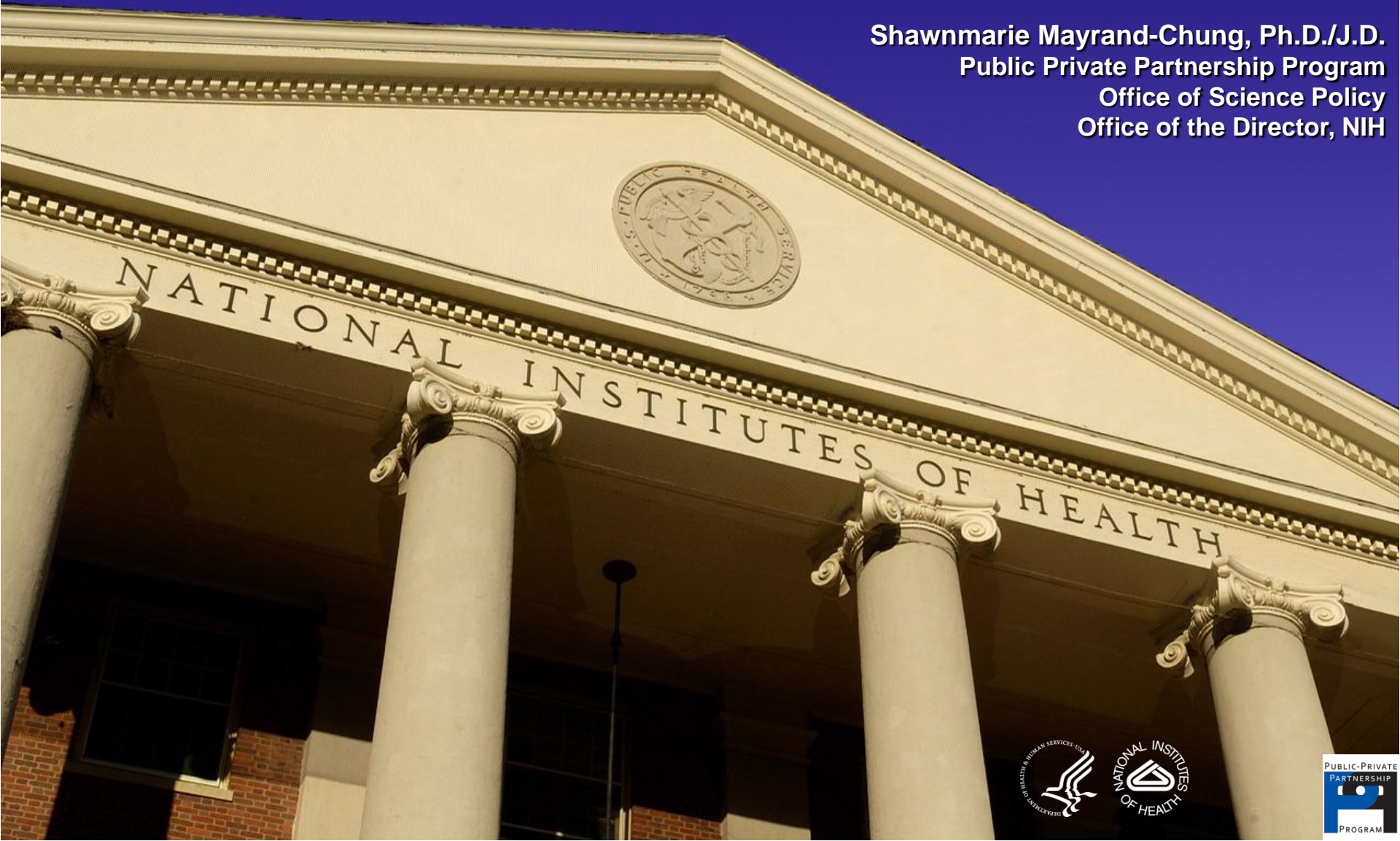


# Fostering Public-Private Partnerships

Shawnmarie Mayrand-Chung, Ph.D./J.D.  
Public Private Partnership Program  
Office of Science Policy  
Office of the Director, NIH



# *Partnering with the NIH*

**Partnerships  
must be  
“mission-consistent”**

- **Have a research focus**
  - **Be science-driven**
- **Aimed at improving public health**

# Why Partner?

Partnerships represent one more means for NIH to accomplish its mission – *by leveraging resources*

- Is not selling out
  - Scientific rigor and IC priorities always govern NIH choices of partnership activities
  - We can't ever delegate Federal authority
  - Resource limitations always conspire to leave some good science without NIH support
  - Opting out or refusing partnership opportunities happens
- Does not replace our appropriation
  - New resources (financial and other) allow us to do what we could not do otherwise
  - Permit novel synergies
  - Permit new efficiencies
  - Embrace common goals by working together

# PPPs for Synergy and the Public Health

**FDA**

Enhance regulatory decision making

**NIH  
ACADEMIA**

Opportunities presented by science

**PARTNERING  
FOR THE  
PUBLIC HEALTH**

Improve patient care

Expedite drug development process

**PUBLIC**

**INDUSTRY**

# Public-Private Partnership Program

- Began in 2005 as outgrowth of NIH Roadmap
- Located within the Office of Science Policy/OD
  - Since, the PPP program is not relevant to a single IC, rather is relevant to all 27 ICs
- Trans-NIH in scope and ambit
  - Single IC PPPs, multiple IC PPPs
- Focus is on policy & practicality of PPPs
- Serves as a point of entry for potential outside partners
- Both pro-active and re-active in the Approaches to PPPs development

