Understanding NIH:
Drinking from the Fire-hose

Rosemarie Hunziker, PhD
Tissue Engineering/Regenerative Medicine Program Director
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institutes of Health (NIH)

hunzikerr@mail.nih.gov
301-451-1609

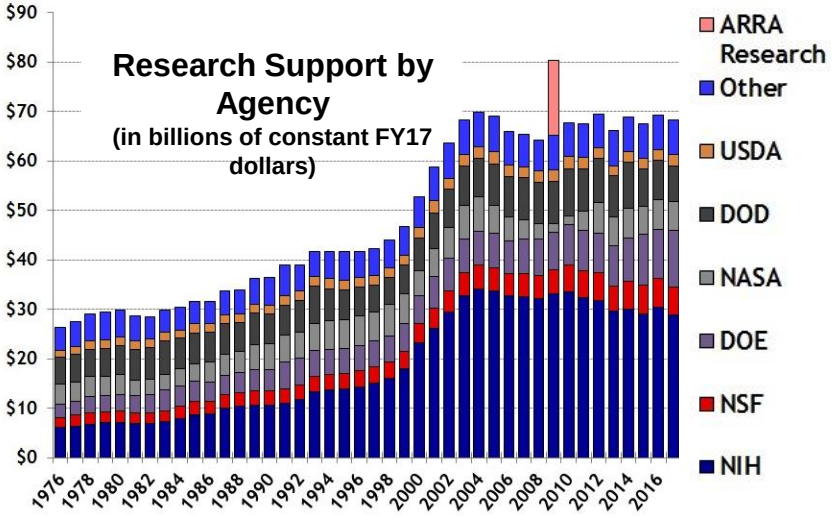
Know Your Target

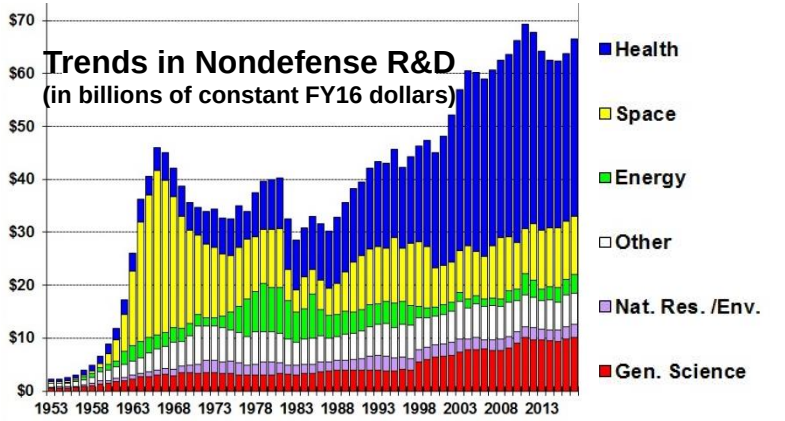
Federal Agencies in Science and Technology have different

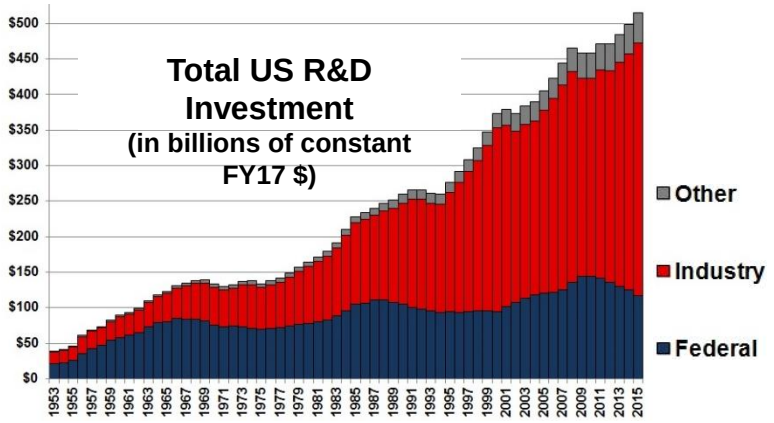
- ✓ missions
- ✓ cultures
- ✓ rules
- ✓ levels of support
- ✓ expectations

But the same overall goal

- ✓ protect the security, health, and well being of Americans
- ✓ maintain knowledge and application superiority
- ✓ fuel the engine of US economic growth

