

# **Council of Councils Meeting DPCPSI Update**

**James M. Anderson, M.D., Ph.D.**

Director

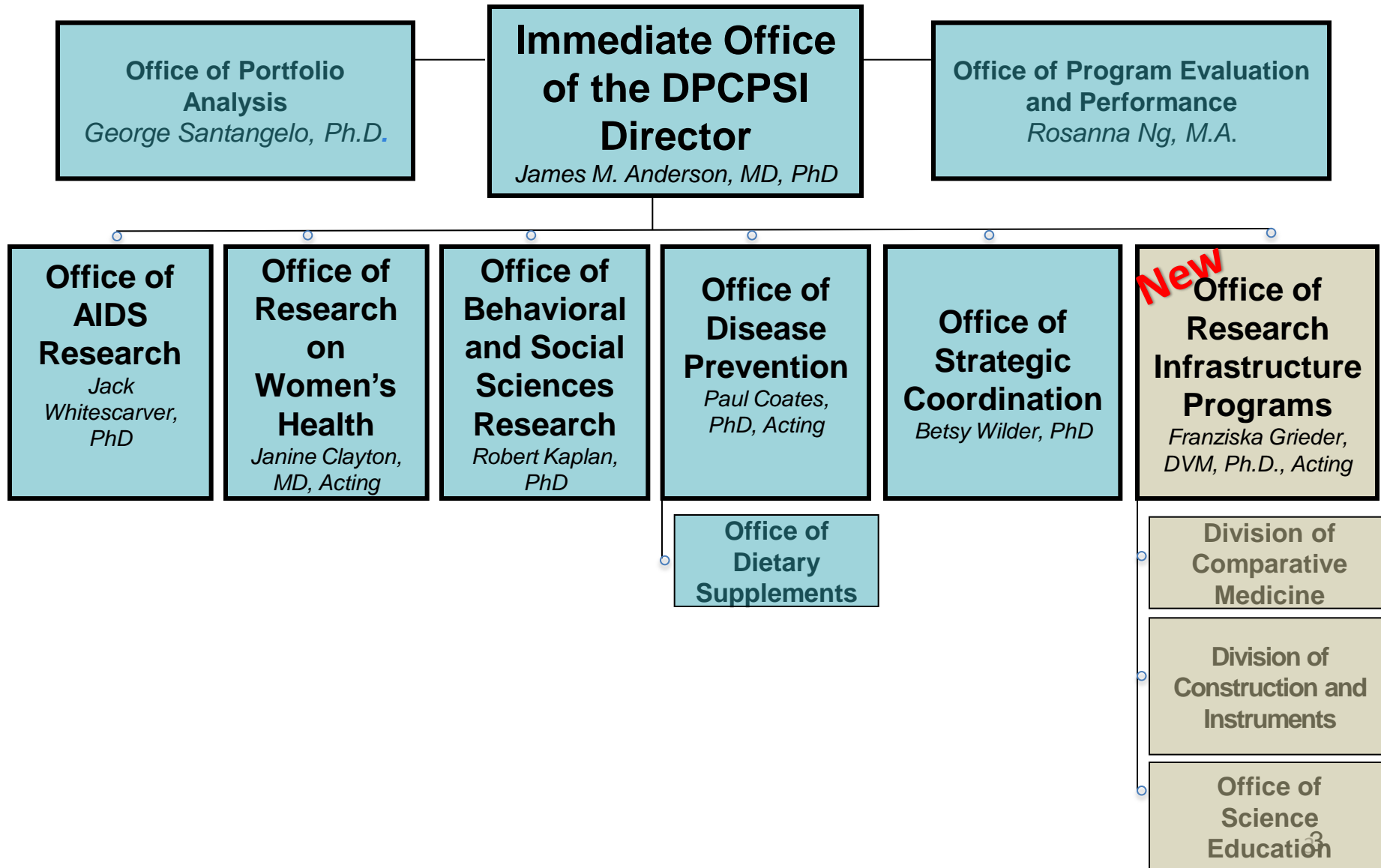
Division of Program Coordination, Planning, and  
Strategic Initiatives

