NIH Extramural Nexus
WHERE GRANTS POLICY, PROGRAM COORDINATION, COMPLIANCE AND ELECTRONIC RESEARCH ADMINISTRATION CONVERGE

September 2007

In This Issue

NEWS FROM THE DIRECTOR OF OER: Creating and Maintaining a Sustainable Scientific Workforce

Dear Extramural Community,

One of the most important aspects of my job is to hear your concerns, and to the extent that I am able, address them so that you can continue to conduct the groundbreaking biomedical research that in this 21st century will help us predict and prevent disease and personalize treatments. In the last two years, I have heard increasing concern for the health of the "the pipeline"—the new generation of investigators that will make the discoveries of the future. And many of you tell me that you are unable to recruit and retain the best minds to conduct research.

I can assure you that the NIH remains committed to the support of a stable and sustainable scientific workforce. Like you, we are concerned about the health of the pipeline and the aging of the NIH Principal Investigator (PI) pool. Will we have enough new investigators to carry out the health-related research of the future?

It is clear that the age distribution of the pool of NIH PIs with research project grants has changed tremendously. Of particular interest is the relationship of NIH-funded PIs to the age distribution of medical school faculty, from 1980 to 2006,using data supplied by the Association of American Medical Colleges (AAMC). The average age of NIH PIs increased from 39.1 to 50.8 over the period from 1980 to 2006. The average age of medical school faculty increased from 43.1 to 48.7 over the same period.

The NIH has attempted several interventions over the years to ensure a sufficient cadre of new investigators into the biomedical investigator pool.

These include the New Investigator Research Award (NIRA), the FIRST Award and most recently, the New Investigator Check Box. Other interventions include the Pathway to Independence Award and the Director's Innovator Award. In fiscal year (FY) 2007, based on historical trends, the NIH established a target of 1,500 new R01 investigators in an attempt reinvigorate the new investigator pool, which in FY 2006 had declined to a nine year low.

Data recently published by Howard Garrison and Kimberly McGuire of the Federation of American Societies for Experimental Biology (FASEB) provide additional insights. In recent years, graduate enrollments have increased and the number of doctoral degrees conferred has climbed rapidly along with the number of biomedical postdocs. Of note, the postdoc increase is driven by steady increases in the total number of international scholars—an increase of about 1,000 per year since 1980. Furthermore, the supply of individuals with sufficient training to consider academic track positions is increasing even though the numbers who find their way into tenured faculty positions is declining. The decline seems to be related in part to fewer available employment opportunities in academia, partially compensated by an expansion of industrial jobs. The decline may also be related to a decline in tenure and tenure track positions as a proportion of all academically employed Ph.D.s In United States medical schools, Ph.D. faculty numbers seem to be declining for the first time since 1970, based on information provided by AAMC.

What percent of the overall biomedical research workforce should be comprised of new investigators to ensure a vigorous biomedical research enterprise? We are all struggling to answer this seemingly simple, yet difficult question. As we think about the broader health-related scientific workforce and about matching the supply of new graduates and international postdocs with the demand for expansion of the biomedical research workforce and its replacement needs, it is clear that we need more information. The academe accounts only for about one-half of the total academic and non-academic workforce, and PIs probably account for about one sixth of all the individuals involved in NIH extramural research. We need to know more about the entire demand from this enterprise; and we need to know about clinicians, which I haven't discussed at all here.

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The NIH is now engaged in an aggressive effort to collect relevant information. One particular effort involves looking at key personnel involved in the research supported by NIH grants in FY 2006. The findings will inform methods for collecting similar data on an ongoing basis. We are also developing workforce models to determine if we can create simulations that will help identify points of sensitivity that might inform future policies. Professional societies, health-related companies, universities, faculty, postdocs, and students can all play a role in this data gathering exercise, and we will be asking for help over the next several months. The new information will be made available to the community and considered in the quadrennial research personnel needs study conducted by the National Academies of Science. I know that we are all interested in a stable, efficient and productive biomedical research workforce. I am looking forward to working with you toward that end.

If you have comments or questions please write to me at DDER@NIH.gov.