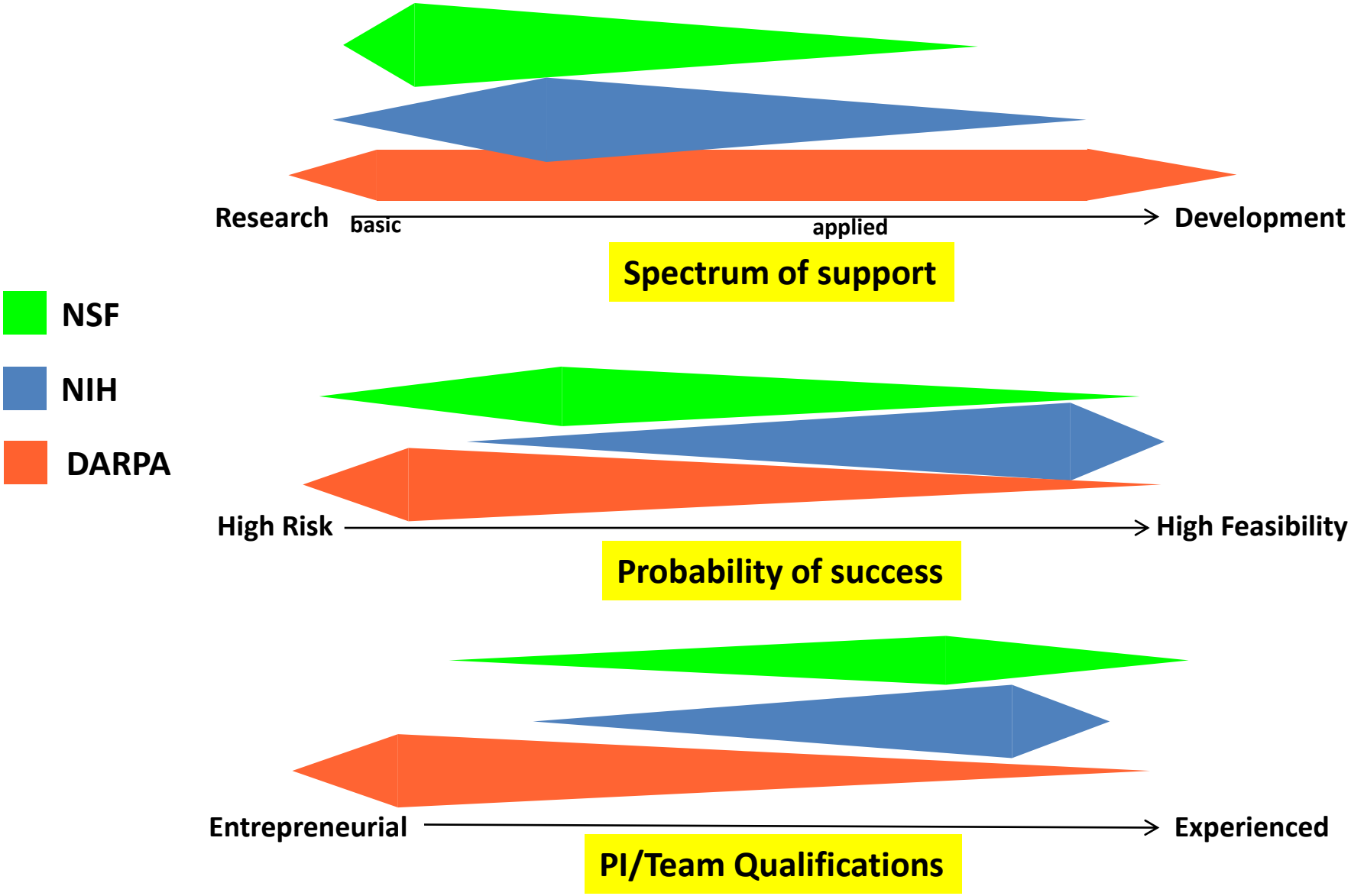






Source: AAAS http://www.aaas.org/page/historical-trends-federal-rd

Different Agencies: Different Cultures

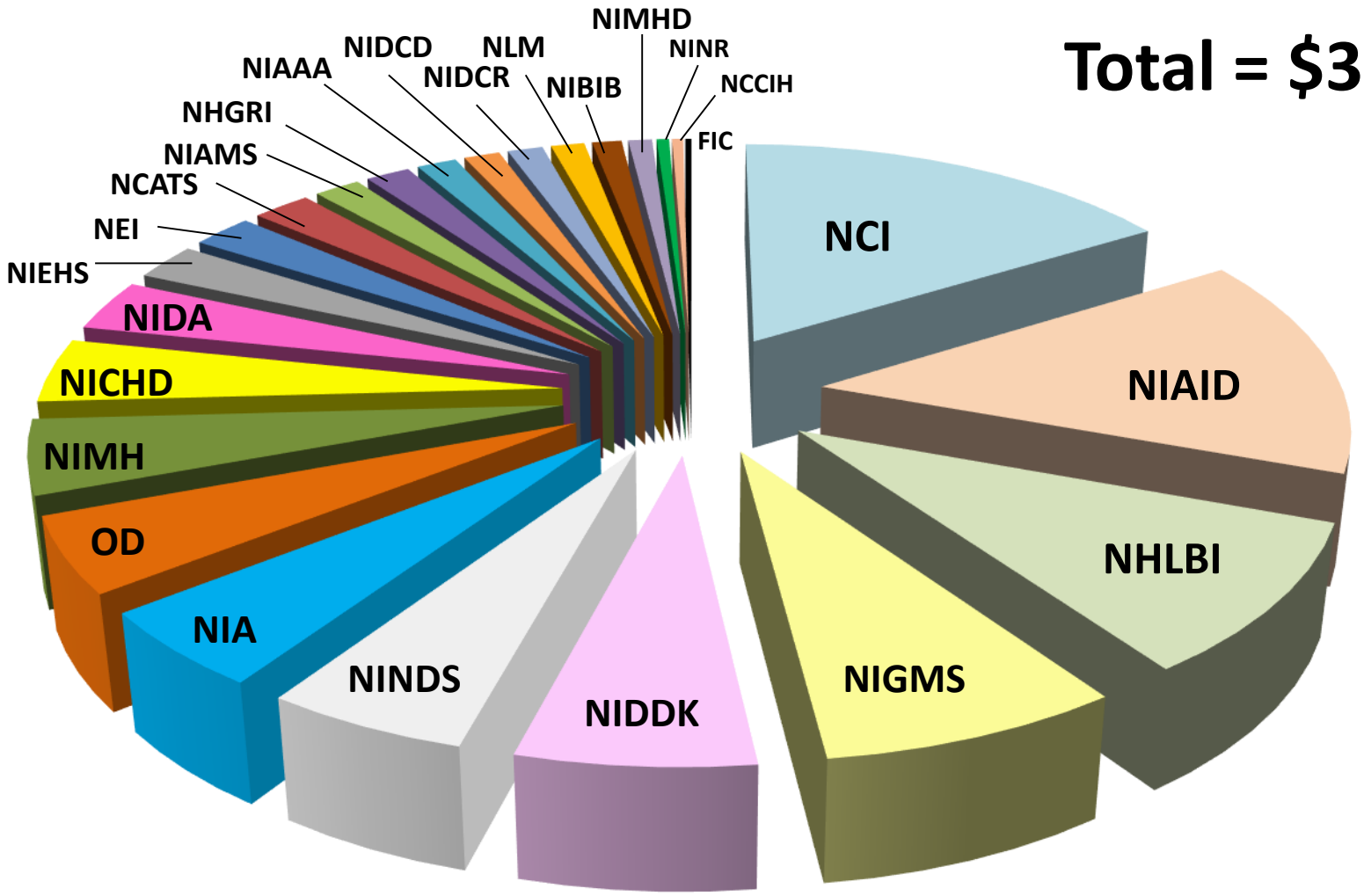


NIH is the steward of **medical and behavioral research** for the Nation.

Its mission is to seek **fundamental knowledge** about the nature and behavior of living systems **and to apply that knowledge** to enhance human health, lengthen life, and reduce illness and disability.

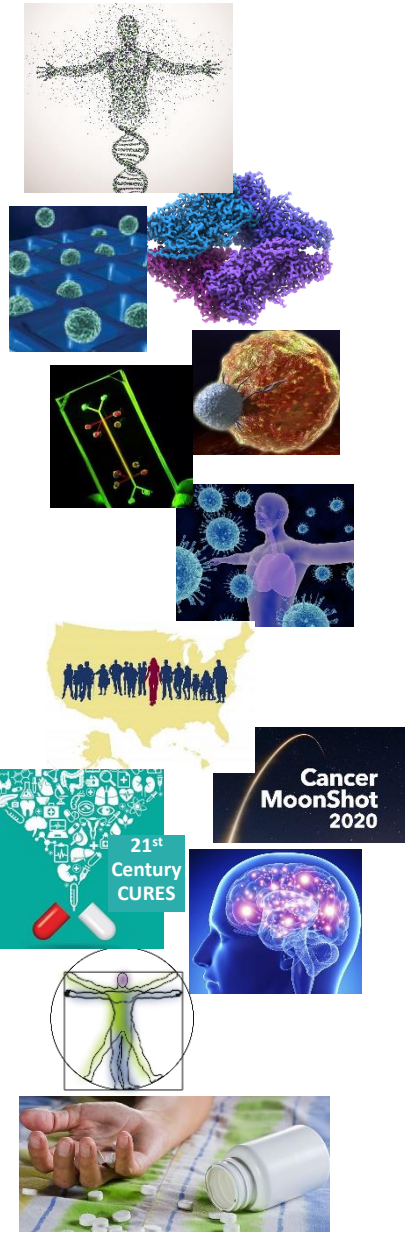
NIH FY17 Budget

NIH Divides most of its investment according to the interests of the component parts (i.e. Institutes or Centers), with 5% allocated to trans-NIH initiatives.



