National Institutes of Health
Council of Councils Planning Meeting
November 8, 2007/Bethesda, MD

8:30-9:00	Welcome
9:00-9:30	Introduction to OPASI
9:30-9:50	History of NIH Reform Act
10:30-11:00	Remarks from the NIH Director

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1:00-2:00	Innovation
2:00-2:50	Initiatives on the Horizon I
3:10-4:00	Initiatives on the Horizon II
4:00-5:00	Next Steps

Brief Introduction to the Reform Act: DPCPSI, Council of Councils and Common Fund

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Alan M. Krensky, M.D., Director
Office of Portfolio Analysis and Strategic Initiatives
National Institutes of Health
Department of Health and Human Services

Key provisions of the NIH Reform Act of 2006

- Establishes a Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI)
- Establishes use of a Common Fund to support trans-NIH research
- Creates a Council of Councils to guide trans-NIH priorities
- Establishes a Scientific Management Review Board (SMRB) to oversee evaluation or organizational structures and authorities that may be used for improvements
- Initiates a public process to review potential organizational changes

"The first omnibus reauthorization of NIH in 14 years"

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

- Authorized to identify Trans-NIH research (through Roadmap process, for example) for support by Common Fund
  - Trans-NIH Research proposals must include milestones and goals for the research activities
  - Appropriate consideration must be given to proposals from first-time NIH investigator applicants
- Must include information on Trans-NIH Research in new Biennial Report
- Moves ODP, ORWH, OAR, and OBSSR within DPCPSI; however, legislation explicitly states that these offices are to retain authorities in effect prior to enactment

Council of Councils

- Advises the NIH Director on matters related to the policies and activities of DPCPSI
- Makes recommendations on the conduct and support of trans-NIH research proposals supported by the Common Fund

Council of Councils Status

- Charter approved by HHS on March 27, 2007
- Federal Register notice published April 9, 2007
- Charter filed with the NIH authorizing committees and Library of Congress on April 11, 2007
- List of nominees and ten alternates forwarded the HHS for approval August 8, 2007
- Planning meeting today: November 8, 2007

Common Fund

- Codifies Common Fund in PHS Act
- No formula for growth established, but cannot drop as a percentage of the NIH Budget
- Common Fund Strategic Planning Report required biennially
- Review required when Common Fund reaches 5% of the NIH Budget

The Office of Portfolio Analysis and Strategic Initiatives (OPASI)

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Office of Portfolio Analysis and Strategic Initiatives
National Institutes of Health
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What is OPASI's Mission?

- To provide NIH Institutes and Centers with the methods, tools, and information necessary to improve management of the large and complex scientific portfolios
- To identify -- in concert with multiple other inputs -- important areas of emerging scientific opportunities or rising public health challenges
- To help accelerate investments in these areas, focusing on those involving multiple Institutes and Centers
- To coordinate and make more effective use of NIH-wide evaluation processes

Structure of OPASI

Develop and use analytic tools and information, like:

- Knowledge management
- Public health need/burden of illness

- Strategic coordination of NIH-wide planning
- Provide an "incubator space" for trans-NIH initiatives
  - NIH Roadmap

Plan, conduct, coordinate, and support program evaluations for:

- ICs
- Trans-NIH initiatives
- GPRA
- PART

OPASI

OPASI STRUCTURE-FUNCTION

The Roadmap and the Common Fund

Roadmap initiatives must demonstrate:

1) High potential to transform how biomedical and/or behavioral research will be conducted
2) Synergistic promotion and advancement of the individual missions of the ICs to benefit health
3) Applicability to issues beyond the scope of any one or small number of ICs
4) Likelihood that no other entity is able or likely to perform the work
5) A public health benefit of having the results of the research in the public domain.