September 5, 2012

# Agenda for the Day

- Comparative Medicine Research Training Opportunities
  - Presentation: Preventing HIV-Induced Cardiac Dysfunction
- Remarks from the NIH Director
- Council Operating Procedures
- Recognition of Departing Members
- Chimpanzee Working Group Update
- Tobacco Control Regulatory Science
- Update on the Office of Portfolio Analysis

# Division of Program Coordination, Planning, and Strategic Initiatives *After January 10, 2012*



# Office of AIDS Research



Strategic Planning

NIH, national and international research coordination

# OAR Scientific Coordination

- International AIDS Society Initiative: “*Toward a Cure for HIV*”
- OAR participation in White House AIDS initiatives
- OAR coordination with Presidents Emergency Plan for AIDS Relief
- NIH International Collaborations with Russia, China, India and the Caribbean
- NIH Collaborations to address the U.S. epidemic



# Coordination of NIH presence at AIDS July 2012 Conference

- Planned and coordinated NIH activities and communications
- Highlighted NIH scientific contributions and research priorities moving forward
- Participation by NIH Director, White House, Cabinet officials, and Congress
- 19 ICs and 4 OD offices
- NIH Exhibit and 35 Meet the Expert sessions
- Journalists tour of NIH
- 12 NIH-sponsored Satellites and workshops, including:
  - New Frontiers in NIH AIDS Research
  - HIV and Aging: A Global Perspective
  - NIH Grantsmanship Workshop
  - Ethical Considerations in HIV Genetics Research



# Office of Research on Women's Health



Coordinate co-funding with ICs  
Clinical Research Inclusion Policy-Focus on the Science



# New Awards for ORWH Interdisciplinary Programs - 2012

SAVE THE DATE – November 15, 2012 – Natcher  
9<sup>th</sup> Annual Interdisciplinary Women's Health Research Symposium



**BIRCWH:** Institutional mentored career development program designed to increase # of women's health researchers.

- **Building Interdisciplinary Research Careers in Women's Health (BIRCWH - K12)**

- 14 new awards in 2012 (new and competitive renewals)
- 13 current sites
- 488 scholars trained to date
  - 80% women; 20% men



**SCOR:** Interdisciplinary research program focusing on sex differences through integrated basic, clinical and translational research.

- **Specialized Centers of Research on Sex Differences (SCOR – P50)**

- 11 awarded in 2012 (new and competitive renewals)
- Research areas: i.e. Urinary Health, Vascular Dysfunction, Musculoskeletal Health, and Substance abuse



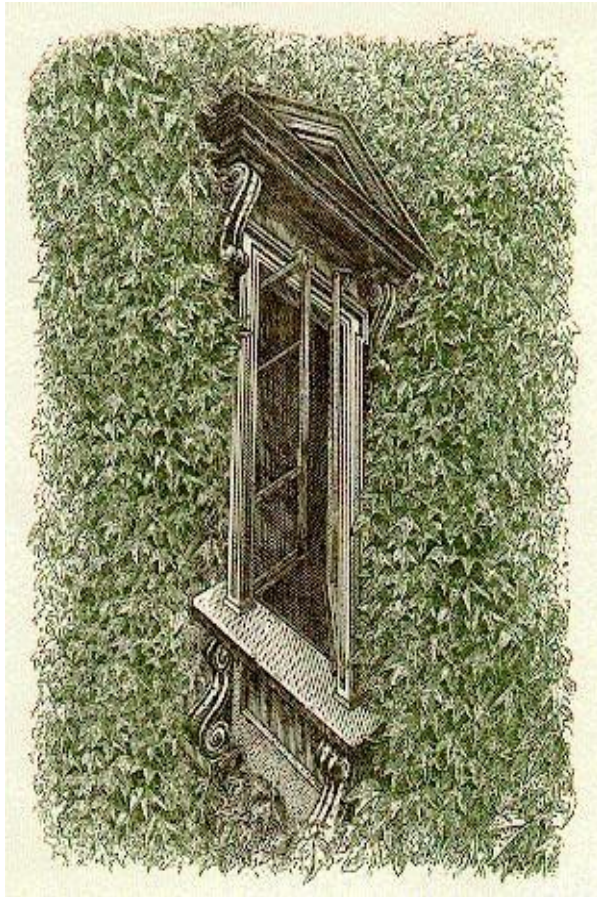
# Co-funded Innovative Women's Health and Sex Differences Research in 2012