About 85% distributed via Extramural grants, contracts, cooperative agreements

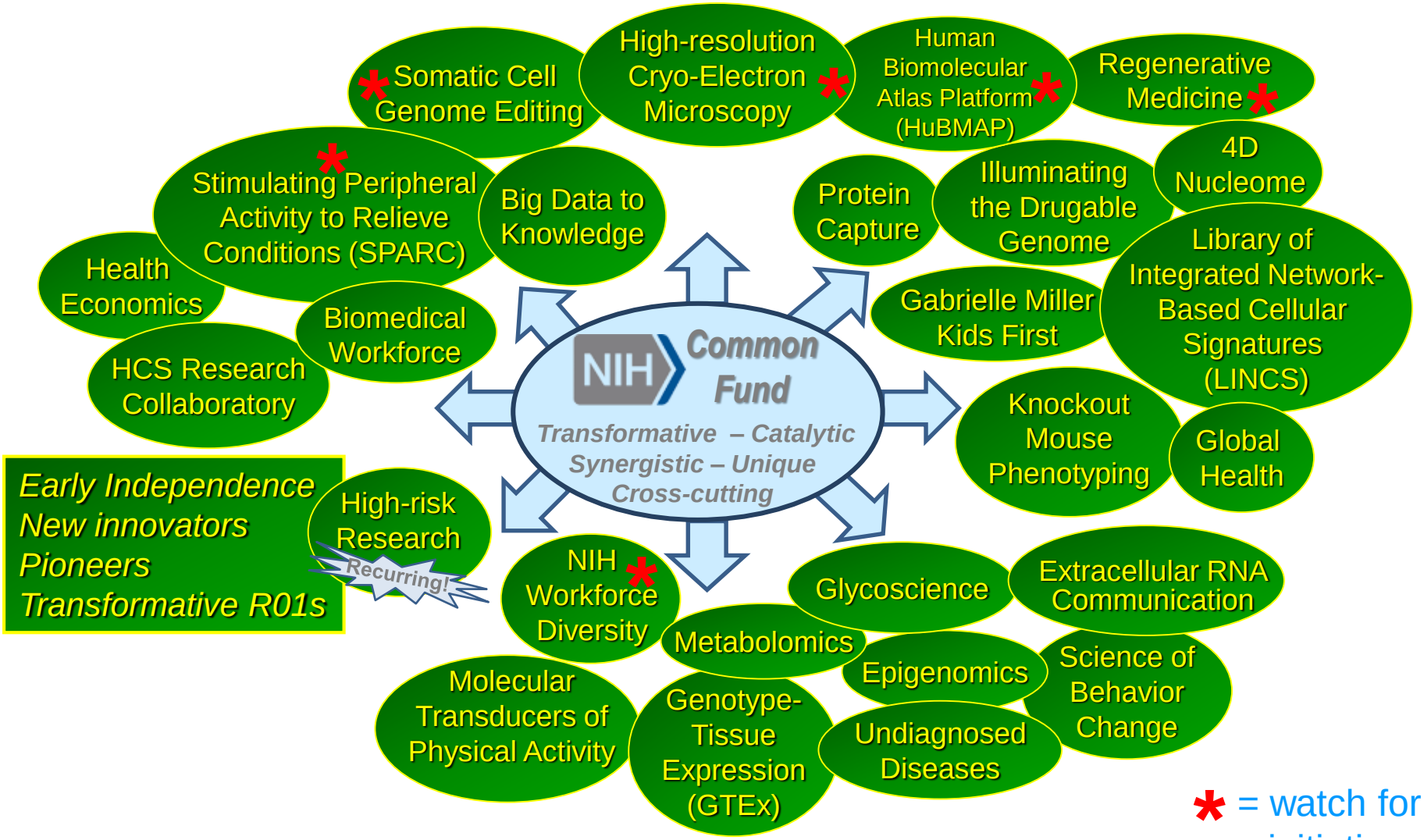
NIH "hot topics"



- **Essential Building Blocks of Research**
  - **Mechanisms of biology and behavior, data science, new technologies**
    - Cryo-Electron Microscopy
    - Single cell analysis
  - **Developing Effective Treatments and Cures**
    - Cancer Immunotherapy
    - Tissue Chips
  - **Health Promotion and Disease Prevention**
    - Vaccines (e.g. influenza)
- **Implementing 21st Century Cures Act**
  - **Precision Medicine Initiative (All of Us)**
    - Integrating clinical, environmental, lifestyle, genetic data over time
    - Individual variability effects on disease onset, progression, prevention, treatment
    - Health records of a million volunteers
  - **BRAIN Initiative**
    - Fundamental science
    - Neuroimaging and mapping
  - **Cancer Moonshot**
    - Prevention and early detection
    - Immunotherapy
    - Pediatric cancer
    - Data sharing
  - **Regenerative Medicine**
    - Clinical research focus
    - Adult stem cells
    - Regulatory science (w/ FDA)
- **Battling Opioid Addiction**
  - New treatments for pain
  - Understanding and managing drug misuse

Source: https://www.hhs.gov/about/budget/fy2018/budget-in-brief/nih/index.html

Trans-NIH Programs



* = watch for new initiatives

http://commonfund.nih.gov/

How Does NIH Solicit Applications?

- **Federal Opportunity Announcements (FOA) published through**
  - the NIH Guide (http://grants.nih.gov/grants/guide/)
  - grants.gov

- **Parent Announcements cover basic activity codes**
  - investigator-initiated applications, spanning NIH mission

- **Special Opportunities to fill gaps**
  - Requests for Applications (RFA), a one-time call with set aside funds
  - Program Announcement (PA) highlights areas of focus
  - Program Announcement with Special Review (PAR) for special consideration and/or "protected" review
  - Program Announcement with Set Aside (PAS) essentially, an RFA with multiple receipt dates

Grant Submissions: Recent Changes

Rigor, Reproducibility, Transparency

- Scientific premise now a scorable criteria; must be justified by data
- Data processing must include statistical analysis (where applicable)
- Relevant biological variables (sex, age, etc.) must be considered in experimental design

IC Participation in R21(and R03) FOAs

- Read the Solicitation! Some ICs do not use these mechanisms
- Some ICs have their own basic versions, or use these mechanisms only for specific topics
- Amount, type of PRELIMINARY DATA a key consideration for R21

Human Subjects

- Inclusion Tables now required for all non-exempt human subjects research
- NIH defines a CLINICAL TRIAL very broadly (answer the four questions)
- FOAs recently subdivided into three types, based on clinical trials (not allowed, optional, required). Be sure to use the correct template!
- Clinical trials funded by NIH grants must be registered at ClinicalTrials.gov and report findings

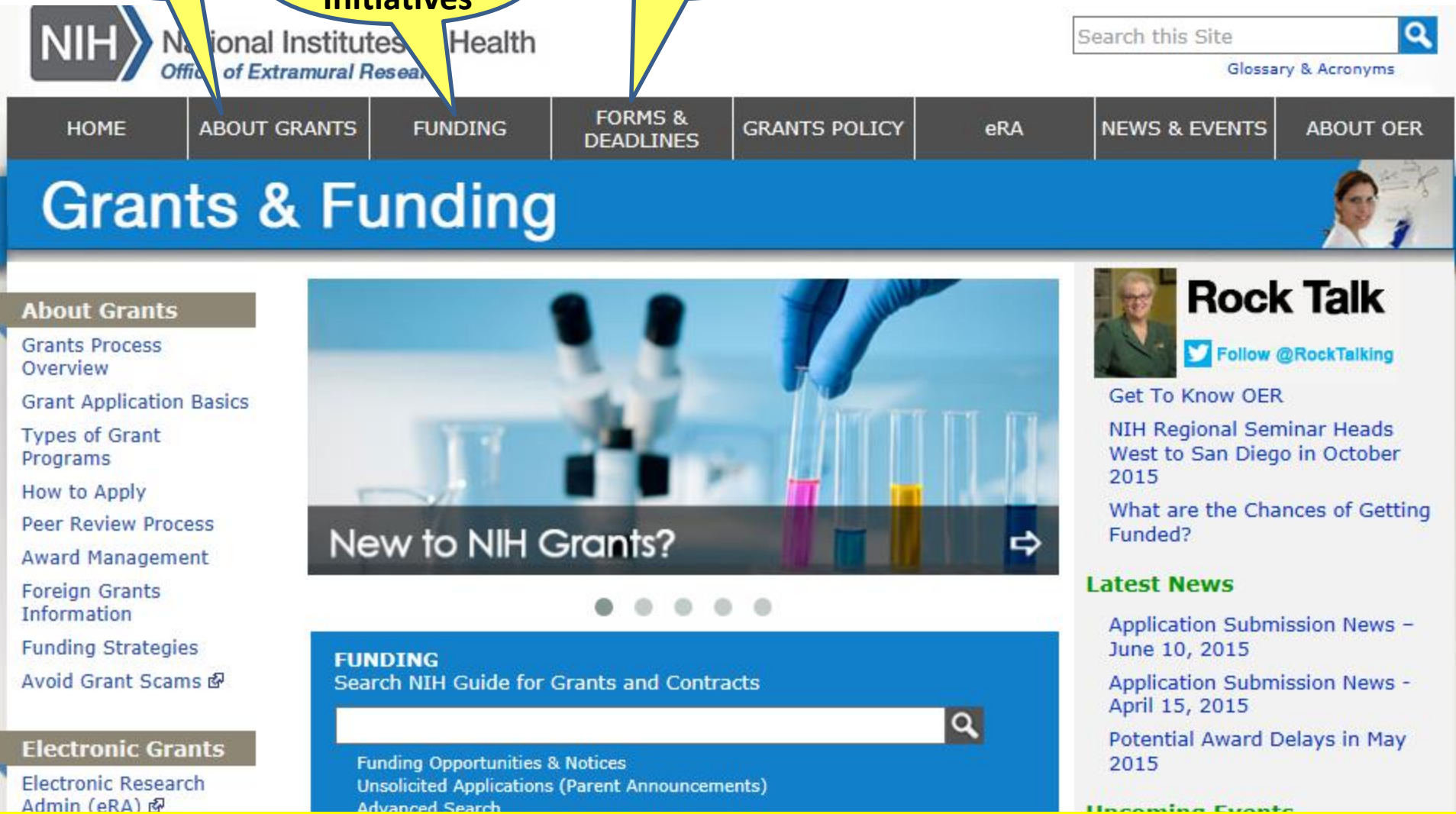
NIH now using "Forms E" for application submission!