Roadmap Initiatives

- Molecular Libraries
- Building Blocks, Pathways and Networks
- Structural Biology: Membrane Proteins
- Bioinformatics and Computational Biology
- Nanomedicine
- Interdisciplinary Research
- High Risk/High Reward: Pioneers and New Innovators
- Clinical Research-CTSA, Promis
- Public-Private Partnerships

Interdisciplinary Research

Neuropsychiatric Phenomics
Robert Bilder, UCLA

Geroscience
Dale Bredesen, Buck Institute

Neurotherapeutics
Paul Hagerman, UC Davis

Obesity
Jay Horton, UT Southwestern

Organ Design/Engineering
Richard Maas, Brigham & Women's

Genome Engineering
Andrew Scharenberg, U Washington

Drug Discovery
Edward Scolnick, MIT/HMS

Stress, Self Control, and Addiction
Rajita Sinha, Yale

Oncofertility
Teresa Woodruff, Northwestern

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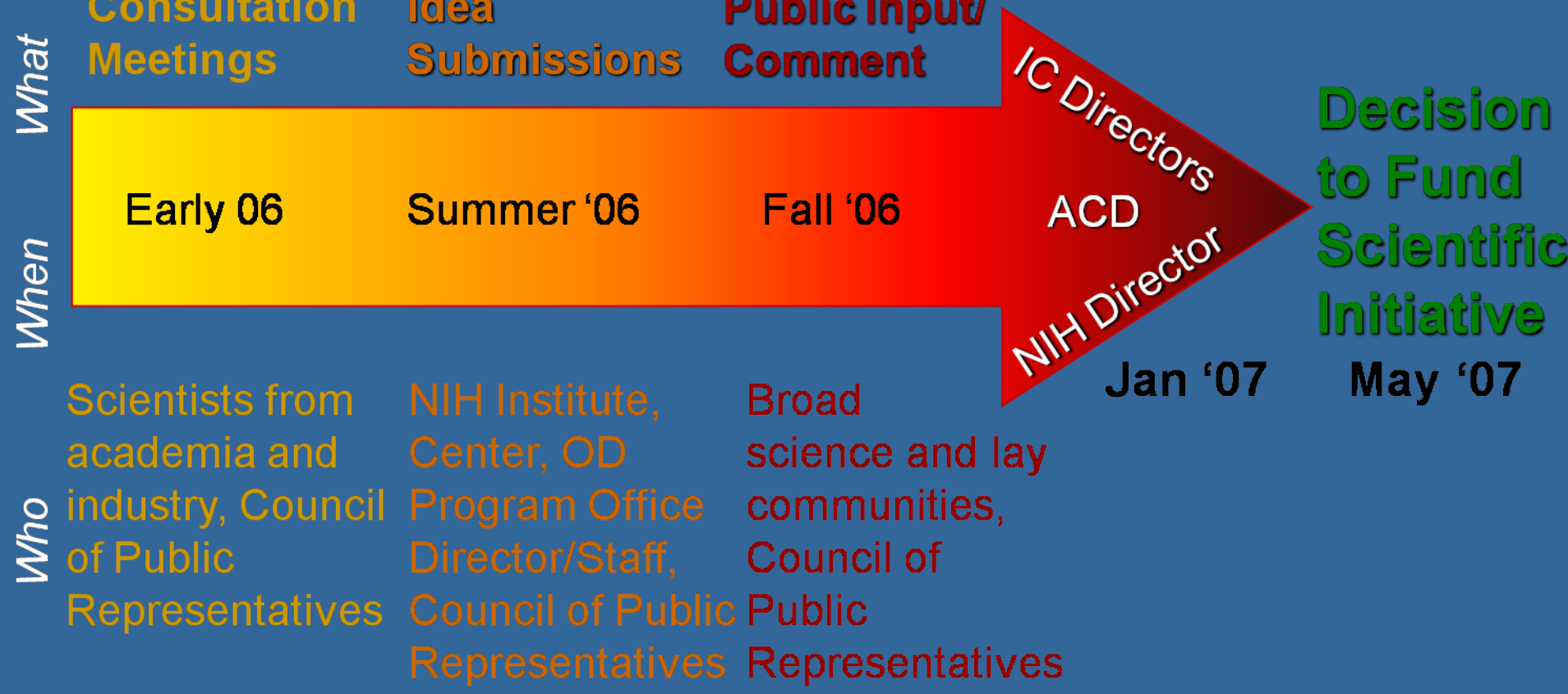
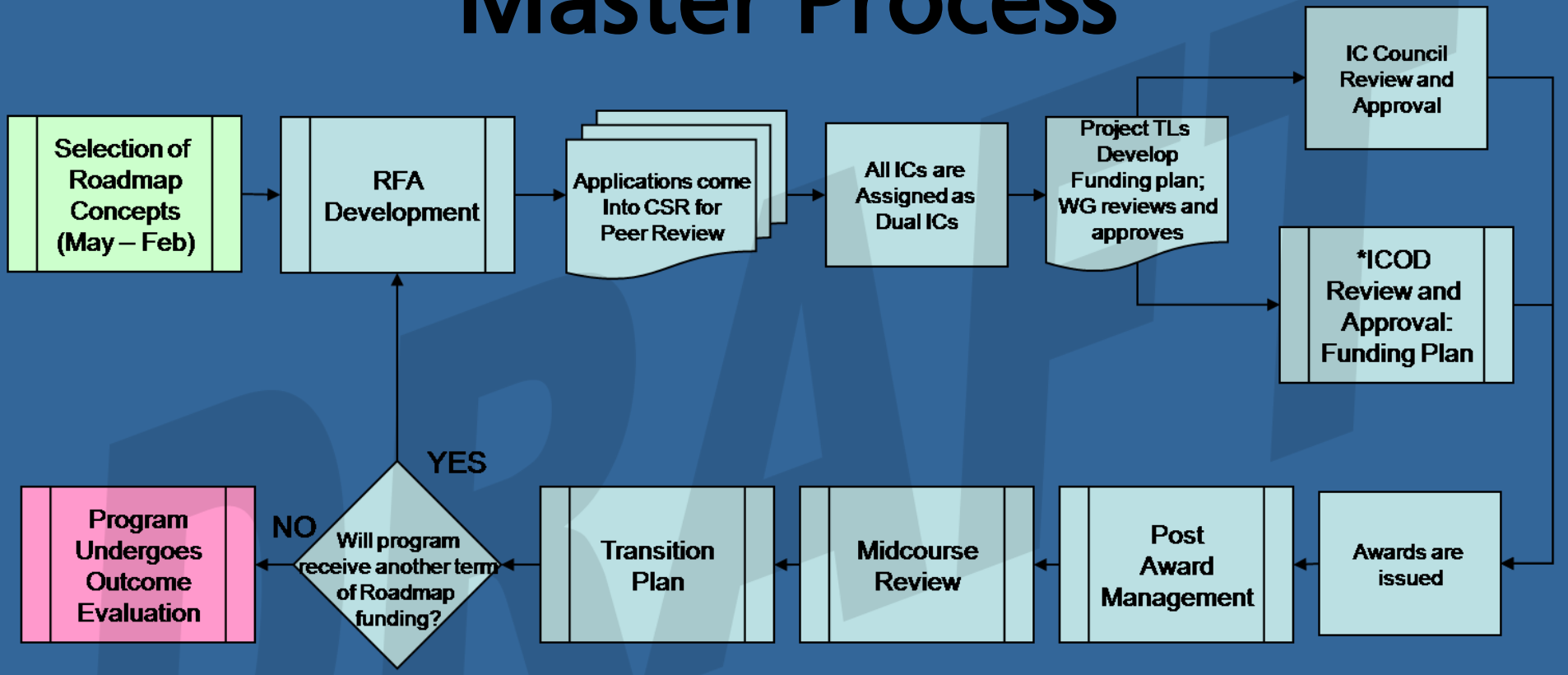
OPASI

