NIH Road Map
&
ORNL NIH Program Road Map:
From Point A to Point B

April 11, 2007

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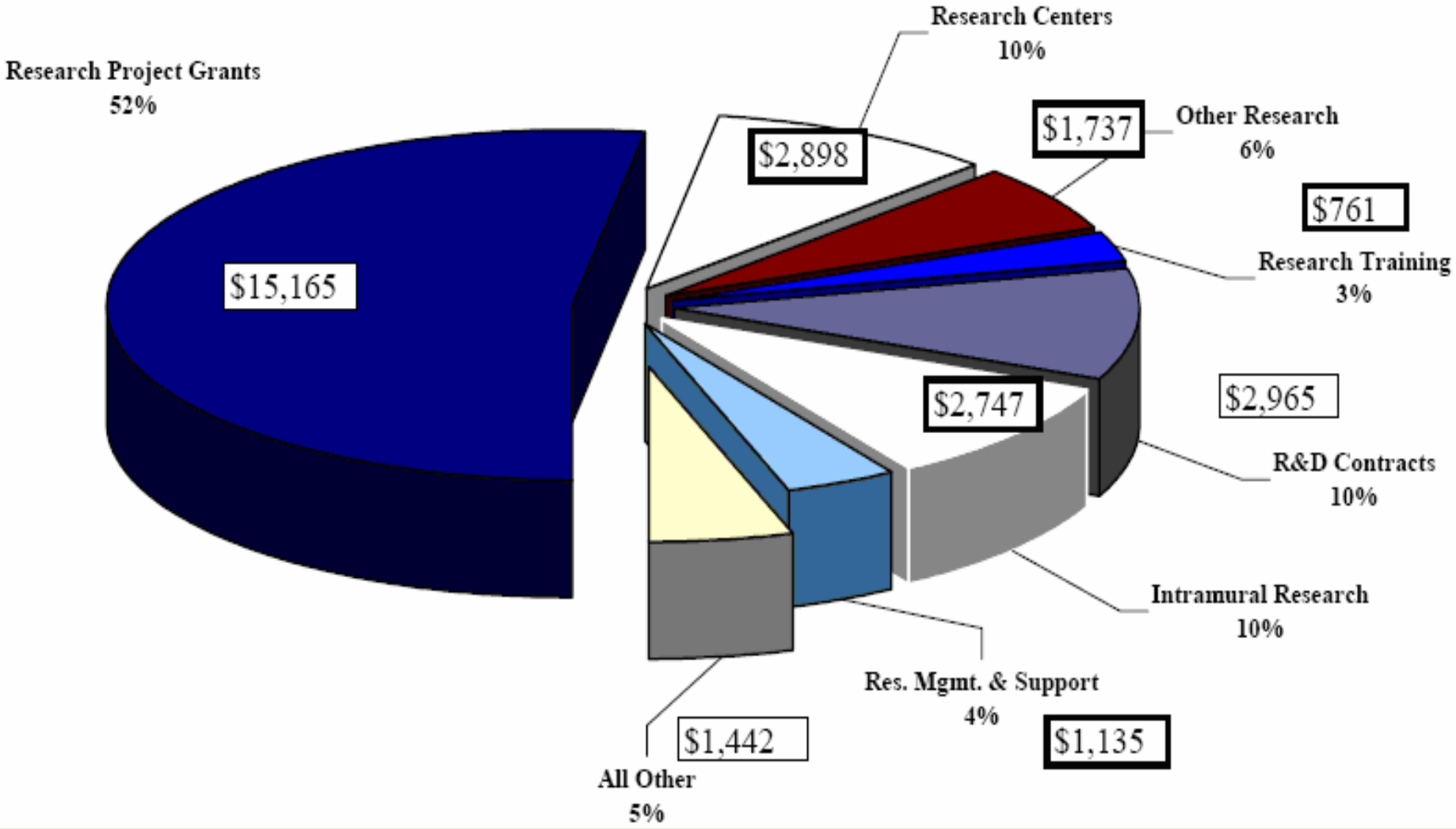
NIH Program Office

Notices

- Next Workshop on SF424 mid June
- Refreshments in the back at break
- Evaluation forms with priority question
- Monthly NIH forums focused on initiatives & priority project FOAs
  - brown bag lunches
- Reminder = NIH Bios e-Form
- e-RA Commons accounts = kfq or d4h

FY 2008 President's Budget Request
Total NIH Budget Authority
$28,850 Million

88% RD



NATIONAL INSTITUTES OF HEALTH
Budget Mechanism - Total
(Dollars in millions)

MECHANISM	FY 2006 Actual 1/		FY 2007 Estimate		FY 2008 Estimate		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	27,366	$11,070	26,668	$10,897	26,098	$10,793	-570	-$104
Administrative supplements	(1,678)	284	(1,435)	172	(1,582)	200	(147)	28
Competing	9,129	3,362	9,622	3,489	10,188	3,569	566	80
Subtotal, RPGs	36,495	14,716	36,290	14,558	36,286	14,562	-4	4