Grants: A to Z

Grant Basics

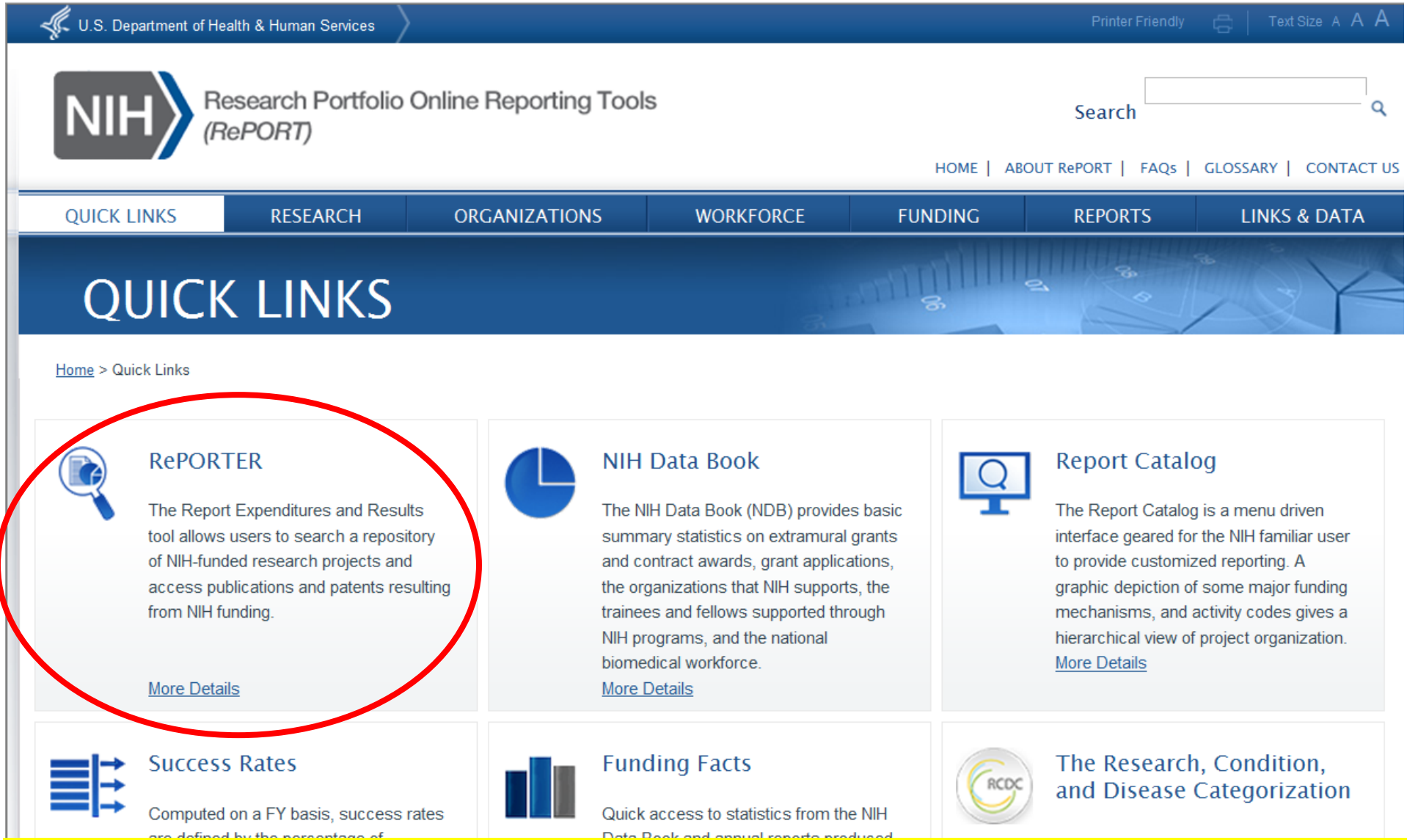
Funding Initiatives

Due Dates, Templates



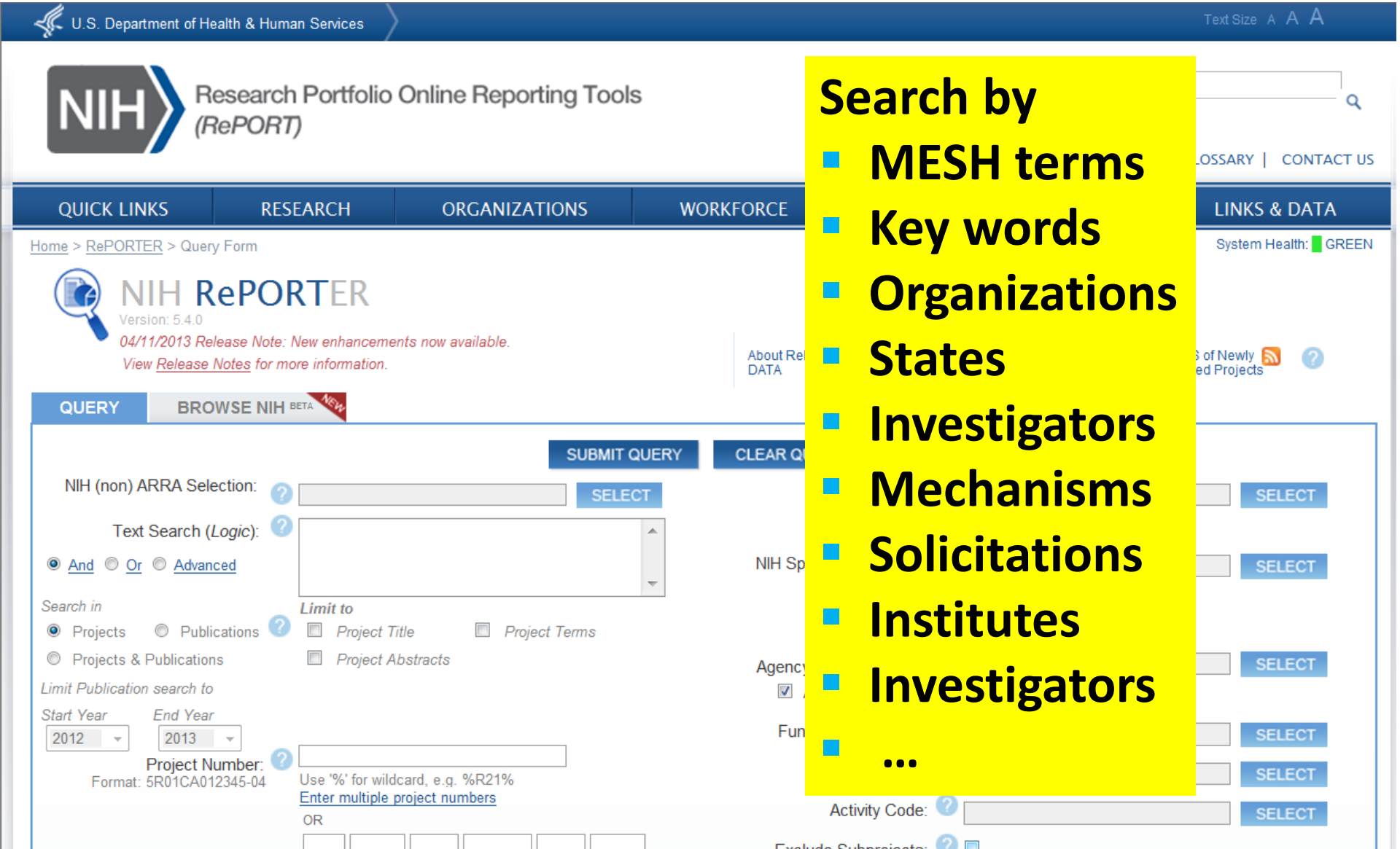
http://grants.nih.gov/grants/oer.htm

Does NIH Already Support My Interest Area?