- ORWH expands reach in implementing Strategic Plan
- FY12 Advancing Novel Science in Women's Health Research (ANSWHR) program – **13 new R21 awards, with 8 IC.** Many topics addressed.
- In partnership with NHLBI, ORWH funds supplement to detect and characterize sex differences in the gut microbiome; and in response to atherogenic diet



# New Philosophy on Inclusion and Clinical Research



- **A new philosophy** and guiding principles related to the NIH policy on inclusion of women and minorities in clinical research
- Developed by a subcommittee of an Extramural Advisory Working Group
- Co-Chaired by Directors, NICHD and ORWH
- **Guiding principles** for the new philosophy include:
  - focusing on the science
  - population matches the scientific goals rather than enumeration of research participants
  - simplifying processes
  - enhancing consistency across NIH
  - increasing the value of reporting

# Outreach and Education

## 52 Weeks for Women's Health

### New Mobile App from NIH



• <http://orwh.od.nih.gov/index.html>



# Office of Behavioral and Social Sciences Research

# OBSSR Holds a Variety of Summer Training Programs

2012 NIH SUMMER INSTITUTE ON  
Social and Behavioral  
Intervention Research

Advancing  
Prevention:  
Knowledge Gaps and New Partnerships

Randomized Clinical Trials  
Involving Behavioral  
Interventions

TIDIRH

National Institutes of Health  
6th Floor, Building 31  
June 28-29, 2012

July 9-12, 2012  
Training Institute for  
Dissemination and  
Implementation  
Research in Health  
Dolce Hayes Mansion | San Jose, California

Institute on Systems  
Science and Health



# Qualified Applicants and Number of Available Spaces for 2012 Summer Training Institutes

Topic	Host Institution	Qualified Applicants	Accepted
Social and Behavioral Intervention Research	Columbia University	140	36
Institute for Systems Science and Health	Washington University, Saint Louis	99	46
Training Institute for Dissemination and Implementation Research in Health	U.C. San Francisco	203	30
Behavioral Randomized Clinical Trials	Arlie House, Virginia	125	36
mHealth	Northeastern University	370	28



**Office of Disease Prevention**  
National Institutes of Health



**Office of  
Dietary Supplements**  

---

National Institutes of Health



# New ODP Director

- **David M. Murray, Ph.D.**
  - NIH Associate Director for Prevention
  - Director, Office of Disease Prevention
  - Starts September 24, 2012
- **Background**
  - Chair, Division of Epidemiology, College of Public Health, Ohio State University
  - Expert in methods to assess the outcome of interventions
    - design and analysis of group-randomized trials
- Immediate goal to develop a **new strategic plan** for ODP focused on advancing disease prevention and health promotion research
  - Trans-DPCPSI component

# Office of Disease Prevention

- Medicine in the Media Course (Oct 14-17, 2012)
- Consensus Development Conference: Diagnosing Gestational Diabetes Mellitus (Oct 29-31, 2012)
- Physical Activity and Disease Prevention – Identifying Research Priorities (Dec 13-14, 2012)
- Evidence-Based Methodology Workshops
  - Polycystic Ovary Syndrome Workshop (Dec 3-5, 2012)
  - Future workshops (Chronic Fatigue Syndrome, Opioids in Chronic Non-Cancer Pain Conditions)