Total RPG Budget = $14, 562

New Competing = 3.57 billion

NATIONAL INSTITUTES OF HEALTH

Research Project Grants: Number of Awards

FY 1996 - FY 2006

Fiscal Years	Competing	Percent Change	Noncompeting	Percent Change	SBIR\STTR	Percent Change	Total RPGs	Percent Change
FY 1996	6,653	-1.6%	17,854	4.6%	1,012	-5.5%	25,519	2.5%
FY 1997	7,390	11.1%	18,248	2.2%	1,298	28.3%	26,936	5.6%
FY 1998	7,578	2.5%	19,495	6.8%	1,326	2.2%	28,399	5.4%
FY 1999	8,566	13.0%	20,149	3.4%	1,508	13.7%	30,223	6.4%
FY 2000	8,765	2.3%	21,779	8.1%	1,640	8.8%	32,184	6.5%
FY 2001	9,101	3.8%	23,322	7.1%	1,699	3.6%	34,122	6.0%
FY 2002	9,396	3.2%	24,921	6.9%	1,889	11.2%	36,206	6.1%
FY 2003	10,411	10.8%	25,776	3.4%	2,032	7.6%	38,219	5.6%
FY 2004	10,025	-3.7%	27,064	5.0%	2,190	7.8%	39,279	2.8%
FY 2005	9,481	-5.4%	27,353	1.1%	1,934	-11.7%	38,768	-1.3%
FY 2006	9,085	-4.2%	27,296	-0.2%	1,835	-5.1%	38,216	-1.4%

Research Grant Awards:	FY 2004 Number	FY 2005 Number	Total, FYs 2004/2005 new grants (*excludes overlap)
Total new grants	193	186	379
Investigators	177	175	326*
Investigators new to NIH	28	29	56*
Academic Institutions[#]	96	91	134*
States	29	30	33*

Appropriation	FY 2006 Budget Authority 1/	FY 2007 Estimate 1/ 2/	FY 2008 Estimate 1/	2008/2007
	Includes AIDS	Includes AIDS	Includes AIDS	$ Change
NCI	4,795	4,791	4,782	-9
NHLBI	2,916	2,919	2,925	7
NIDCR	389	389	390	1
NIDDK 2/	1,853	1,854	1,858	4
NINDS	1,533	1,534	1,537	3
NIAID 3/	4,379	4,382	4,592	210
NIGMS	1,934	1,935	1,941	6
NICHD	1,264	1,264	1,265	1
NEI	666	666	668	2
NIEHS	636	641	637	-3
NIA	1,045	1,046	1,047	1
NIAMS	507	508	508	0
NIDCD	393	393	394	0
NIMH	1,402	1,403	1,405	3
NIDA	999	999	1,000	1
NIAAA	435	436	437	1
NINR	137	137	138	1
NHGRI	486	486	484	-2
NIBIB	298	298	300	2
NCRR	1,109	1,110	1,112	3
NCCAM	121	121	122	0
NCMHD	195	195	194	-1
FIC	66	66	67	0
NLM	314	314	313	-2

Research/Disease Areas (Dollars in millions and rounded)	FY 2007 Estimate	FY 2008 Estimate
Biotechnology	9,946	9,920
Prevention	6,784	6,775
Cancer	5,556	5,534
Genetics	4,865	4,848
Neurosciences	4,816	4,808
Brain Disorders	4,711	4,704
Infectious Diseases	3,118	3,085
Behavioral and Social Science	2,993	2,981
HIV/AIDS 1/	2,903	2,905
Aging	2,423	2,414
Cardiovascular	2,343	2,341
Heart Disease	2,082	2,081

Emerging Infectious Diseases	1,853	1,835
Mental Health	1,817	1,814
Biodefense	1,731	1,723
Bioengineering	1,553	1,551
Vaccine Related	1,486	1,507
Substance Abuse	1,485	1,484
Orphan Drug	1,253	1,248
Digestive Diseases	1,250	1,245
Neurodegenerative	1,214	1,209
Human Genome	1,063	1,061
Basic Behavioral and Social Science	1,056	1,054
Nutrition	1,038	1,034
Diabetes	1,035	1,031

NIH FY 2008 EXTRAMURAL TARGETS

NIBIB	$271,469	- Applied Sciences & Technology - Discovery Science & Technology - Technological Competitiveness-bridging The Sciences	NCRR	$1,069,627	-Clinical & Translational Research -Biotechnology Research -Comparative Medicine - Research Infrastructure
NIGMS	$1,864,839	- Cell biology & Biophysics - Genetics and Development Biology - Pharmacology, Physiology and Biological Chemistry - Bioinformatics and Computational Biology	NIDCR	$305,831	- Integrative Biology - Clinical Translational - Biotechnology & Innovation
NCI	$4,014,753	- Develop Effective & Efficient Treatments - Understand the Mechanisms of Cancer - Cancer Centers & Specialized Centers	NIAAA	$360,789	- Embryo & Fetus - Youth/Adolescence - Young Adult - Mid-Life Senior Adult
NIAID	$3,783,179	- HIV/AIDS - Biodefense & Emerging Infectious Diseases - Infectious & Immunological Diseases	NIEHS	$446,755	- Clinical Research - Basic Mechanisms in Human Biology - Interdisciplinary, Integrated Research - Community-Linked & Global Environmental Health Research - Exposure Biology /Exposure Measurement - Pathways for Future Environmental Health Sciences

