of Review, NCRR

Dr. Hollingsworth shared significant review criteria for BRIN applications. Each application should have an integrated approach, organizational/operational framework, and a strategy for implementing educational tools. An innovational approach develops state-of-the-art core facilities, takes a role in bioinformatics, and enhances faculty interaction. He outlined the administration review criteria which includes an experienced PI, a steering committee, a plan for sharing responsibility, formalized agreements, priority setting, and recruiting plans. The plan must effectively enhance quality and competitiveness, promote research and interactions, show evidence of commitment, and plan to develop the scientific environment.

Grants Management Perspectives - Bryan Clark, Grants Management Officer, NCRR

Mr. Clark introduced the fundamentals of managing BRIN grants including application, budgetary, and policy issues. There is a \$2 million cost cap per state with a maximum of two applications per state. The award will be funded for three years and is currently non-renewable at that the end of the project period. The costs for the Administrative core, meetings, salaries for mentors, renovation costs, and equipment for non-research activities should be included in the budget. The salary cap for investigators is \$141,300 and renovations costs are allowable if they are below \$100,000. If costs exceed \$100,000, they must be approved by the NCRR Office of Grants Management. The budget preparation and justification for such items should be simple, complete, convincing, and accurate. Personnel salaries and fringe benefits should be determined by considering each individual's type of appointment, effort on the project, institutional-base salary, benefits, and project role. In addition, budget preparation should include expenses for consultant fees, equipment, supplies, and travel. Consortium agreements must include facilities and administrative costs, a detailed justification, and a budget statement signed by authorizing official of the consortium institution. Once an award has been approved, a Notice of Grant Award will be sent via e-mail to the recipient institution. Prior approval is needed before unused balances can be carried forward. A carry-over request authorizes the use of unexpended funds from a previous budget period. It must be non-recurring, include a formal written request, and be for a special need or project. A financial status report is due annually within 90 days after the budget period ends. This report prompts any unuse of funds and allows a 15-month window for revisions. Mr. Clark concluded by listing Grants Management staff that can provide additional information. Mr. Clark's attached presentation provides more detail.