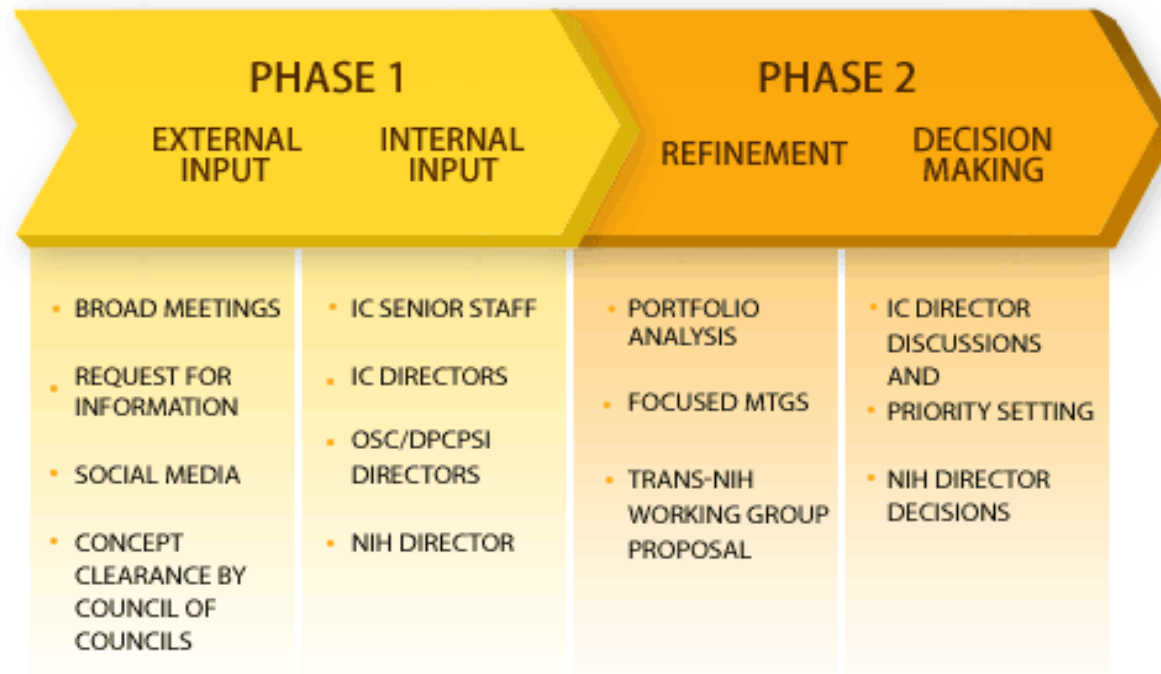
# Office of Dietary Supplements

- Human Performance and Dietary Supplements Summit (Aug 9-10, 2012, enhance knowledge of fitness professionals)
- Phenylketonuria Meeting (Aug 23-24, 2012, practice guidelines)
- Future Workshop: Folic Acid at High Levels (State of Science of adverse health effects)