NIH FY 2008 EXTRAMURAL TARGETS

NCMH	$179,409	- Health Disparities Research - Research Capacity-building & Infrastructure - Outreach and Information Dissemination	NCCAM	$98,188	- Clinical Research - Non-Clinical Research - Training
NLM	$69,270	- Medical Library Assistance - PHS 301 - SBIR/STTR	NIDA	$849,531	- Basic and Clinical Neuroscience and Behavioral Research - Epidemiology, Services and Prevention Research - Pharmacotherapies and Medical Consequences - Clinical Trials Network
NIMH	$1,160,330	- Health, Behavior & AIDS Research - Adult Translational Research & Treatment Development - Pediatric Translational Research & Treatment Development - Neuroscience & Basic Behavioral Science - Services & Intervention Research	NIDCD	$335,296	- Hearing and Balance - Smell and Taste - Voice, Speech, and Language

NIH FY 2008 EXTRAMURAL TARGETS

NICHD	$1,034,826	-Center for Development Biology and Perinatal Medicine -Center for Population Research -Center for Research for Mothers and Children -National Center for Medical Rehabilitation Research	NIAMS	$427,184	-Arthritis and Rheumatic Diseases -Skin Biology and Diseases -Muscle Biology and Diseases -Musculoskeletal Biology and Diseases -Bone Biology and Diseases
NHLBI	$2,618,394	-Heart and Vascular Diseases -Lung Diseases -Blood Diseases and Resources	NEI	$569,806	-Retinal Disease Research -Corneal Diseases, Cataract, and Glaucoma Research -Sensorimotor Disorders and Rehabilitation Research
NIA	$892,801	-Biology of Aging Program -Behavioral and Social Research Program -Neuroscience and Neuropsychology of Aging Program -Geriatrics and Clinical Gerontology Program	FIC	N/A	-N/A
NHGRI	$363,109	- Basic Genomics - Translational Genomics	NINDS	$1,323,610	- Channels, Synapses & Circuits - Neural Environment - Neurodegeneration - Neurogenetics - Repair & Plasticity - Systems & Cognitive Neurosciences - Technology Development, Infrastructure & Resources