— *Norka Ruiz Bravo, Ph.D.,* Director, Office of Extramural Research and NIH Deputy Director for Extramural Research

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IN THEIR OWN WORDS

Editors note: Welcome to a new feature in the NIH Extramural Nexus, *where on an occasional basis we will showcase interviews with NIH leaders*.

An Interview with OPSAI Director Dr. Alan Krensky: "I want to show value added to the NIH"

The *NIH Extramural Nexus* met September 13 with Alan M. Krensky, M.D., NIH deputy director for the Office of Portfolio Analysis and Strategic Initiatives (OPASI). Dr. Krensky leads OPASI, a newly established office in the NIH Office of the Director that will help identify important areas of emerging scientific opportunities and public health challenges. OPASI will help accelerate investments in these areas to make sure new ideas have a chance to develop. Dr. Krensky came to the NIH

from Stanford University where he served both as a researcher and an administrator (see the *NIH Record*, February 9, 2007, page 3).

What are your priorities as the first director of this new office at the NIH?

I think the important word is "new" office, and I am a "new" director. Dr. Zerhouni's vision of the Roadmap, portfolio analysis, strategic initiatives, and evaluation are ideas that resonate for me. I wholeheartedly believe in that construct. So the simple answer to your question is that I want to show value added to the NIH through portfolio analysis, strategic initiatives, and evaluation. Other than these, there is no one particular area on which I will focus, other than those that the Institute and Center (IC) directors have chosen for the Roadmap.

Please define knowledge management and discuss how successful knowledge management will help NIH in its mission to improve the public health.

Knowledge management is a tool for portfolio analysis. What does the NIH spend its money on? Each IC historically has accounted for that using it own definitions, its own rules, its own methodologies. What Congress and stakeholders have said for some time now is that it is better to have one system that is communicated the same way each time and that can be duplicated.

Knowledge management itself consists of computer systems that have to do with how you deal with data. How you go about taking grants and giving them a particular "fingerprint" (just like a human fingerprint) that will identify what a grant is about and then how you use that information—this represents the cutting edge of information sciences. The techniques and technologies are still evolving. What is done with that information, be it by stakeholders, Congress, or the ICs, is up to each of those groups. OPASI is about providing this functionality. It is about having one system that is credible, reproducible, transparent, and available.

How would you describe OPASI's relationship to the extramural community—both the internal extramural staff and the external

NIH REGIONAL CONSULTATION MEETINGS ON PEER REVIEW AVAILABLE IN OCTOBER

There are two remaining dates for the NIH consultative regional meetings that have been organized by the Peer Review Working Group of the Advisory Committee to the Director.

These meetings are intended to obtain advice from the scientific community on all aspects of the peer review process.

The four-hour consultation meetings are:

- New York City
  October 8
  Embassy Suites
- San Francisco
  October 25
  Parc 55 Hotel

NIH's Request for Information (RFI): NIH System to Support Biomedical and Behavioral Research

and Peer Review closed on September 7. Analyses of the responses to the RFI will be made available upon completion.

Details are available at the Enhancing Peer Review at NIH Web site.

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research community?

This raises many issues. One issue for me is the concept of boundaries. OPASI is going to work across boundaries—in the intramural community and the extramural communities, both inside and outside NIH. When you say extramural, per se, I go back to portfolio analysis, strategic initiatives, and evaluation.

In terms of portfolio analysis, folks will be able to see not only where their IC stands but also the whole NIH—where there may be gaps, where there may be redundancies. This should be very helpful for the extramural community.

As for strategic initiatives, the Roadmap itself is a learning laboratory where, in a sense, we are doing experiments. The Pioneer Awards program is an example of one experiment. This program has been very successful and now some of the ICs want to have one of their own.

In terms of evaluation, evaluations help to determine policies. If something works well, we should do it. If it does not work well, we should rethink it or redo it. ICs have already done a lot in this area, and I believe that OPASI will enhance the effort.

All three arms of OPASI have relevance for the extramural community both here at NIH and for the outside world. For example, we just announced nine new research consortia that will be our proof of principle on this (see related article *NIH Interdisciplinary Research Consortia Launched* in this issue). These consortia are what OPASI is all about.