# **Office of Strategic Coordination**

# Common Fund Strategic Planning Process

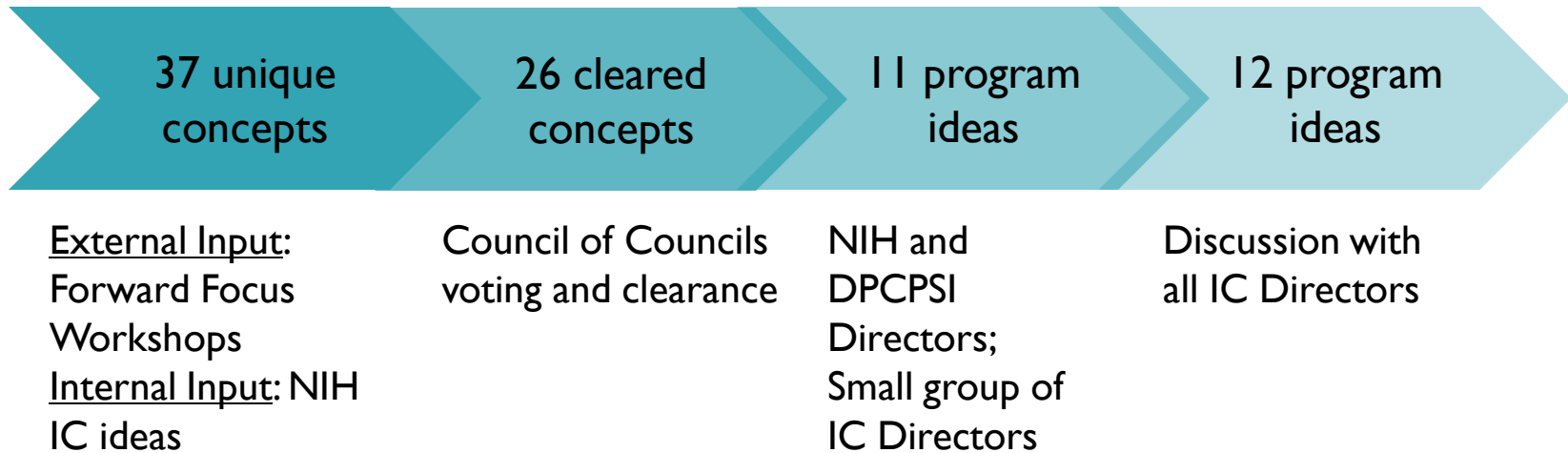


**Forward Focus Workshops (May 2012):** to gather input from the broad community on the biggest obstacles to progress in biomedical research or the greatest scientific opportunities that are ripe for exploration

San Francisco, CA and Chicago IL: open public meetings; 60-100 attendees from academia, industry, government, general public

Potomac, MD: 26 invited researchers, nominated by NIH Institutes and Centers, and Office of the Director

# Idea Selection Process



## Current Status:

### Being implemented in FY 2013

- Extracellular RNA Communication
- Undiagnosed Diseases Program

## Planning Activities for FY 2013/2014

- Citizen Science
- Deorphanizing the Druggable Genome
- Glycomics
- Individual Exposome Project
- Planning a Synthetic Cohort
- Epigenomic Pharmacology\*
- Management of Chronic Diseases in Clinical Trials\*
- Recommendations from the ACD Working Groups on Biomedical Workforce, Diversity in the Biomedical Workforce, and Data and Informatics

*\*to be incorporated within existing programs*

# Council of Councils Input

## Example comments from cleared concepts:

- *Very exciting and clearly potentially transformative*
- *Will have innovative successes and also irrevocable dead-ends.....Deserving of pilot, but not significant Common Fund investment unless results pan out*
- *Need to ensure sustainability of resource; provide support for pilot investigations; provide support for web interfaces/wikis that allow user access/contribution in real time*
- *Thoroughly approve of this. It is trans-NIH and is a missing part of our knowledge about the pathobiology of human disease*
- *The scope seems very wide, and perhaps subcomponents of this proposal could be developed that would focus efforts*

## Example comments from concepts not cleared:

- *This is already being done in many venues*
- *This does not seem to propose anything transformational: what is stated above seems to me to be what bioethicists have been doing for the last decade or more*
- *Some of this work is being supported elsewhere, and I don't believe the "grand goal" is obtainable*