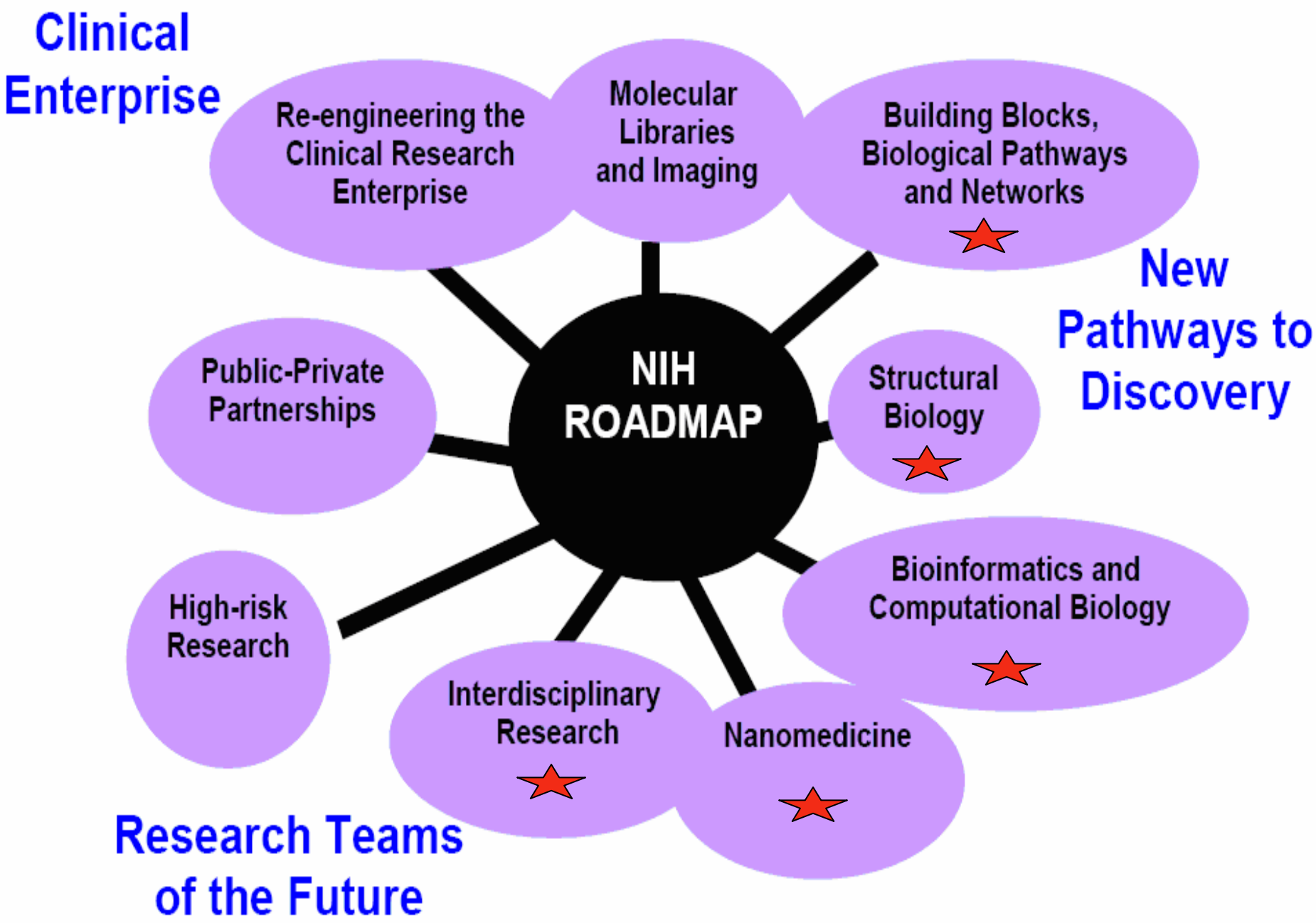
NIH FY 2008 EXTRAMURAL TARGETS

NIDDK	$1,614,615	- Diabetes, Endocrinology & Metabolic Diseases - Digestive Diseases & Nutrition - Kidney, Urological & Hematological Diseases - Type 1 Diabetes	NINR	$123,265	- Self-Management, Symptom Management, and Caregiving - Health Promotion and Disease Prevention - Research Capacity Development - Technology Integration - End-of-Life

AVENUES OF EXTRAMURAL RESEARCH

FY 2006 R01 RESEARCH GRANTS

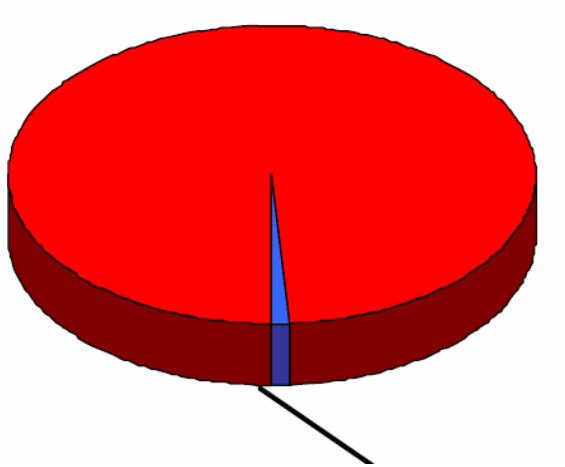
1. **Investigator-Initiated ~90%**
2. Program Announcement ~7.5%
3. **Request for Applications ~13.4%**
4. Request for Proposals


Clinical Enterprise
Re-engineering the Clinical Research Enterprise
Molecular Libraries and Imaging
Building Blocks, Biological Pathways and Networks
New Pathways to Discovery
Public-Private Partnerships
NIH ROADMAP
Structural Biology
High-risk Research
Bioinformatics and Computational Biology
Interdisciplinary Research
Nanomedicine
Research Teams of the Future

Funding the Roadmap for Medical Research

FY 2007 Appropriation = $28,858

Non-Roadmap
98.3%
($28,372 Million)



Roadmap
1.7%
($486 Million)

NATIONAL INSTITUTES OF HEALTH
NIH Roadmap by Initiative
(dollars in thousands)

Title of Initiative	Lead Administrative ICs	FY 2005 Actual	FY 2006 Appropriation	FY 2007 Estimate
New Pathways of Discovery				
Molecular Libraries and Imaging				
Creation of NIH Bioactive Small Molecule Library & Screening Centers	NIMH, NHGRI	$38,495	$51,282	$69,637