The consortia forge new disciplines made of a spectrum of people, broad-based teams working together as a single discipline. It's meant to be a paradigm shift, not that it wasn't happening already. But by making this a Roadmap initiative, it will gain the recognition it should have as a model. ICs are already doing this by bringing their interdisciplinary people together. We are seeing ICs coming together in new ways. There is a lot of collaboration, a lot of coordination.

Now that OPASI is formally established, what difference might NIH extramural grantees (scientists and institutions) notice in their

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HOUSE AND SENATE APPROVE NEW BILL EXTENDING FDA AUTHORITY

A bill that amends the Federal Food, Drug, and Cosmetic Act and extends U.S. Food and Drug Administration authority regarding drug safety was passed by The U.S. House of Representatives September 19 and the Senate September 20.

President Bush is expected to sign the bill into law shortly

The bill contains a number of NIH-specific provisions that:

- expand ClinicalTrials.gov
- reauthorize the Best Pharmaceuticals for Children Act
- increase research on pediatric devices

We will keep you informed of implementation plans and progress in future editions of the *NIH Extramural Nexus*.

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interactions with NIH?

Because of what is going on in science, we have to analyze our portfolio. I believe in a portfolio of large, medium, and small and a balance. This is not to the exclusion of R01s. R01s are still the major mechanism for supporting science.

We have an expert evaluation team in OPASI and its efforts are extremely important in deciding if the process is good and if the outcome is appropriate.

The establishment of OPASI represents something "new under the sun" in the planning and managing of the NIH research portfolio. As is normal with any organizational change, anxieties arise. How are you addressing these concerns?

I personally don't think there is anything "new under the sun." What attracts the sunlight at different times may vary. All these ideas have been percolating and all these functions have been done before; but they have not been brought together into one office in the Office of the Director. What is different is that NIH is bringing these functions together in a central coordination effort to do what the ICs feel, in the end, is value added. This is *not* top down. It is *not* manipulating 27 ICs. It is really seeing where there is commonality, where there are places to work together. When I use my hands in explaining OPASI's function, I use them like this. *Note: Dr. Krensky put his arms out waist high, palms up, as if he were supporting something important*.

There will be change, but it will be change for the better, change managed in the direction that the community defines as the right way to go. There is outreach at every level, intramural NIH, extramural NIH, Congress, stakeholders, professional societies, and advisory committees to the ICs. I think the idea of portfolio analysis resonates with everyone; the idea of strategic initiatives resonates with everyone. I am finding tremendous support for the Roadmap initiatives and understanding in the community that the Roadmap is a learning laboratory for short-term projects that we will test and, if they work well, support for use broadly.

» Science in the News

We are about the approach to science, the process, and the ICs working

Manic Phase of Bipolar Disorder Benefits from Breast Cancer Medication

The National Institutes of Health and NASA Partner for Health Research in Space

NIH Scientists Demonstrate Genetic Variant is Linked to Greater Effectiveness of Smoking Cessation

Strength in Numbers: NIH Debuts Campaign to Empower Individuals to Pursue Careers in Research

New Initiative to Study the Glycobiology of Cancer Could Aid Understanding of Cancer Risk and Detection

Unique Grape Skin Extract Inhibits Prostate Cancer Cell Growth in the Laboratory

together. The process is just like research, and OPASI is a special place where ICs can cooperatively come together to manage the process. OPASI is institutionalizing a lot of what was already going on at NIH in terms of cooperation and collaboration—putting an institutional structure together to serve as a lightning rod to bring people together.

Visit the OPASI Web site for more information on the organization, its three divisions and its mission.

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NEW RESOURCE FOR ADVANCING INNOVATIVE TECHNOLOGIES JOINS THE COMMERCIAL ASSISTANCE PROGRAM

Moving a promising technology from bench to bedside entails an arduous trek for NIH licensees and SBIR/STTR awardees. As part of continuing efforts to foster the development and entry into the marketplace of new technologies, NIH recently launched the Pipeline to Partnerships (P2P) Web-based resource.

P2P is a searchable database of technologies available for development opportunities that allows NIH licensees and Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) awardees to showcase their technologies for an audience of potential strategic partners and investors. P2P will further advance emerging technologies by facilitating partnerships with potential investors to share costs, infrastructure and expertise. All submissions by licensees and grantees will be on a voluntary basis, with no endorsement or direct involvement from NIH in the partnering.