http://report.nih.gov/quicklinks.aspx

NIH Searchable Databases Contain Abstracts of All Funded Projects



RePORTer Delivers a Treasure Trove…

There were **10** results matching your search criteria. Show/Hide Search Criteria

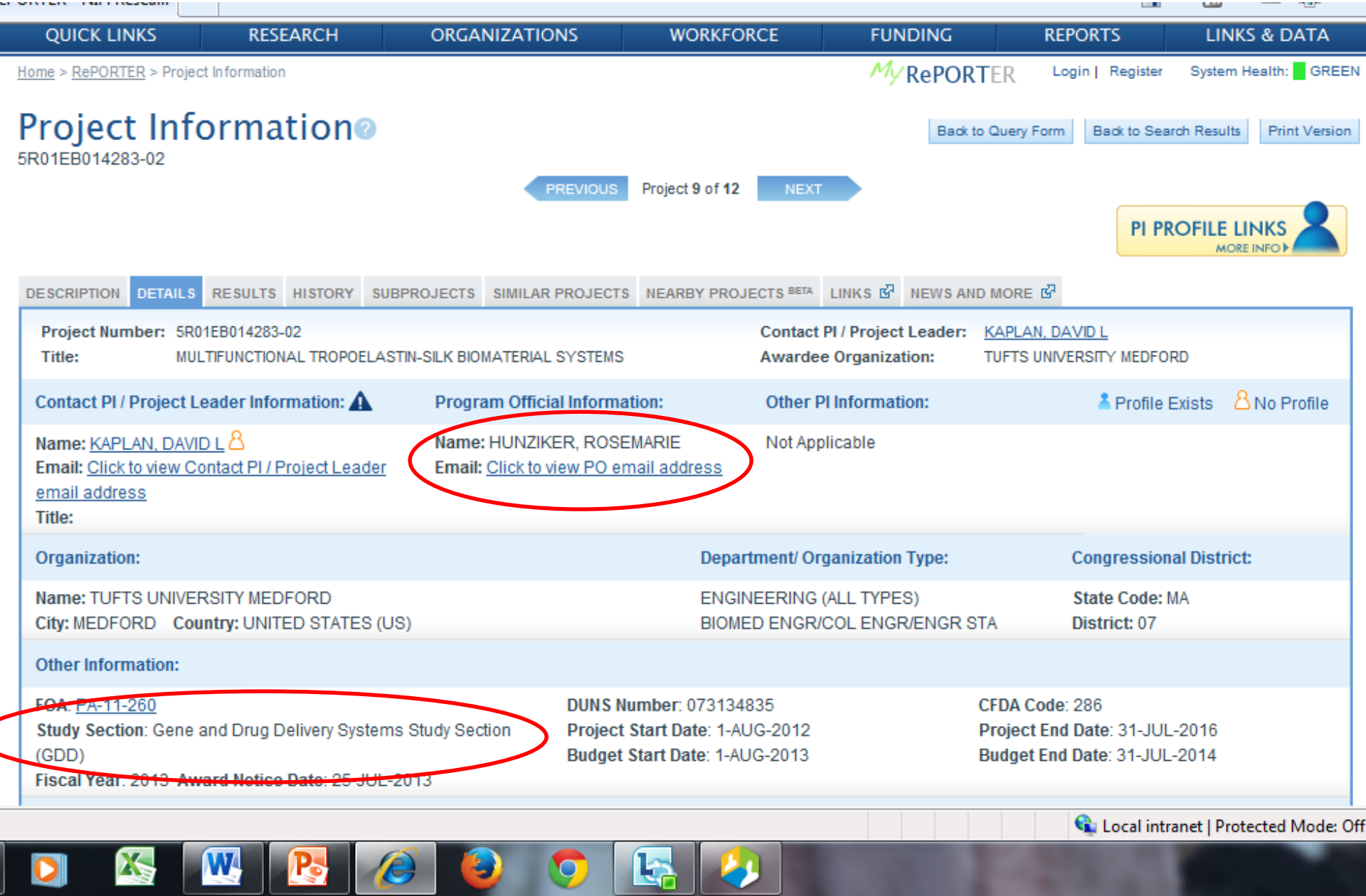
Click on the column header to sort the results

T: Application Type; Act: Activity Code; Project: Admin IC,Serial No.; Year: Support Year/Supplement/Amendment

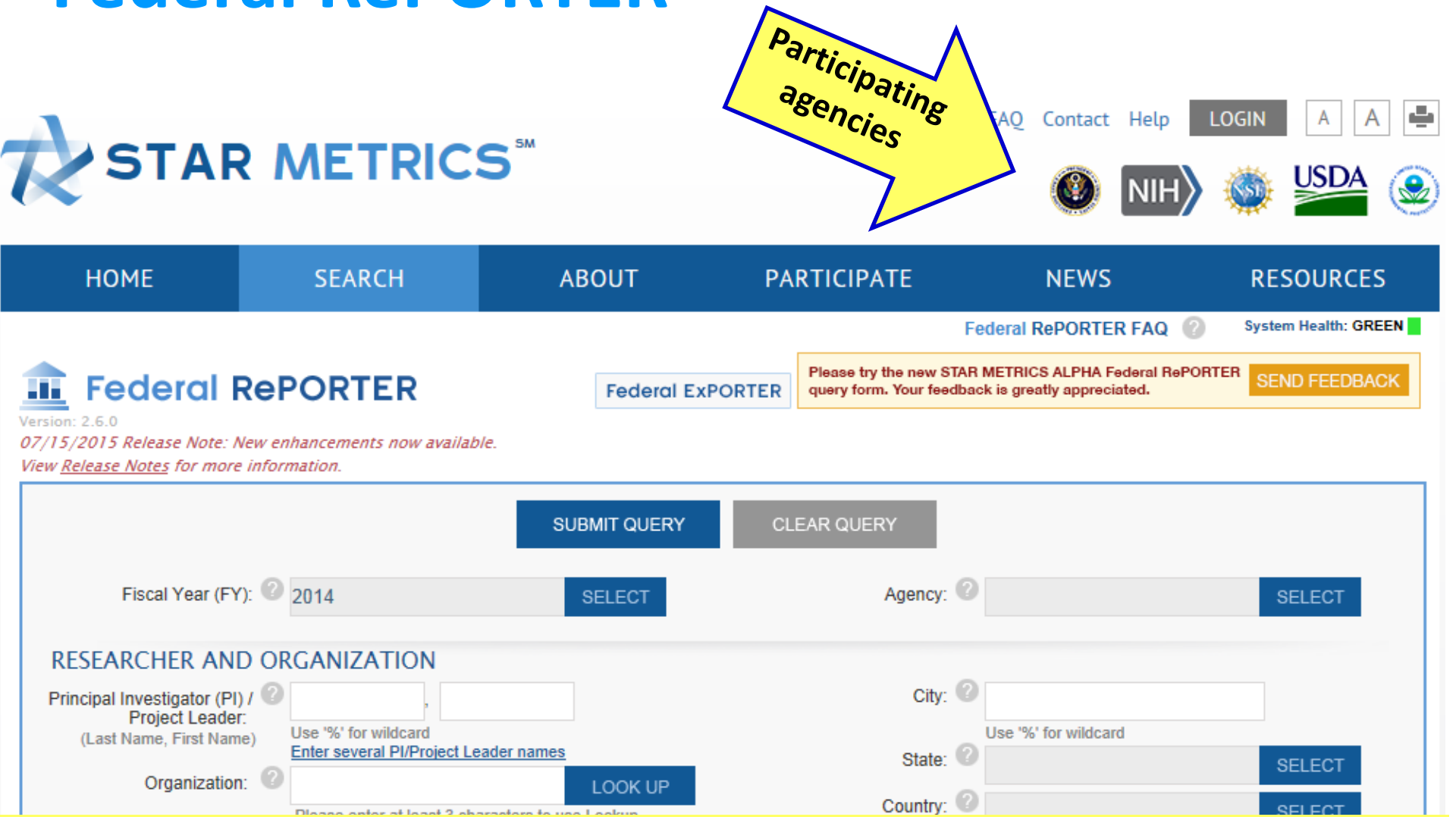
T	Act	Project	Year	Sub #	Project Title	Contact PI/ Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
1	R01	CA166111	01A1		TUMOR ANTIGEN-SPECIFIC T-CELLS AND HEPATOCELLULAR CARCINOMA	KAPLAN, DAVID E	UNIVERSITY OF PENNSYLVANIA	2013	NCI	NCI	$249,000	
5	R01	AR055993	03		TISSUE REGENERATION BY BIOPHYSICAL SIGNALING	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIAMS	NIAMS	$323,395	
5	R01	AR061988	02		ELECTROTHERAPEUTIC STRATEGIES FOR CONNECTIVE TISSUE REPAIR	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIAMS	NIAMS	$645,728	
3	P41	EB002520	09S1		TISSUE ENGINEERING RESOURCE CENTER	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2013	NIBIB	NIBIB	$40,625	
5	P41	EB002520	09		TISSUE ENGINEERING RESOURCE CENTER	KAPLAN, DAVID L	[illegible]ERSITY	2012	NIBIB	NIBIB	$1,152,600	
5	R01	EB011620	03		BIOMATERIAL APPLICATIONS OF RECOMBINANT BACTERIAL COLLAGENS	KAPLAN, DA[illegible] et al.	[illegible]ERSITY MEDFORD	2012	NIBIB	NIBIB	$324,245	
1	R01	EB014283	01A1		MULTIFUNCTIONAL TROPOELASTIN-SILK BIOMATERIAL SYSTEMS	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	$305,288	
1	U01	EB014976	01		MODELS TO PREDICT PROTEIN BIOMATERIAL PERFORMANCE	KAPLAN, DAVID L et al.	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	$646,995	
1	R01	EB016041	01		IN VITRO BIOREACTOR SYS FOR PLATELET FORMATION	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NIBIB	NIBIB	$337,137	
5	R01	EY020856	03		TISSUE ENGINEERING CORNEA REPLACEMENTS	KAPLAN, DAVID L	TUFTS UNIVERSITY MEDFORD	2012	NEI	NEI	$369,557	