Cheminformatics	NHGRI, NLM	5,414	10,395	→ 10,593
Technology Development	NIGMS, NINDS, NHGRI, NIBIB	14,885	21,184	→ 26,075
Development of High-Specificity/High-Sensitivity Imaging Probes	NIGMS	5,336	5,115	→ 5,316
Imaging Probe Database	NCI	500	409	534
Core Synthesis Facility to Produce Imaging Probes	NHLBI	1,980	3,000	3,000
Subtotal, Molecular Libraries and Imaging		*66,610*	*91,385*	*115,155*
Building Blocks, Biological Pathways and Networks				
National Technology Centers&Metabolomics Development	NIDDK, NCRR	14,946	15,494	→ 16,098
Metabolomics Technology Development	NIDDK, NCRR	13,856	13,816	→ 3,950
Standards and Reagents for Proteomics	NCRR, NIDDK, NHGRI	100	494	0
Assessment of Critical Reagents for Proteomics	NCRR, NHGRI	100	494	0
Subtotal, Building Blocks, Biological Pathways and Networks		*29,002*	*30,298*	*20,048*
Structural Biology				
Centers for Innovation in Membrane Protein Production	NIGMS	9,898	4,869	→ 4,876
Membrane Protein Production and Structure Determination	NIGMS	0	5,000	→ 5,000
Subtotal, Structural Biology		*9,898*	*9,869*	*9,876*
Bioinformatics and Computational Biology				
National Centers for Biomedical Computing	NIGMS	23,755	23,685	→ 23,703
Nanomedicine				
Conceptual Planning for Nanomedicine Development Centers	NEI	0	0	0
Nanomedicine Development Centers ★	NEI	5,939	11,843	→ 11,851
Subtotal, Nanomedicine		*5,939*	*11,843*	*11,851*
Subtotal, New Pathways of Discovery		***135,204***	***167,080***	***180,633***