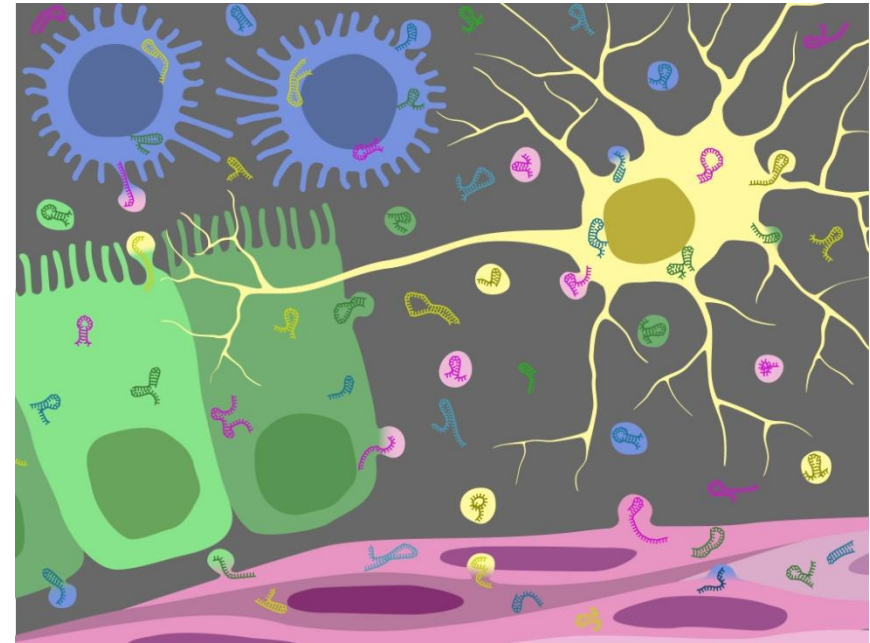


# New FY 2013 Program: Extracellular RNA Communication

*Opportunity to explore new paradigms of intercellular and inter-species communication based on the release, transport, uptake, and regulatory role of exRNAs*

## Current Funding Opportunity Announcements:

- [RFA-RM-12-010](#): Establishment of a central repository for exRNA standards, protocols, and data
- [RFA-RM-12-011](#): Development of reference profiles for healthy human exRNAs in a variety of body fluids
- [RFA-RM-12-012](#): Support of coordinated analyses to define fundamental biological principles of exRNA generation, distribution, uptake, and effector function
- [RFA-RM-12-013](#), [RFA-RM-12-014](#): Investigation of the possible clinical utility of exRNAs as biomarkers and therapeutic delivery vehicles



*RNAs can be exported from cells in extracellular vesicles, or bound to lipids or proteins, to circulate through the body and affect distant cells*

# New FY 2013 program: Undiagnosed Diseases Program

*Opportunity to build on the success of the Intramural Undiagnosed Diseases program to promote the use of next generation genomic sequencing for disease diagnosis in academic medical centers across the country*

## Goals of the Common Fund-supported program:

- Expand UDP to the extramural community through a network of centers, including both NIH (Intramural) and selected Extramural sites
- Training clinical researchers in the use of contemporary genomic approaches in the diagnosis of rare diseases
- Engage basic researchers to elucidate the mechanisms underlying the diseases so that treatments may be identified



# Early Independence Award Update

The ACD has recommended that NIH double the number of EIAs each year. However, do we know whether these awards are successfully promoting independent careers?

## **First Cohort:**

*Site visits in first year of award allow NIH to assess:*

- *Awardees' progress toward establishing a vibrant independent research program*
- *Integration of Awardee into the local institutional community as an independent peer*
- *Whether other issues may have surfaced that need to be addressed.*

*Site visits completed for 9 of the 10 awardees (10th to occur in Sept.). Included interviews with:*

- *Awardee*
- *Department chair and Institutional official (e.g. Dean)*
- *Faculty mentors and faculty colleagues*
- *Lab staff*

*Conclusions:*

- *Awardees have established their labs*
- *Research progress varies. Depends on how much was involved in setting up lab post-award.*
- *Sufficient infrastructure and resources are in place.*
- *No major concerns were noted*

# Early Independence Award Update

**Program evaluation:** *A process evaluation is being conducted in “real time” to provide feedback to incorporate into FOA development and program management.*

*Significant issues and adjustments made to date:*

*Some outstanding applicants have tenure track appointments at the time of application. Since the premise of the program is to enable stellar young scientists to “skip the postdoc,” is an EIA the appropriate award for these applicants?*

- *Applicants are now asked to address suitability of the EIA for their career, and this is considered during review*