Click for Abstract

… of Useful Information.



Even broader functionality from Federal RePORTER



http://federalreporter.nih.gov/

Need Help with Your Proposal… Who Ya' Gonna' Call?

✓ **about the scientific and technical aspects of your application…**

- Find them on the solicitation
- See also the IC's programmatic descriptions (http://www.nih.gov/icd/index.html).

✓ **for questions during the review…**

- Listed on the eRA Commons link to your submitted proposal
- See also the review group rosters at the CSR web site

✓ **for help with the business aspects of a proposal…**

- Listed on the eRA Commons link to your submitted proposal
- See also the IC's programmatic descriptions (http://www.nih.gov/icd/index.html).

Program Director **Scientific Review Officer** **Grants Specialist**

NIH Program Officials: your primary contact

Pre-Application

- Assess the “fit” to the IC, Program(s)
- Start the conversation early: develop your ideas together
- Choose the right activity/mechanism
- Brief on Review Issues: Dos/Don’ts

Post Review

- Analyze the Summary Statement: deeper insights from the Review
- Understand the rating and assess the likelihood of funding
- BEWARE! Nothing is certain until you have it in writing

During the Award

- Discuss problems in execution (rebudgeting, re-scoping, extensions…)
- Find an administrator to address unusual issues
- Brag about important discoveries

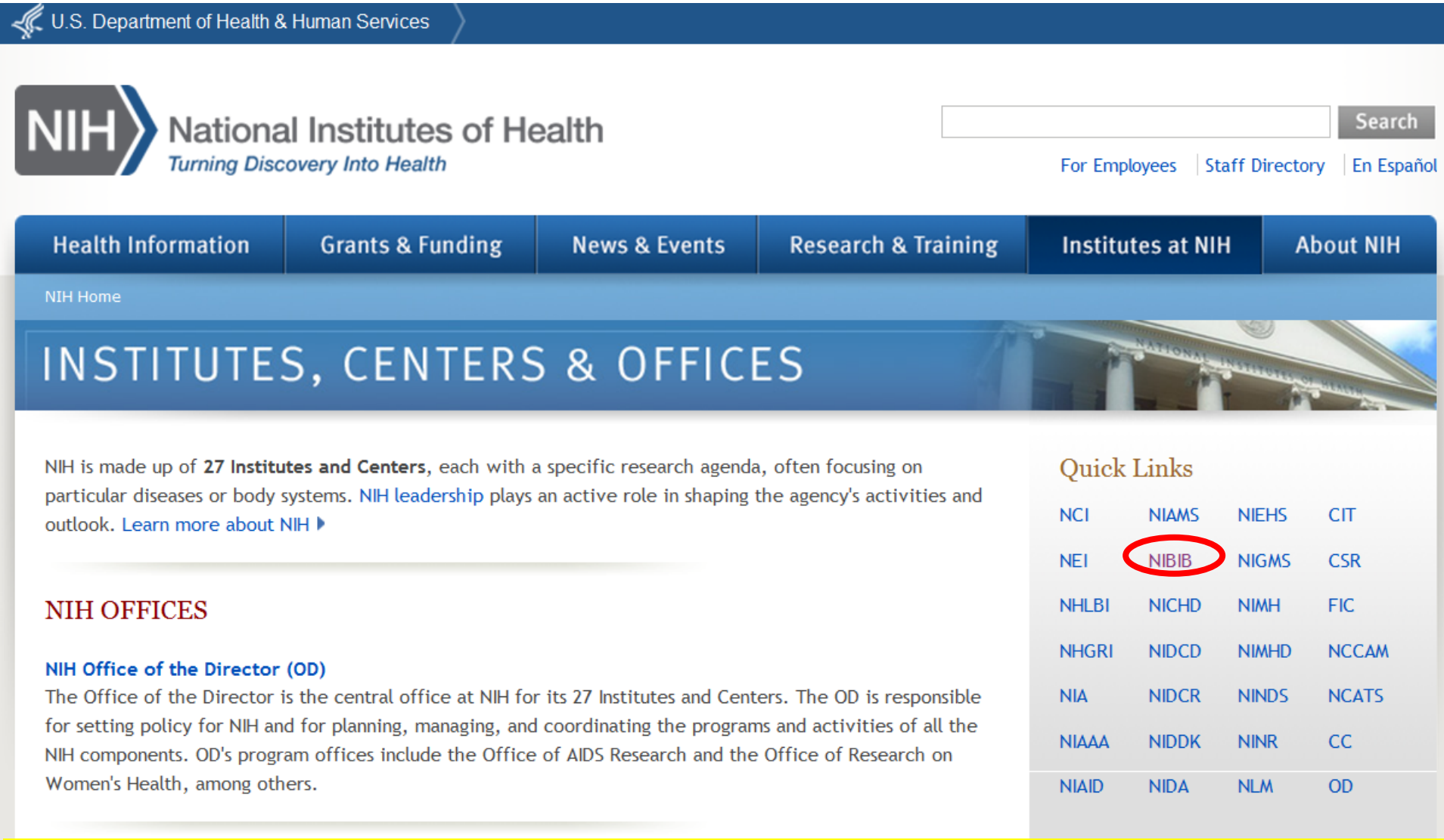
Anytime

- Arrange introductions so you can serve on advisory boards, workshop panels, etc.
- Discover what’s New and Coming Soon in Funding Opportunities

Application → Review → Award

NIH National Institute of Biomedical Imaging and Bioengineering

NIH Institute/Center Web Sites



www.nih.gov/icd/

Each NIH Institute/ Center *has a HOME PAGE*

Model: http://www.xxxxx.nih.gov

http://www.nibib.nih.gov/

NIBIB National Institute of Biomedical Imaging and Bioengineering
National Institutes of Health
ENGINEERING & IMAGING FOR THE FUTURE

En Español | Quick Links

HOME | ABOUT NIBIB | RESEARCH | FUNDING | TRAINING & CAREERS | NEWS & EV

Research

+ Labs At NIBIB (Intramural)

Scientific Program Areas (Extramural)

Biotechnology Resource Centers

Quantum Grants

Resources for Researchers

SIGN UP FOR OUR LISTSERV

Biomaterials Program Area

Staff Contact

Rosemarie Hunziker, Ph.D.

