

# Partnering with the Government: the NIH perspective



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# Science at the NIH includes:

- **Biology and pathobiology,**
  - Basic ← Translational → Clinical
- **Chemistry, biochemistry, structural biology**
- **Physics, biophysics, imaging physics, radiation physics**
- **Informatics, bioinformatics, computational biology, *in silico* modeling**
- **Regenerative medicine, medical device development, prosthetics, biomaterials science**

# NIH Program

- **Intramural Science**

- **Scientists**
- **Labs**
- **Care facilities**
- **Clinical Center**

- **Extramural Science**

- **Grants and Contracts**
- **SBIR/STTR**
- **Program Staff**

# Public-Private Partnerships

- Partnerships cover the arena not covered by:
  - Scientist to scientist collaborations
  - Tech Transfer Arrangements
- Memorialized in MOUs
- No prearrangements with respect to IP that might be generated

# PPP Program

- Located in the NIH OD
  - Relevant not to a single IC, relevant to *ALL* ICs
- Trans-NIH in scope and ambit
  - Single IC PPPs, multiple IC PPPs
- Focus = policy and practicality
- Pro-active and Re-active
- NO requirement for IC to engage in PPPs
  - No requirement for IC PPPs to involve PPP Program
  - Resource, not new reporting obligation

# Why would the government want to partner?

- **Complementing and leveraging Federal resources**
  - We cannot do it all alone
- **Synergy**
  - What we can do better together
- **New opportunities**
  - Agility and speed

*To accomplish our mission better, faster, more efficiently, more effectively....*



# NIH Authorities

- **How we can spend money:**
  - **Procurement**
  - **Hiring**
  
  - **Grants**
  - **Contracts**

# NIH contribution to PPPs

- Commitment to the public health
- Really smart people
  - Intramural scientists
  - Extramural program staff
- Scientific capacity, e.g.,
  - Reagents
  - Analytical capabilities
  - Technologies
- Clinical capacity
  - Clinical Center
- Informatics infrastructure
  - Databasing
  - Computation



# With whom can we partner? Mission consistent...

- **Just about anyone, IF....**
  - **Science driven**
  - **Rigorous**
  - **Fair**
  - **Inclusive**
  - **Transparent**
  - **Compliant with Federal law, regulation and policy**
  - **Priority to the agency**
    - **Sometimes we say no (!), even to excellent opportunities**

# Requirements for Success:

- Trust among the partners
  - *The best agreements and policies will be insufficient if trust is missing!*
- Ability to work out HOW to work together
  - *This is on a more basic interpersonal level than that which any agreements cover....*
- Determination to make the partnership succeed
  - *Provides the motivation to do what is hard....*

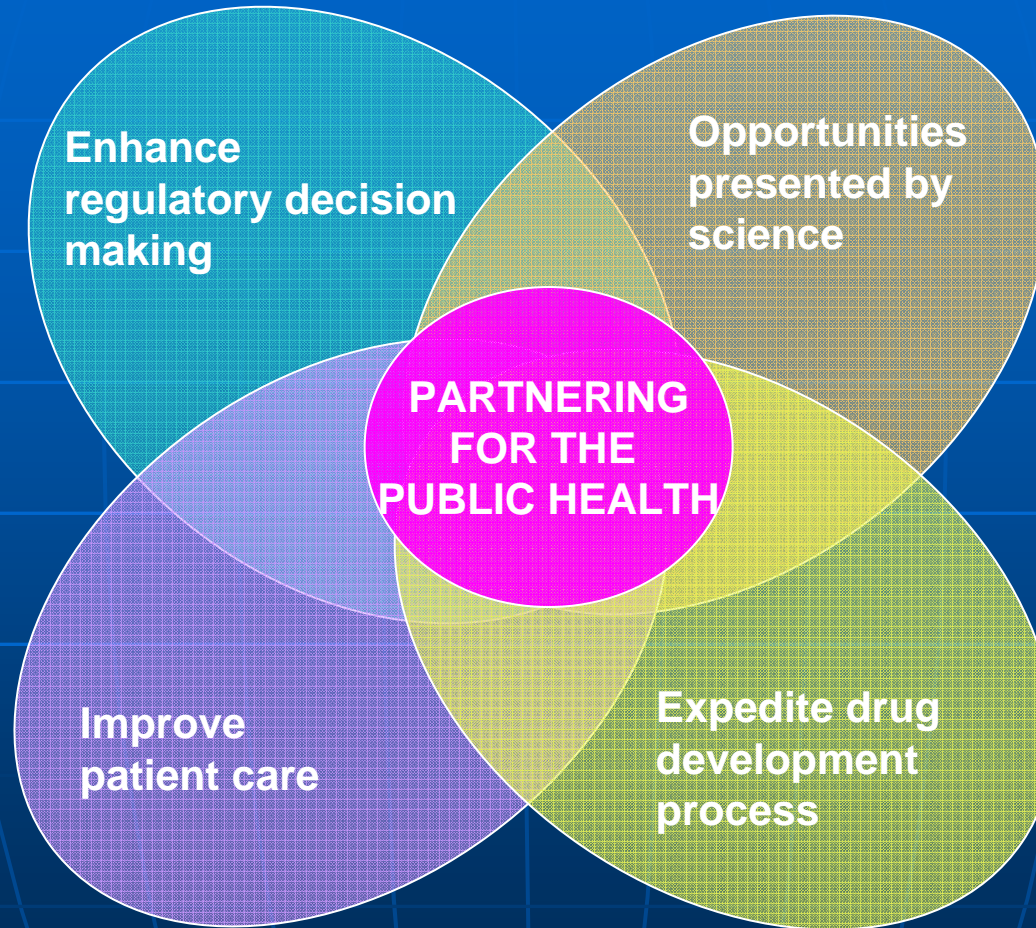
# Requirements for Success: nuts and bolts

- Need to arrive at shared and acceptable business practices for each partnership
  - Shared goals and objectives
    - Understanding how partners are similar and how partners differ from one another
  - Shared understanding of the task and requirements
    - Required anew for each partnership
  - Establishment of a common culture
    - “buy-in” from all participants
  - Communication
    - Critical, as are good problem solving skills

# PPPs for Synergy and the Public Health

FDA

NIH



PUBLIC

INDUSTRY

*More petals on the diagram can represent more interests...*

# Be aware that....

- **Delegation of Federal Authority**
  - Can't do it- it is illegal!
- **Bayh-Dole Act**
  - Governs IP rights to federally funded inventions
- **Federal Advisory Committee Act**
  - We can only take 'ADVICE' via statutory advisory committee
- **Grants and Contracts policy and regulations**
  - Cannot be contravened

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

- Where does the funding come from and where does it go?
  - likewise, resources of other sorts
- 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?

# Important Link

## NIH PPP Program

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

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