How New Initiatives are Chosen

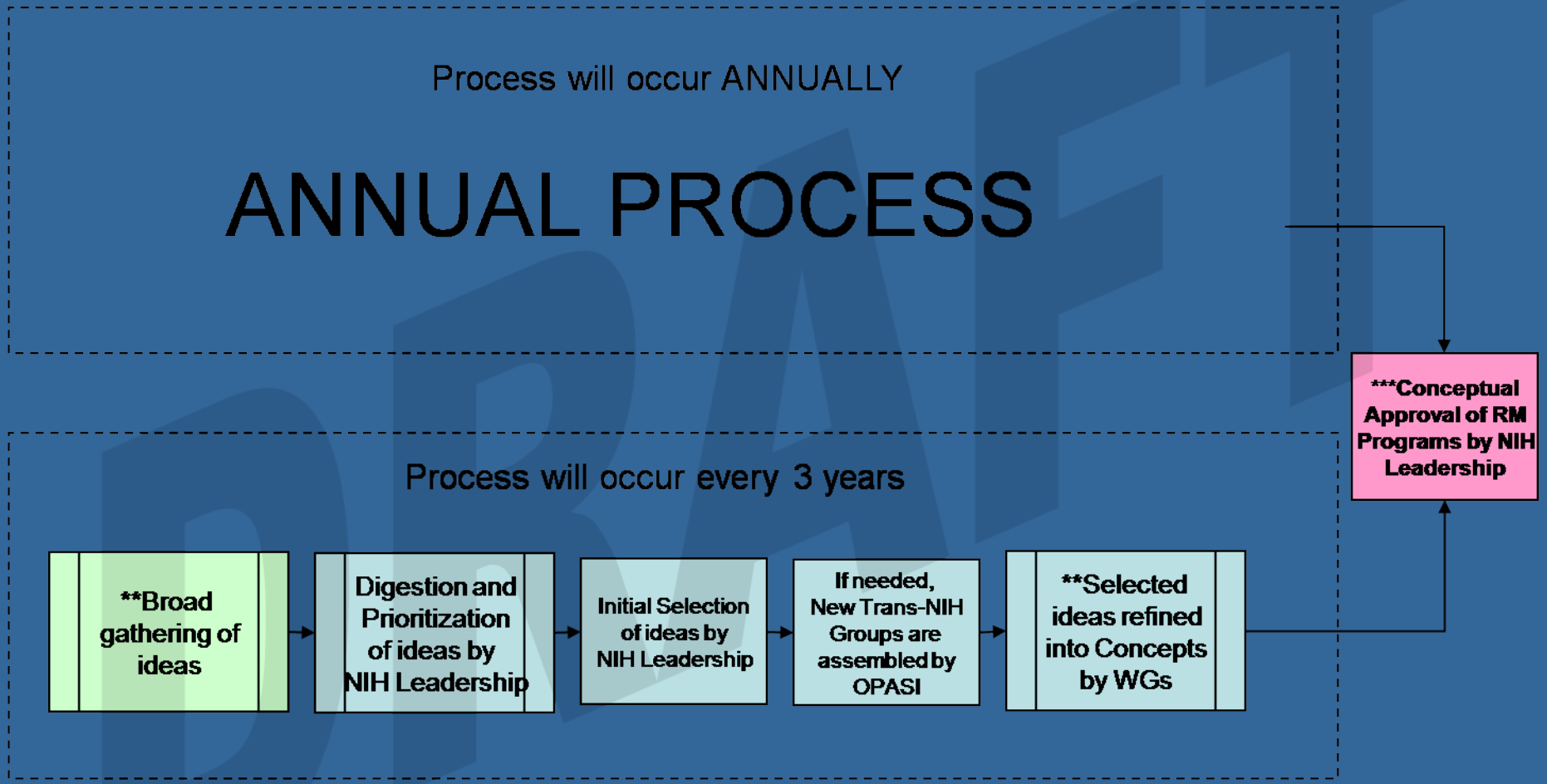


Master Process



Review and Award Cycles	Cycle I	Cycle II	Cycle III
RFA Release	December	April	July
Application Receipt	February - March	June - July	September -October
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Review	September - October	January - February	May - June
Earliest Project Start Date	December	April	July

Selection of Roadmap Concepts



NOTES:

** **Council of Councils feedback will be solicited during these processes.**

*** RFAs for Summer release would go to the following May council for payment, and RFAs for Fall release would go to the following September council for payment in the next fiscal year.