Description

This program supports the research and development of new or novel biomaterials that can be us for a broad spectrum of biomedical applications such as implantable devices; tissue engineering; imaging agents; and biosensors and actuators.

Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed o these materials and their clinical performance.

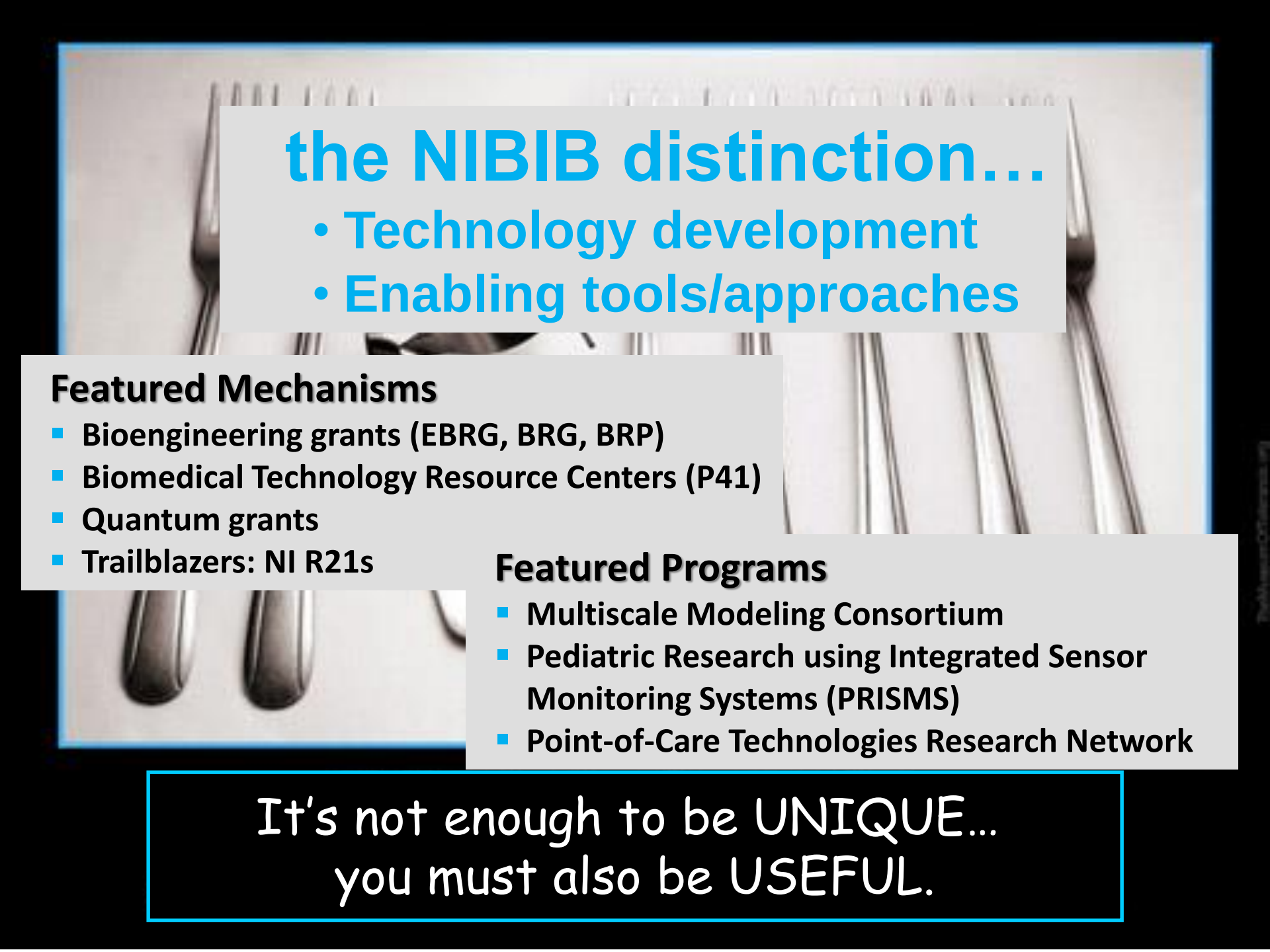
Relevant Study Sections

Biomaterials and Biointerfaces (BMBI)

NIH Supports Non Hypothesis-Driven Research

There are two kinds of scientific revolutions, those driven by new tools and those driven by new concepts… The effect of a concept-driven revolution is to explain old things in new ways. The effect of a tool-driven revolution is to discover new things that have to be explained.

-Freeman Dyson, 1997



the NIBIB distinction…

- Technology development
- Enabling tools/approaches

Featured Mechanisms

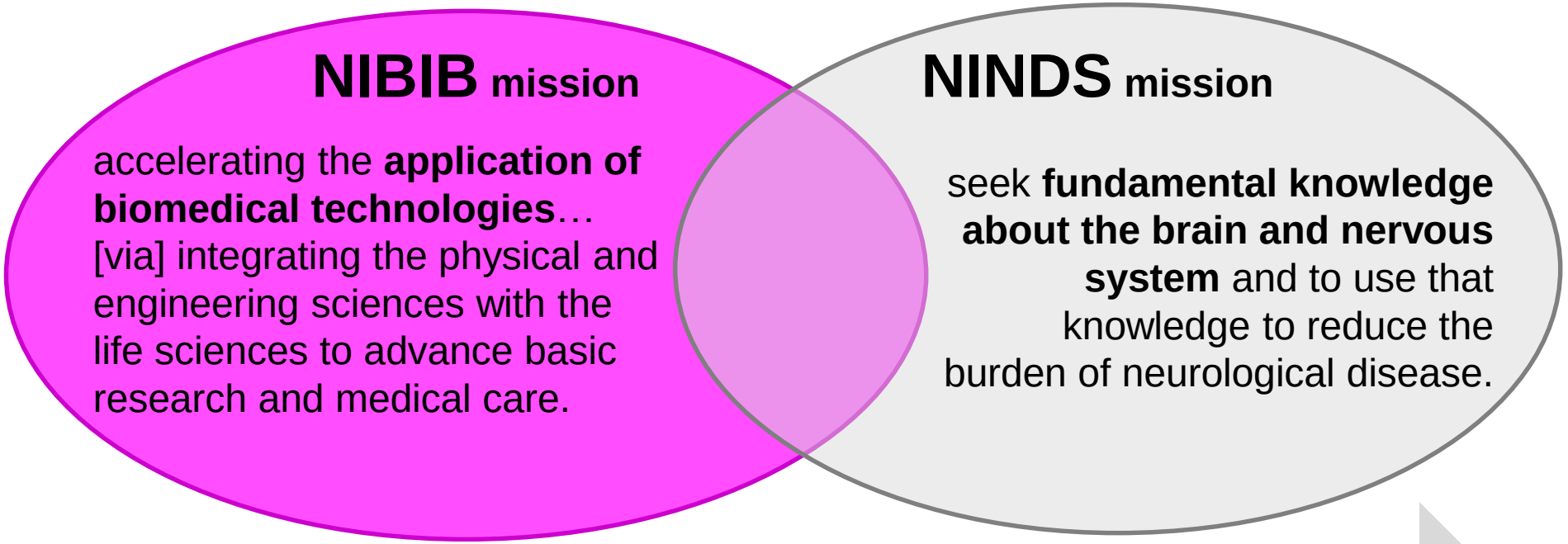
- Bioengineering grants (EBRG, BRG, BRP)
- Biomedical Technology Resource Centers (P41)
- Quantum grants
- Trailblazers: NI R21s

Featured Programs

- Multiscale Modeling Consortium
- Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS)
- Point-of-Care Technologies Research Network

It's not enough to be UNIQUE…
you must also be USEFUL.