Research Teams of the Future				
Interdisciplinary Research				
Interdisciplinary Research Centers	NCRR	12,365	11,499	→ 39,945
Interdisciplinary Research Training Initiative	NIDDK, OBSSR, NIGMS	10,888	14,404	15,150
Innovation in Interdisciplinary Technology and Methods	OD/OBSSR	3,669	150	3,050
Removing Structural Barriers to Interdisciplinary Research	CSR, OD/OER	0	0	0
Using the NIH Intramural Research Program as a Model for Research	OD/OIR	0	0	0
Interagency Conference on the Interface of Life Sciences and Physical Sciences	NIDCR	0	0	0
Subtotal, Interdisciplinary Research		*26,922*	*26,053*	*58,145*
High-risk Research				
NIH Director's Pioneer Awards	NIGMS	16,217	17,063	→ 21,885
Public-Private Partnerships				
Designation of a Central Point of Contact	OD	0	444	450
High-Level Science Driven Partnership Meetings	OD	0	110	110
Subtotal, Public Private Partnerships		*0*	*554*	*560*
Subtotal, Research Teams of the Future		***43,139***	***43,670***	***80,590***
Re-engineering the Clinical Research Enterprise				
Clinical Research Policy Analysis and Coordination	OD/OSP	2,858	3,000	3,100
Feasibility of Integrating and Expanding Clinical Research Networks	NHLBI	18,543	31,434	34,614
Translational Research Core Services	NIDDK	1,315	5,600	8,200
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	NIAMS	6,319	6,200	6,200
Regional Translational Research Centers	NCCAM	108	0	0
Enhance Clinical Research Training via the National Multi-disciplinary CR Career Development Program and CRTP and MSTP Expansions	NICHD, OD/OIR, NICHD	31,498	1,425	1,400
Create a National Clinical Research Associates Program	NICHD	70	170	10,000
Clinical and Translational Science Awards	NICHD	0	70,402	117,936
Subtotal, Re-engineering the Clinical Research Enterprise		***60,711***	***118,231***	***181,450***
Dedicated Roadmap Administration		*662*	*481*	*0*
Total Roadmap		**239,716**	**329,462**	**442,673**

NIH Roadmap Themes & Initiatives 2004-2005

I New Pathways To Discovery

- A. Building Blocks, Pathways, & Networks
- B. Molecular Libraries & Imaging
- C. Structural Biology
- D. Bioinformatics & Computational Biology
- E. Nanomedicine

II Research Team of the Future

- A. High-Risk Research
- B. Interdisciplinary
- C. Public Private Partnerships

III Re-engineering the Clinical Research

- A. Clinical Research

I New Pathways To Discovery

A. Building Blocks, Pathways, & Networks Implantation Group:

1. National Technology Centers for Networks & Pathways **(Ed Uberbacher)**
2. Metabolomics Technology Development **(Bob Hettich/Tim Tschaplinski)**
3. Standards for Proteomics & metabolomics/Assessment of Critical Reagents for Proteomics **(Bob Hettich/Tim Tschaplinski)**

I New Pathways To Discovery

B. Molecular Libraries & Imaging Implementation Group

1. Molecular Libraries Screening Center Network
2. Cheminformatics
3. Technology Development **(ORNL)**
4. Development of High Specificity/High Sensitivity Probes to Improve Detection **(Thomas Thundat)**
5. Comprehensive Trans-NIH Imaging Probe Database **(Thomas Thundat)**
6. Core Synthesis Facility to Produce Imaging Probes **(ORNL)**

I NEW PATHWAYS TO DISCOVERY

C. Structural Biology implementation **(Dean Myles)**
Protein Production Facilities

D. Bioinformatics & Computational Biology Implementation
(Barbara Beckerman)
National Centers for Biomedical Computing

E. Nanomedicine Implementation
(Mitch Doktycz)
Planning for Nanomedicine Centers

II Research Teams of the Future

A. High-Risk Research Implementation
   1. NIH Director's Pioneer Awards (4)
   2. New Innovators Awards (3)

B. Interdisciplinary Research Implementation
   1. Interdisciplinary Research Centers (UNC)
   2. Interdisciplinary Research Training initiative **(GU, UT, VU, Duke)**
   3. Interdisciplinary Research in the Behavioral Social Sciences
   4. Removing Structural Barriers to Interdisciplinary Research
   5. NIH Intramural Program as a model for Interdisciplinary Research
   6. Interagency Conference on the interface of Life Sciences & Physical Sciences

C. Public Private Partnerships Implementation
   1. Designation of a Public-Private Sector Liaison
   2. High-Level Science-driven Partnership Meetings