# Partnerships: NIH Contributions

- Discovery science and scientists
- Technical development of tests, assays and diagnostics
- Clinical Trials
- Development of databases, biobanks and repositories
- Application in clinical research and practice
- Scientific Review

# Partnerships: Partner Contributions

- Intellectual Input
- Scientific Perspective
- Resources (for example):
  - Patient recruitment
  - Data
  - Samples
  - Analytical techniques and platforms
  - Reagents
  - Financial contributions

# With whom can we partner?

Just about anyone, IF . . .

- Science driven
- Rigorous
- Fair
- Inclusive
- Compliant with Federal law, regulation and policy
- Priority to the agency



# Who are our Partners?

Other Federal Agencies (“*public-public*” partnerships)

Public & Patient Advocates

Professional Societies

Industry

## How to Partner with NIH?

Alignment of missions & goals relatively easy

Alignment of cultures is not so easy

- Different timelines and concepts of time
- Different internal processes & decision points
- Different vocabularies
- Challenging specifics . . .

*Devil is in the details!*

# What “details” challenge us?

Intellectual Property

Data Sharing & Publication

Transparency of Process

Inclusiveness & Fairness of Access

Conflict of Interest

**Working out the details is a project specific process, i.e. *“custom tailoring for the science and the partners”***

# *Steps in Partnership Development*

- Identify a scientific or clinical problem better answered in partnership than alone
- Consider partnership options
- Discuss how to structure the relationships to optimize the science
- Memorialize the PPP goals and structure in a MOU and clear it appropriately

# *Steps in Partnership Development*

- Identify a scientific or clinical problem better answered in partnership than alone
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# Consider Partnership Options

Partnerships can . . .

Be established as a whole (NIH) *or*  
Be established through one or more IC  
*and*  
one or more outside entities

***NIH-managed***

*Be established directly between the NIH*

***FNIH-managed***

*Be developed via the Foundation for NIH (FNIH)*

# Foundation for the NIH

- Established by Congress in 1990
- Charter is to support the mission of the NIH
- 501c(3) charitable foundation
- Non-governmental
  - Therefore they can solicit contributions
  - They can award grants and contracts
- Close relations with NIH
- NIH Director and FDA Commissioner are members of the FNIH Executive Board

# Steps in Partnership Development

- Identify a scientific or clinical problem better answered in partnership than alone
- Consider partnership options — Partnerships can:
  - *Be established directly between the NIH*
  - *Be developed via the Foundation for NIH (FNIH)*
- Discuss how to structure the relationships to optimize the science
- Memorialize the PPP goals and structure in a MOU and clear it appropriately

# What do we consider in deciding how to structure a partnership?

- Where does the funding come from?
- What will the products of the partnership be?
  - What needs to happen to them? (examples: data, samples, images as shared public resources)
- Is new IP expected to be developed via the partnerships?
  - Who needs to have rights to the IP?
- Is there a need to, e.g., leverage NIH review or grants management?



# What does it mean to partner?

## Equal vs. Unequal Partners

### Ask:

- Who makes decisions?
- Who gets the products and profits from the activity?
- Who does the work?

# Steps in Partnership Development

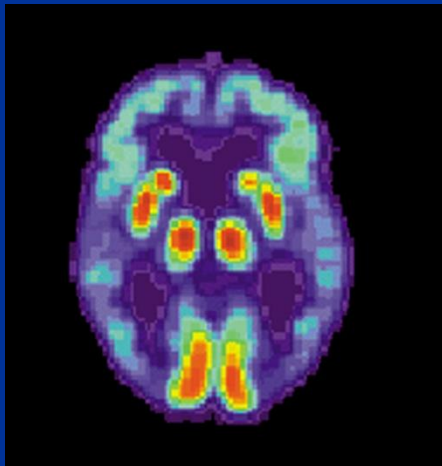
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# Why Should NIH Partner?

- NIH as a partner supports rigorous science
- NIH as a partner can ensure the highest standards of practice, scientific impartiality, fairness, inclusiveness
- NIH as a partner can promote the generation of public resources
- NIH as a partner promotes translation of discovery to benefits in public health

# *Ongoing PPPs: examples*

## **Osteoarthritis Initiative**



## **Alzheimer Disease Neuroimaging Initiative**

# *Ongoing PPPs: examples*



THE  
**biomarkers**  
CONSORTIUM

# The NIH PPP can help . . .

IDENTIFY potential or additional partners.

DECIDE whether to establish your partnership directly or to approach the FNIH or another foundation.

ARTICULATE the structure and policies of a PPP.

DEFINE approaches and coordinate consultations with the FNIH, or other foundations, the OGC, the Office of Technology Transfer, and other relevant resources.

EVALUATE potential or actual conflicts of interest or mission in a partnership.

# NIH PPP Program

[www.ppp.od.nih.gov](http://www.ppp.od.nih.gov)

Dr. Shawnmarie Mayrand-Chung

mayrands@[od.nih.gov](mailto:mayrands@od.nih.gov)

301-443-YPPP (9777)