Targeting IC Priorities: an example



Novel polymer scaffold for tissue regeneration

Neural progenitor cells in biomimetic matrix in rat brain

Pivotal large animal studies for stroke therapy

Planning Meeting Output:
Blueprint for Successful Research

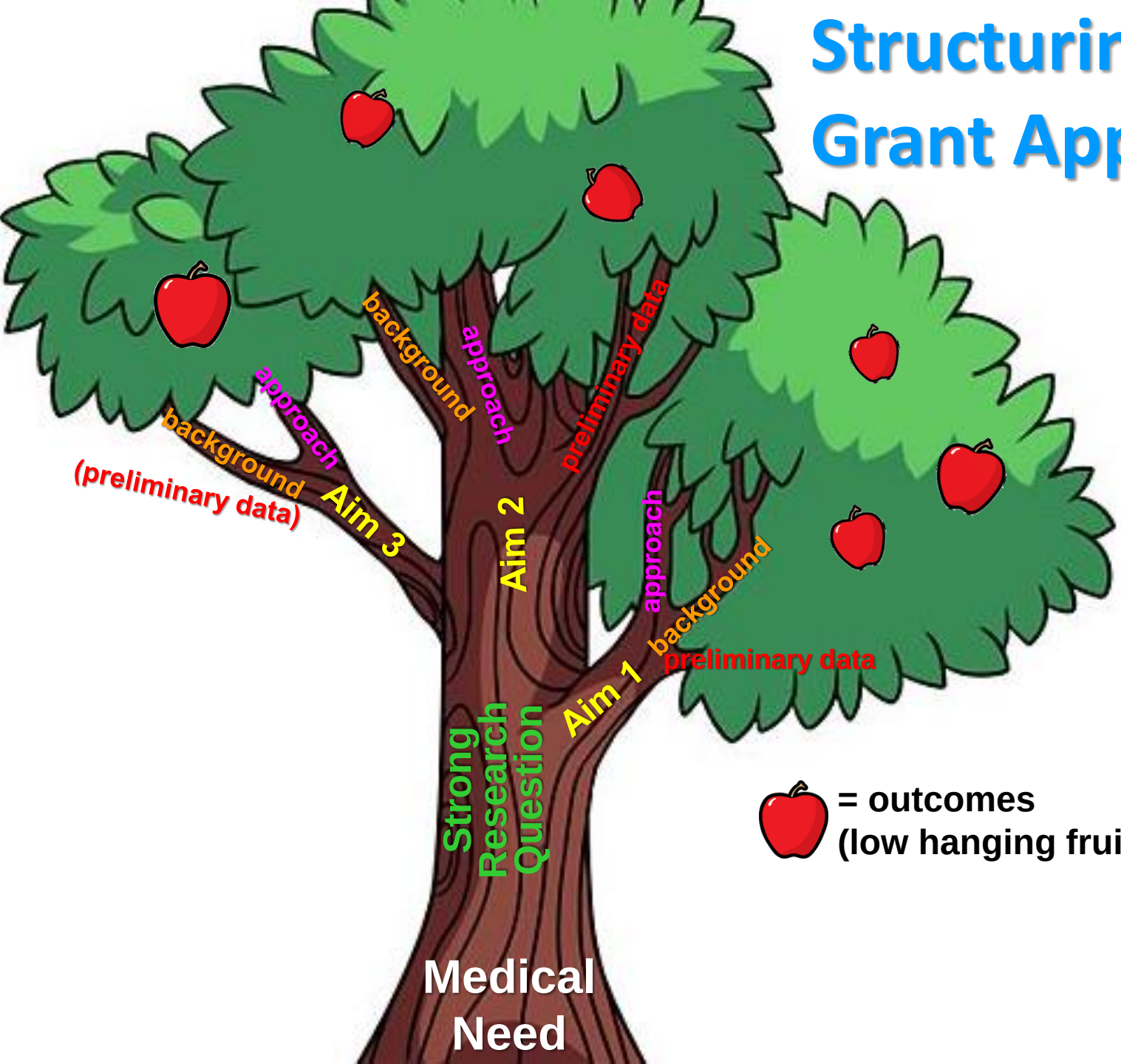
Project Title: *really a quick summary*
Principal Investigator(s) and Key Personnel: *defines role, commitment*
Overall goal: *resolve an important issue in a timely manner*
Specific goal: *best stated as a hypothesis (a boastful claim, substantiated by data)*
Impact: *2-3 sentences, define success, distill innovation and significance*

RESEARCH Responsibilities, Costs, Milestones and Timeline

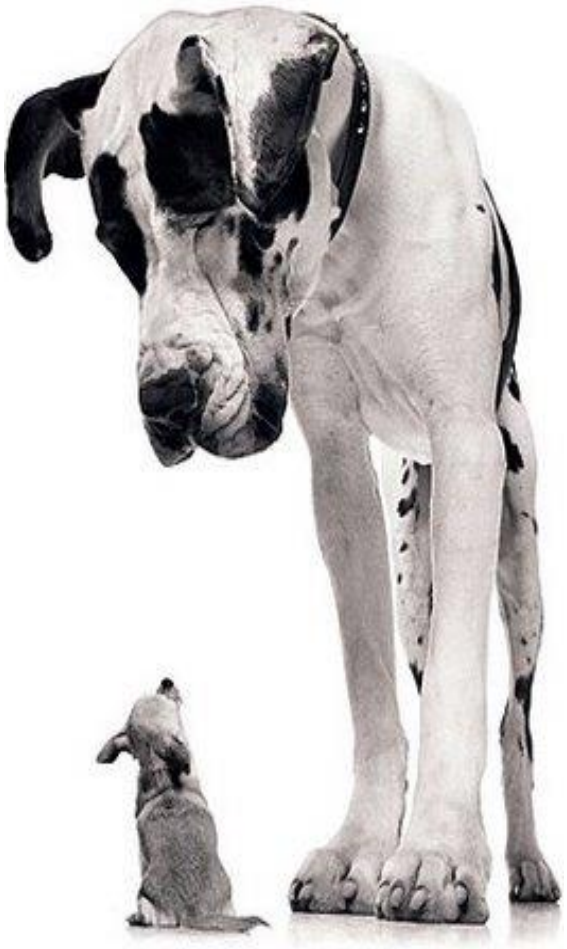
	Overseer	Cost	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
1. Validate the … ***(THIS AIM MUST WORK**—i.e. no/low risk here!)*										
1a. Compare… confirm…										
1b. Optimize the dose/time course…										
2. Elucidate the mechanism… *(May omit for high risk (e.g. R21) grants.)*										
2a.						*				
2b.										
2c.										
3. Assess the biocompatibility of … in a … *(Transition to next grant.)*										

* *High-risk element. Propose and discuss alternatives. Decision point.*

Structuring Your Grant Application




Start where you are.
Use what you have.
Do what you can.
- Arthur Ashe
Hope for the best.
- Rosemarie Hunziker



Are you ready to run with the big dogs?

Rosemarie Hunziker, PhD

Program Director,
Tissue Engineering/Regenerative Medicine

National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institutes of Health (NIH)

301-451-1609
Rosemarie.Hunziker@nih.gov
www.nibib.nih.gov