*Many applicants seek EIA positions at the same institution where they did their graduate training, raising concern that the position will not actually be independent of the former mentor*

- *Applicants now address rationale for seeking to omit post-doctoral training, evidence of training ability and leadership, and host institution interactions*
- *NIH has established a “matching portal” in effort to facilitate movement of applicants to new environment*
- *NIH has increased outreach to promote the opportunity for applicants to move from the graduate institution and to help with the application process. For example – webinar to be held Sept 10, 2012.*

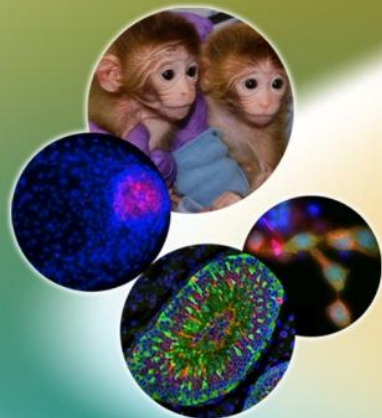
*Applicants and institutions have indicated that the time to apply is insufficient, since institutions have to undergo an internal process to select the top two candidates.*

- *Time between FOA publication and application receipt deadline has been extended from 3.5 months to 6.5 months*

# Office of Research Infrastructure Programs







# Improving Animal Models for Regenerative Medicine

National Institutes of Health, OD  
Office of Research Infrastructure Programs  
Division of Comparative Medicine



**NIH Symposium** • May 23–24, 2012 • Lister Hill Auditorium, NIH Bethesda, MD

For information about this event, please contact [RegenerativeMedicine@lmbps.com](mailto:RegenerativeMedicine@lmbps.com).

## Conclusions and Recommendations

- Standardize large animal stem cell lines and develop reagents and resources (e.g., swine, monkeys, other non-rodents).
- Improve and develop new humanized animal models.
- Further develop species for high throughput screening (e.g., zebrafish).
- Improve imaging technologies (in vivo tracking of stem cells).
- Further develop animal stem cell models to study and address safety concerns (e.g., genetic instability, tumorigenesis, epigenetic memory, immune reactions).

## Outcomes

- Workshop report on the ORIP web site.
- Review submitted for publication in a major journal.
- New DCM Program Announcements for FY13.
- Enhance DCM collaboration with other NIH ICs, Intramural Center for Regenerative Medicine.



## Evolution of Disease Model Resources

### 9th Comparative Medicine Resource Directors Meeting

- **Purpose**
  - Increase collaborations and sharing among DCM-funded Resources
  - Inform Resource and NIH Staff about accomplishments and challenges
  - Identify best practices
  - Highlight new methods for publicizing capabilities, e.g., videos
  - Report progress and conclusions to stake holders via a report on the ORIP web site
- **Attendees**
  - 50 Directors and personnel from 37 DCM-funded Resources from 21 states
  - 32 NIH staff from 13 NIH divisions in 9 ICs and OD
- **A major need: Improved data sharing across Resources and with the research community.**
  - Interactive informatics systems that can be used across Resources
  - Systems for integrating large amounts of genetic data related to disease models
  - Ontologies that work across species, including humans



# Comparative Medicine Brain Storming Meeting

## Next Generation Animal Models Targeting Personalized Disease Phenotypes

- **Rationale**

- Urgent need to improve the predictability of animal models and develop new types of individualized therapies.
- Personalized animal models can be used for discovery, target validation and pre-clinical / co-clinical drug development.

- **Recent advances can form the basis of these investigations.**

- Whole genome and exome sequencing; individual patient “omics.”
- “Personalized” immune mice for autoimmune diseases.
- Specialized mouse cohorts in co-clinical cancer drug trials.
- Microbiome reconstruction for modeling host-metagenome interactions

- **The Meeting: Sept. 6, 2012 in Bethesda**

- 14 invited thought leaders, 10- 12 NIH staff.
- Will form the basis for a larger workshop in 2013 and PAs.



# Questions?