P2P joins the Commercial Assistance Program (CAP), now in its fourth year. CAP helps NIH SBIR Phase Two awardees with business and strategic planning.

NIH recently announced the CAP for 2002-2007 SBIR awardees. About 75 participants will be selected to attend training workshops and mentoring and consulting sessions. Selected participants will receive individualized assistance in areas such as strategic business planning,

regulatory approvals, preparing an investor brochure, establishing licensing opportunities, and investment and strategic partnerships. The program also includes a forum for companies to present their business opportunities to potential investors and partners.

Questions about these programs may be directed to sbir@od.nih.gov.

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THE NIH SYSTEM FOR ENHANCING THE SCIENCE, SAFETY AND ETHICS OF RECOMBINANT DNA RESEARCH

The techniques of recombinant DNA have revolutionized biological research since their development over 30 years ago, enabling many critically important research methods and products. Although controversial when first developed—and to this day raising many important scientific, ethical and safety considerations—our experience with this technology has been positive, thanks in large part to the biosafety standards found in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*).

Institutions receiving any NIH funding for research involving recombinant DNA must adhere to the *NIH Guidelines* and apply them to ***all*** research involving recombinant DNA, regardless of funding source. This is sensible since, for biosafety and containment practices to be maximally effective, they must be uniformly observed.

These institutions are required to establish an Institutional Biosafety Committee (IBC) to review, approve, and oversee research subject to the *NIH Guidelines*. They must also register the IBC with the NIH Office of Biotechnology Activities (OBA), which is responsible for overseeing implementation of the *NIH Guidelines*. More information on IBCs can be found in Frequently Asked Questions (FAQs) on OBA's Web site.

Putting recombinant DNA into humans raises special safety and ethical considerations. These are detailed in Appendix M of the *NIH Guidelines*, which specifies points to consider in the design and submission of

human gene transfer trials to NIH. Trials raising notable scientific, safety or ethical considerations may be selected for public review by the NIH Recombinant DNA Advisory Committee. Once a trial is initiated, additional information is to be submitted to NIH, including reports of serious adverse events. More information about Appendix M requirements can be found on OBA's Web site in a set of FAQs regarding protocol review.

Investigators are encouraged to report adverse events using the Genetic Modification Clinical Research Information System. This system provides an online reporting format enabling the creation of reports that can be submitted electronically to the NIH and that can also be sent to the FDA and institutional oversight committees.

Careful adherence to the *NIH Guidelines* will help ensure that our experience with recombinant DNA will prove equally positive into the next 30 years. Toward that end, NIH is developing modifications to the grant application that will address recombinant DNA research and help identify studies for IBC review and oversight. In the meantime, investigators and administrators are encouraged to contact OBA for guidance on how they can ensure compliance with the spirit and the letter of the *NIH Guidelines*.

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NIH POLICY FOR GWAS DATA SHARING ANNOUNCED

The NIH achieved a major milestone in the development of personalized medicine with the release of a new policy, published at the end of August and focused on sharing data from genome-wide association studies (GWAS).

A genome-wide association study is any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. The GWAS sharing policy is a new component of NIH's overall research-sharing policies, which include data sharing, model organism sharing and resource sharing.

Whole genome information, when combined with clinical and other phenotype data, offers the potential to identify common genetic factors that influence health and disease, to increase understanding of basic biological processes affecting human health, and to improve disease prediction and patient care. Therefore, the NIH GWAS policy is intended to facilitate sharing of genetic data and information from GWAS, while protecting research participants in GWAS and their genetic information from potential harm.

The new policy applies to competing grant applications and proposals for contracts that include GWAS and are submitted to the NIH for the January 25, 2008 and subsequent receipt dates, and to NIH intramural projects approved on or after January 25, 2008. An application or proposal will be identified as including GWAS by applicants and/or NIH staff.

Information about the policy, answers to pertinent questions, and an explanation of the public consultation process are available on the NIH GWAS Web site.

Detailed implementation guidance will be provided for the extramural community in the coming months through various resources, including the NIH GWAS Web site and future editions of the *NIH Extramural Nexus*.