III RE-ENGINEERING CLINICAL RESEARCH

A. Clinical Research Implementation

Clinical Research Networks Nectar

1. Clinical Research Policy Analysis & Coordination
2. Clinical Research Workforce Training
3. Dynamic Assessment of Patient-Reported Chronic Disease Outcomes
4. **Translational Research**

NIH Roadmap Initiatives 2008

- **Microbiome** – understand microbial communities and their relation to human health (Tony Palumbo, Bob Hettich, Martin Keller, Tim Tschaplinski)
- **Protein capture/proteome tools** – proteomics in human and animal models, markers for disease (Bob Hettich, Tim Tschaplinski)
- **Phenotyping services and tools** – characterize complex disease and disorders (Mouse House)
- **Inflammation as a common mechanism of disease** – uncover immune mechanisms and mediators of inflammation, genetics factors, environmental triggers (Barbara Beckerman & group)
- **Epigenetics** – study of stable genetics modifications that result in gene expression and function w/o a corresponding alteration in DNA sequence; epigenetic changes often associated with disease (Battelle & Mouse House)

NIH Roadmap Initiatives 2008

Smaller pilots:

- Genetic connectivity map – discover linkages between disease, drug candidates and genetic manipulation
- Transient molecular complexes – essential for understanding how diseases develop and progress

Where We Were

(2000 – 2004) $7,650 million/4 years

- **Tennessee Mouse Genome Consortium – Johnson, $4.3 million**
- **Nano Arrays and Actuation Using Cell Mimetics – Doktycz, $1.7 million**
- **Nano Arrays for Real-Time Probing Within Living Cells – McKnight, $1,649 million**

WHERE WE ARE (2005-2007)

- **Innovation Deterministic Particle Transport for RTP – *Kirk, $0.311 million***
- **Nanoscale architecture for Controlled Gene Expression – *McKnight, $1,801 million***
- **Protein Surface Mapping: Experimentation and Computation – *Hettich, $1,003***
- **Nanosensing and Actuation Using Cell Mimetics – *Doktycz, $1,656 million***
- **Ontological Discovery for Ethanol Research – *Chesler, $0.585 million***
- **Post Exposure Injury Assessment Tools – *Eckerman, $0.791 million***
- **LiverTox Advanced QSAR and Toxicogenomic Software for Hepatotoxicity Prediction – *Lu, $0.3 million***
- **Automated Screening for Diabetic Retinopathy by Content-Based Image Retrieval – *Tobin, $0.580,***
- **UAB Affiliated Recessive PKD Core Center – *Michaud, $0.460 million***
- **Developing Man-made Nanoparticle into Diagnostic and Therapeutic Agent to Identify, Target and Kill Brain Tumor Cells – *Mirzadeh , $0.070 million***

WHERE WE ARE

(2005-2007) cont. $10,712 million/ 2 years

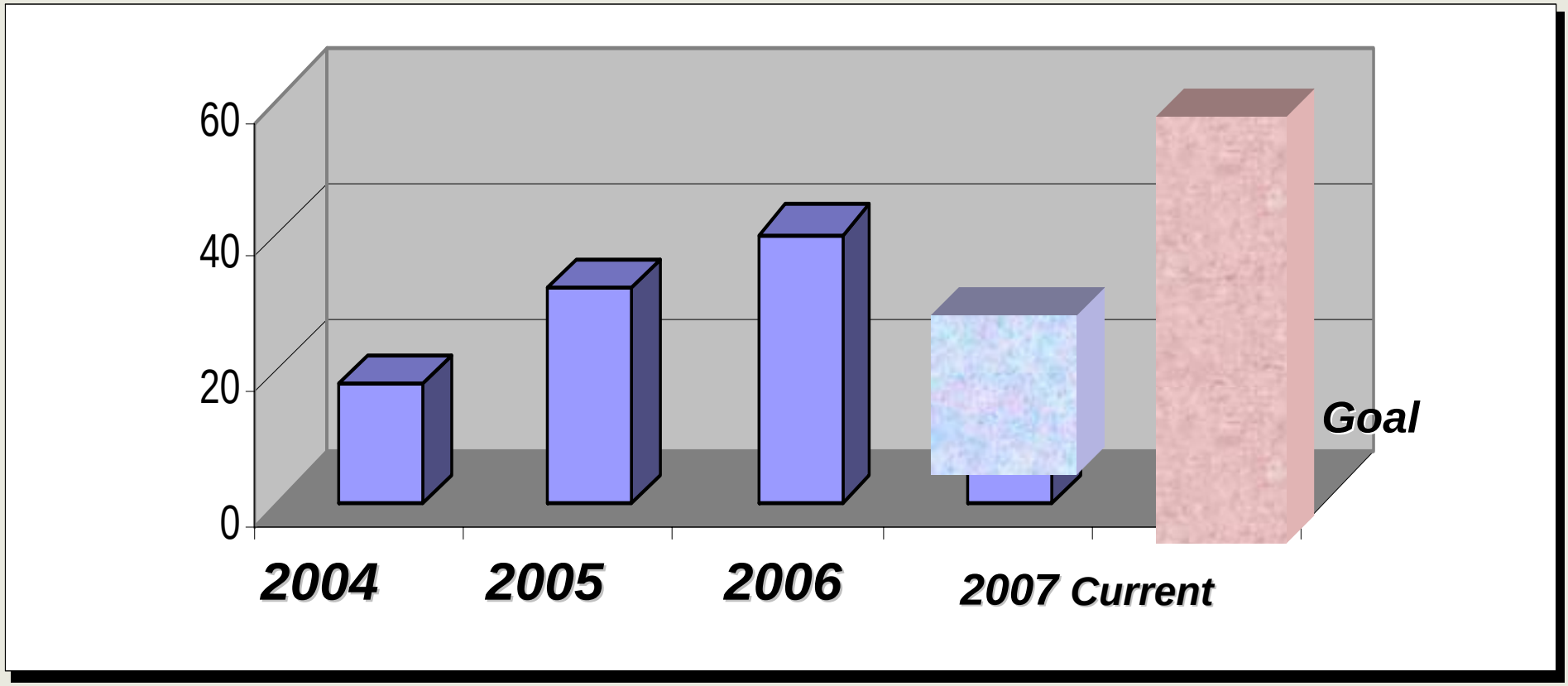
- **Real-time Characterization of Inhaler Doses - *Cheng, $0.092 million***
- **Computational R&D for Rapid Sequencing Nanotechnology – *Lee, $0.716 million***
- **Experimental R&D for Rapid Sequencing Nanotechnology – *Lee, $0.737 million***
- **INIA: Gene to Phenotype Networks for Alcohol & Drug Addiction – *Miller, $0.474 million***
- **Ultra High-Throughput Screen (uHTS) based on Surface Enhanced Ramen Scattering – *Voy, $.509 million***
- **SBIR Phase I: Bioengineering Nanotechnology Initiative - "Biopolymer Based Nanocomposite for Wound Care“ – *Evans, $0,050 million***
- **Nanoscale Fluidic Technologies for Rapidly Sequencing Single DNA Molecules – *Baddorf, $0.512 million***
- **"INIA-Stress: Informatics and analysis core – Chesler, $0.288 million**