DRAFT

Roadmap Topics Under Discussion

- The microbiome
- Epigenetics
- Protein capture agents and proteomics
- Standardization of human disease phenotypes
- Inflammation as a common mechanism of disease

Beyond the Roadmap: Trans-NIH Coordination

- Obesity
- Neuroscience Blueprint
- Regenerative Medicine
- Informatics
- Pharmacogenomics
- Health Disparities

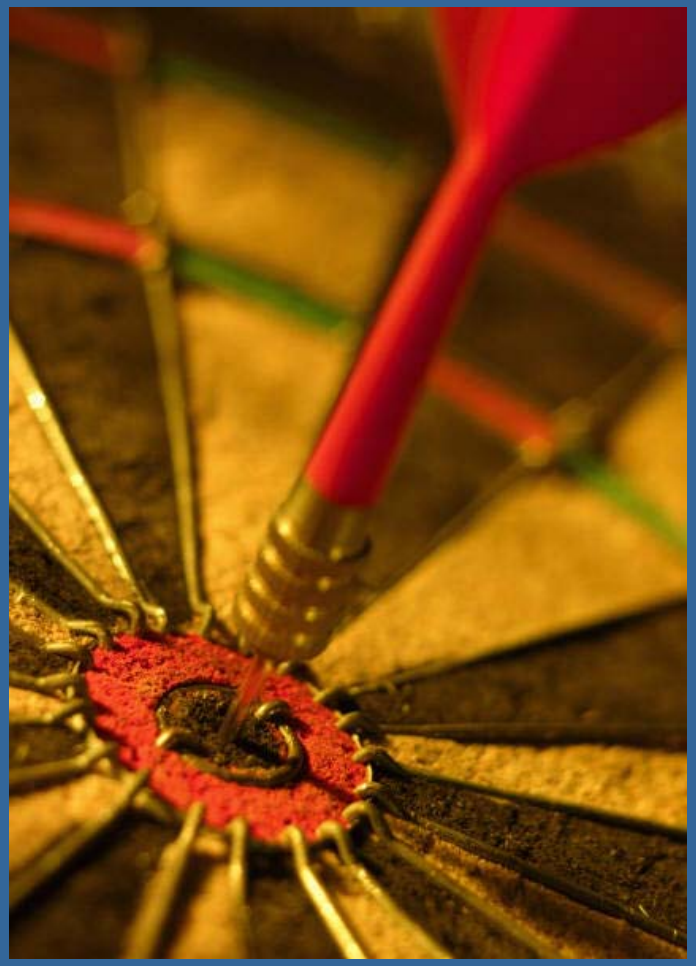
How Will OPASI Likely Affect Transdisciplinary Research?

- Roadmap initiatives, by nature, are more likely to cross disciplinary and organization boundaries
- Larger, infrastructure-type Roadmap projects will be open to access from multiple disciplines and research areas
- Portfolio analysis tools will promote broader understanding of the complete NIH investment portfolio and promote connections across disciplines, institutes/centers, disease research topics

Factors for Success

- Science First
- Planning based on evidence
- Maintaining transparency
- Communicating plans
- Managing change

In the end, the success of OPASI will be measured in its ability to fill gaps, alleviate redundancies and add value to strategic planning and the portfolio of the largest biomedical research institution in the world.

Discussion

1. What areas will most benefit from a “trans” approach?
2. Where are there economies of scale, opportunities, needs?
3. What are the boundaries?