Please direct any questions or comments related to the GWAS sharing policy to GWAS@mail.nih.gov.

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POWERFUL AWARD TREND RESOURCE IN THE WORKS

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Have you ever wondered which applications were awarded for a specific Funding Opportunity Announcement (FOA) or wanted to know the award dollars break down by FOA type for a specific NIH Institute or Center?

The NIH Office of Extramural Research's Division of Information Systems is building a powerful new resource to its Award Trends Web site that puts this type of reporting right at your fingertips. Check out Total Award Dollars by Type of Funding Opportunity Announcement FY 2006 and 2007.

This tool was created in response to research community requests for greater transparency in award funding and easier access to reporting data.

We expect to improve the tool based on your needs. Direct your questions, comments or suggestions on this work in progress to DISHelp@mail.nih.gov.

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EYE ON PI

NIH Educational Debt Repayment Available to Ph.D. Research Scientists

NIH's Loan Repayment Program (LRP) recently announced its *Strength in Numbers* campaign, which offers a renewed commitment to qualified postdoctoral scientists who are seeking careers in biomedical and behavioral research. The program funds up to $35,000 annually in educational loan repayment.

Not limited to NIH grantees, any research scientist may take advantage of the LRP. To qualify, applicants must possess a doctoral-level degree, devote 50 percent or more of their time to research funded by a nonprofit organization or government entity and have educational loan debt equal to or exceeding 20 percent of their institutional base salary. Applicants must also be U.S. citizens or permanent residents.

Visit the NIH LRP Web site for more details and to apply. For additional

Feedback

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Feedback from recipients and subscribers of the *NIH Extramural Nexus* is vital. Comments, questions, and suggestions for topics will enable *Nexus* editorial staff to deliver appropriate content to the grantee community.

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(Adobe® Reader® Required)

information or questions, contact Suman King.

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From Commerce to the Community: New Patent Rules Issued

In the August 21, 2007 edition of the *Federal Register*, the United States Patent and Trademark Office (USPTO) announced its final rules on patent claim examination and continuation applications. The USPTO expect the rule to to improve the effectiveness and efficiency of patent examination. Highlights of these rule changes are available at the USPTO and have an effective date of November 1, 2007.

Many NIH-funded institutions, from R01 to Small Business Innovation Research (SBIR) grantees, pursue patenting of their discoveries made under federal funding. However, the long-term costs and effects of these rule changes on biotechs, universities, and nonprofit institutions continue to be discussed in the community.

The USPTO is the federal agency in the Department of Commerce that grants U.S. patents to inventors who have successfully convinced the USPTO that their discoveries are patentable. It is charged with promoting the progress of science and the useful arts by securing, for limited times, to inventors the exclusive right to their respective discoveries.

The USTPO has a glossary of terms available.

For additional information, contact The Office of Patent Legal Administration by telephone at (571) 272-7704, by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450, or by FAX to (571) 273-0100, marked to the attention of the Office of Patent Legal Administration.

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Principal Investigator's eRA Commons Account

Did you know that Principal Investigators (PIs) are assigned one eRA Commons account that follows them throughout their entire careers? With more and more grant administration tasks moving away from paper in favor of electronic alternatives, proper maintenance of your eRA Commons account is critical. Here are a few tips:

- If you change institutions, provide your eRA Commons User Name and the email address listed in your Personal Profile to the business office of your new institution and ask them to "affiliate" your account. Your account can be affiliated with multiple institutions. Each institution will be able to view your history within that institution. You will have access to your full history at all institutions.
- Whenever your personal information (e.g., email address, phone, address, employment history, degree) changes, take a few minutes to review and update your eRA Commons Personal Profile information.
- Keep your email address current. Not only is the email address used for certain NIH notifications, the email address in your profile is used if you need to take advantage of the "Forgot Password?" link beneath the login fields on the eRA Commons home page.

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Multiple PI Update

Since the inception of the NIH policy to allow multiple Principal Investigators on grant applications in February, NIH has received more than 1,800 applications.

To date, NIH has made approximately 50 multiple PI awards and expects to make more in fiscal year 2008.

