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

Immediate Office of the DPCPSI
Director
James M. Anderson, MD, PhD

Office of Program Evaluation and Performance
Rosanna Ng, M.A.

Office of AIDS Research
Research on Women’s Health
Jack Whitescarver, PhD

Office of Behavioral and Social Sciences Research
Janine Clayton, MD, Acting

Office of Disease Prevention
Paul Coates, PhD, Acting

Office of Strategic Coordination
Betsy Wilder, PhD

Office of Dietary Supplements

New
Office of Research Infrastructure Programs
Franziska Grieder, DVM, Ph.D., Acting

Division of Comparative Medicine
Division of Construction and Instruments
Office of Science Education
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
9th 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:
  o focusing on the science
  o population matches the scientific goals rather than enumeration of research participants
  o simplifying processes
  o enhancing consistency across NIH
  o 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
# Qualified Applicants and Number of Available Spaces for 2012 Summer Training Institutes

<table>
<thead>
<tr>
<th>Topic</th>
<th>Host Institution</th>
<th>Qualified Applicants</th>
<th>Accepted</th>
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<tbody>
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<td>Social and Behavioral Intervention Research</td>
<td>Columbia University</td>
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<td>Institute for Systems Science and Health</td>
<td>Washington University, Saint Louis</td>
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<td>46</td>
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<td>Training Institute for Dissemination and Implementation Research in Health</td>
<td>U.C. San Francisco</td>
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<td>Behavioral Randomized Clinical Trials</td>
<td>Arlie House, Virginia</td>
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<td>mHealth</td>
<td>Northeastern University</td>
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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)
- 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)
- 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

37 unique concepts -> 26 cleared concepts -> 11 program ideas -> 12 program ideas

External Input:
Council of Councils voting and clearance
NIH and DPCPSI Directors;
Small group of IC Directors
Discussion with all IC Directors

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
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.
• **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 stakeholders 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
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?