OVER 45 MILLION STILL PENDING

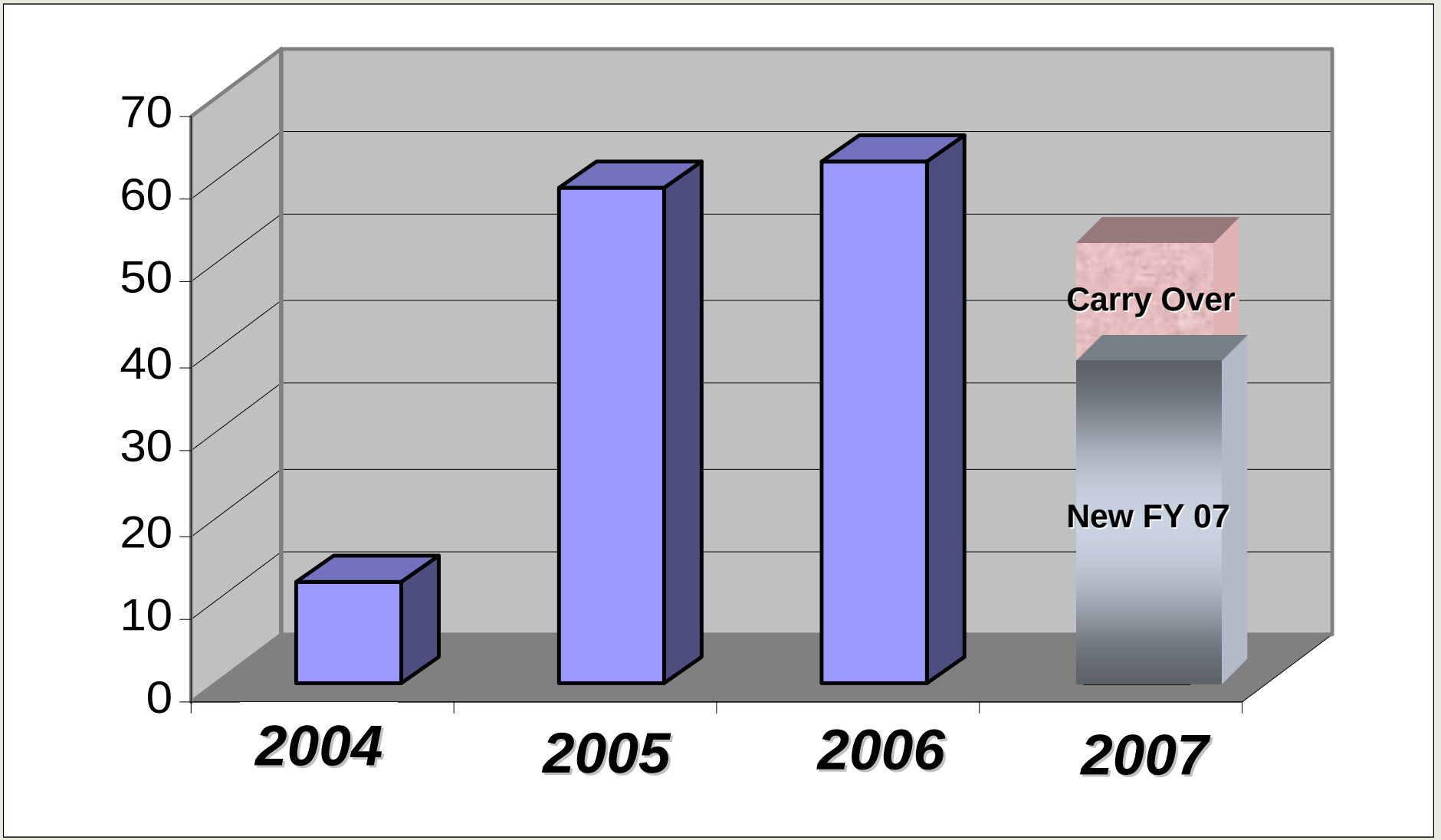
FY 2004 thru 2007

Fiscal Year	2004	2005	2006	2007
Proposals Submitted	18	38	40	22
Total $ Under Review In millions	12	59	62	45

Grant Submission Growth



Growth Of Monies Under Review



WHERE WE WANT TO BE

$25 to 50 Million Portfolio

Recognized & Valued at NIH for Expertise & Resources

1. **CNMS-Nanomedicine**
   - Drug Delivery devices, biomedical materials, cell-mimetics
   - Instrumentation
   - Characterize the physical, chemical, structural and biological properties of nanostructured assemblies/materials
   - Nanotoxicology
2. **Mouse House Resource**
   - Establish a self-sustaining laboratory for systems genetics
   - Build reference population Model (CC)
   - Exposure Systems Biology
   - **Phenotyping services and tools** – characterize complex disease and disorders
3. **CSMB, SNS, & HFIR**
   - **Structural & Functional Analysis of Proteins, Nucleic acids, & membranes**
   - Computational Modeling
   - Methodology for computation of enzyme catalysis/dynamics
   - HIV vaccine development
   - Amyloid drug design
   - Imaging hydrogen atoms
   - Study of biomembranes and proteins

WHERE WE WANT TO BE

4. **Microbiome**
   - **– Understand microbial communities and their relation to human health**
   - **- Digestive Diseases and relationship with gut Flora**
5. **CSED (Biomedical Engineering & Biomedical Science & Technology)**

   Center for Musculoskeletal Research (CMR)
   - **Biomechanics**
   - **Biomaterials**

   Computational Predictive Modeling & Simulation
   - **Complex biological processes**
   - **Geospatial research**
   - **Knowledge discovery**
   - **Biomedical application & Imaging decision support**
   - **Biomedical informatics**
6. **Environmental Health Sciences**
   - **Genomic & environmental influence on human health**
   - **Monitoring & sensing technologies**
   - **Therapeutic modalities**
   - **Remediation**
   - **Climate change influence on human health**

How We Will Get There

- **Mirroring & complementing NIH strategy**
- **Nurturing our young investigators**
- **Partnerships with Major Medical Schools**
- **Strategic Hires**
  - Cellular Biologists
  - Immunologists
- **Education**
  - Workshops for PIs & Administrative Staff
  - Grantsmanship seminars
- **Forums for "Big" opportunities**
  - Strategically forming teams with MHC partners

How We Will Get There

- **Supporting PIs with RESOURCES**
  - $ for time
  - Technical editors
  - Boiler Plates, etc.
- **Support Visibility within the specific scientific communities** i.e., meetings with high visibility, conferences etc
- **Post-Docs**
- **Starbucks café!**

REMEMBER

AVENUES OF EXTRAMURAL RESEARCH

FY 2006 R01 RESEARCH GRANTS

1. **Investigator-Initiated ~90%**
2. Program Announcement ~7.5%
3. **Request for Applications ~13.4%**
4. Request for Proposals

GENERAL LEE & Viper

Discussion

- Track record- helping young investigators
- Seed money would be useful to launch R21 applications-can the SEED money committee consider this?
- Partnering-why would NIH fund National Lab application since we are so expensive? We have to give them value
- Kristina wants list of all LDRD or Seed proposals that have led to NIH funding
- Microbial biome should be great potential-link to mouse model—have SEED proposal for this
- NIH office to facilitate trips to help partnering relationships-getting info to appropriate investigators
- Study sections are a diverse crowd—must give them value
- What can we offer DOE so they can respond with a new initiative
- Low Dose resurgence and continuity-what can we compete for and how can we marry them with NIH funds

- We are the leaders in the microbial biome/mouse area—show this to DOE and tell DOE what calls make the most sense
- GGG study section (NIH) very technological, but applications that are above others are those with a biological driver
- Those that have been on NIH study sections should write a letter to ???
- UT has Science Alliance funds that MIGHT be targeted to match LDRD funds—have our committee talk to their committee to see about more possibility of this
- Funds from foundations don't pay the full recovery overhead for the lab, but if the lab could consider these as seed and allow the funds to come in with the smaller overheads, we could be ahead
- Leverage our funds to UT collaborators
- Decon/health effects—are there any NIH funds for this
- Review process-very few proposals are funded on the first submission—RESUBMIT with specific comments addressing the reviewers comments
- NIH/ORNL postdoctoral program?? What is happening with this