The program will be evaluated as part of the Roadmap Interdisciplinary Research initiative, and, in a future *NIH Extramural Nexus*, we will provide an update on the multiple PI initiative.

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ELECTRONIC SUBMISSION UPDATE

Updated Application Guides Now Available

The U.S. Department of Health and Human Services Public Health Service *Grants.gov Application Guide SF424 (R&R)* and the corresponding *Grants.gov SBIR/STTR Application Guide* have been updated to include additional guidance on dealing with subaward budgets, recent policy change to exclude federal holidays from the two day application viewing window, and suggested clarifications from the applicant community (see summary of changes).

We realize posting an updated application guide close to a major R01 grant application submission deadline may cause some anxiety. However, the updates simply incorporate previously announced policy and applicant-suggested clarifications into a single information source.

Thanks to all the applicants who took the time to provide feedback on the application guide. Keep the feedback coming. Email the NIH Electronic Submission team at NIHElectronicSubmiss@mail.nih.gov.

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Future Electronic Submission Transitions Still on Hold

The transition of NIH Training Grants (T), Career Development Awards (K) and Fellowships (F) to electronic application submission remains on hold until Grants.gov can develop new forms. Grants.gov's current focus at the current time is on finalizing Adobe® versions of all existing forms and incorporating additional federally mandated data fields into existing form sets.

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Use of Adobe Forms

NIH will continue to use PureEdge™ forms at least through March 2008 grant application submission deadlines. Grants.gov deployed an updated system on September 4 that incorporates new search functionality powered by Google™ technology and allows for the use of fillable Adobe forms®. Although some Grants.gov Adobe forms are now available for agency use, NIH is still awaiting the final Adobe forms to complete the SF424 (R&R) form set used by NIH for electronic application submission.

Once Grants.gov delivers the full set of Adobe forms, NIH will need to test and make any necessary adjustments prior to their use.

NIH will post its plans to transition to Adobe forms in the *NIH Guide for Grants and Contracts*, when they are finalized.

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ROADMAP UPDATE

NIH Director Announces Recipients of New Innovator Award

NIH Director Elias A. Zerhouni, M.D. September 18 announced the recipients of the NIH Director's New Innovator Award, a part of the NIH Roadmap for Medical Research.

The NIH Director's New Innovator Award addresses two important goals: stimulating highly innovative research and supporting promising new investigators. Many new investigators have exceptionally innovative research ideas, but not the preliminary data required to fare well in the traditional NIH peer review system. As part of NIH's commitment to increasing opportunities for new scientists, it has created the NIH Director's New Innovator Award to support exceptionally creative new investigators who propose highly innovative projects that have the potential for unusually high impact.

This award complements ongoing efforts by NIH and its institutes and centers to fund new investigators through R01 grants and other mechanisms.

The 29 New Innovator Award recipients will each receive $1.5 million in direct costs over five years.

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NIH Director's 2007 Pioneer Awardees Announced at Symposium

The NIH September 19 held its third annual NIH Director's Pioneer Award Symposium. It featured research talks by the 2006 Pioneer Award recipients, poster presentations by the 2004, 2005 and 2006 awardees, and announcement of the twelve 2007 awardees.

The NIH Director's Pioneer Award program—a key component of the NIH Roadmap for Medical Research—supports exceptionally creative scientists who take highly innovative, and potentially transformative approaches to major challenges in biomedical research.

The symposium was streamed live over the Internet via NIH VideoCasting and is now archived for viewing.

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NIH Interdisciplinary Research Consortia Launched

NIH has announced that its Roadmap for Medical Research will fund nine interdisciplinary research consortia as a way to integrate aspects of different disciplines to address health challenges that have been resistant to traditional research approaches.

Funded at $210 million over five years, the consortia consist of multiple research projects with multiple principal investigators, core research support facilities, training, career development, and education components. These components will be divided among several NIH Institutes and Centers for programmatic oversight. To maintain the interdisciplinary research program as a whole, the grants will remain

linked electronically through unique identifiers, and the National Center for Research Resources (NCRR) and the Office of Portfolio Analysis and Strategic Initiatives (OPASI) will oversee the entire program.

Complete information is available in the official Research Consortia Launch press release.

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