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**FOUNDATION**  
FOR THE  
National Institutes of Health

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## **Advisory Committee to the Director**

**Amy Porter, Executive Director, FNIH**

**Julie Wolf-Rodda, Director of Partnership Development, FNIH**

**June 6, 2008**

**PARTNERS FOR INNOVATION, DISCOVERY, LIFE**



## Overview: Foundation for NIH

- Mission

- Sole entity authorized by Congress to raise private funds in support of NIH's mission of improving health through scientific discovery and translational research

- Organization

- Independent nonprofit 501(c)(3) public charity created by the U.S. Congress and incorporated in 1996; able to partner with a broad range of entities
- Both private- and public-sector represented on board of directors
- NIH Director and FDA Commissioner are *ex officio*



## Foundation for NIH Board of Directors

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Chief Executive Officer, Venturehouse Group LLC

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Chairperson, Friends of Cancer Research

Distinguished Service Professor, Johns Hopkins University School of Medicine

Dean, Dartmouth Medical School

University Distinguished Service Professor, Johns Hopkins Medical Institutions

Director, National Institutes of Health

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## Overview: Foundation for NIH

- Function
  - Creates innovative public-private biomedical partnerships that complement NIH priorities and enhance NIH activities
  - Involves NIH and other federal partners, industry, academia, the philanthropic community
  - Provides a neutral forum able to engage all partners to work together with an equal ability to contribute
  
- Track Record
  - Proven expertise in public-private partnership development and management
  - Currently supporting 50+ projects; raised over \$410M since 1996



## Overview: Foundation for NIH

- Responding to the increasing complexity and cost of biomedical research
  - Expanded need for multidisciplinary expertise, access to advanced technology
  - Escalating costs of clinical research and product development
  - Distribution of scientific and financial obligations for “big science” and “high-risk, high-payoff” projects
- Providing opportunities for creative collaboration
  - Innovative mechanisms to enable partners from various sectors to leverage their energy, ideas, and other resources to create opportunities that might otherwise be unattainable
  - Dialogue among diverse partners including researchers, funders, regulators and industry
  - Participation of all partners in concept development and in ongoing activities
- Accelerating transition of basic research findings into biomedical interventions and public health applications



## Partners Can Collaborate With Confidence

- **Charity Navigator 2007.** Independent verification of the financial health and effective management of FNIH
  - *“How responsibly a charity functions day-to-day as well as how well it is positioned to sustain its programs over time”*
  - [www.charitynavigator.org](http://www.charitynavigator.org)
  
- **The Foundation for NIH**
  - Top-rated charity among the 593 health category charities rated
  - Third highest among all 5,327 charities evaluated
  - 96 cents of every dollar spent support programs



## How the Foundation Works with NIH

- Developing **public-private partnerships that build on existing NIH programs** to take advantage of new scientific opportunities
  - Genetic Association Information Network, Alzheimer's Disease Neuroimaging Initiative, Imaging Database Resources Initiative, Schizophrenia Metabolic Initiative
  
- Enabling private partners to **expand the number of funded NIH grants**
  - Avon-NCI Progress for Patients, Cognitive Aging Research Program



## How the Foundation Works with NIH (continued)

- Organizing or funding **training programs and career development activities** for young scientists that build on opportunities within NIH intramural and extramural research programs:
  - Clinical Research Training Program, Public Health Informatics Training Initiative, Women's Health Fellowships, The Bernard Osher Foundation NCCAM Practitioner Research Career Development Award
- Facilitating the **participation of NIH intramural laboratories in collaborative research networks** with external partners:
  - Comprehensive T Cell Vaccine Immune Monitoring Consortium



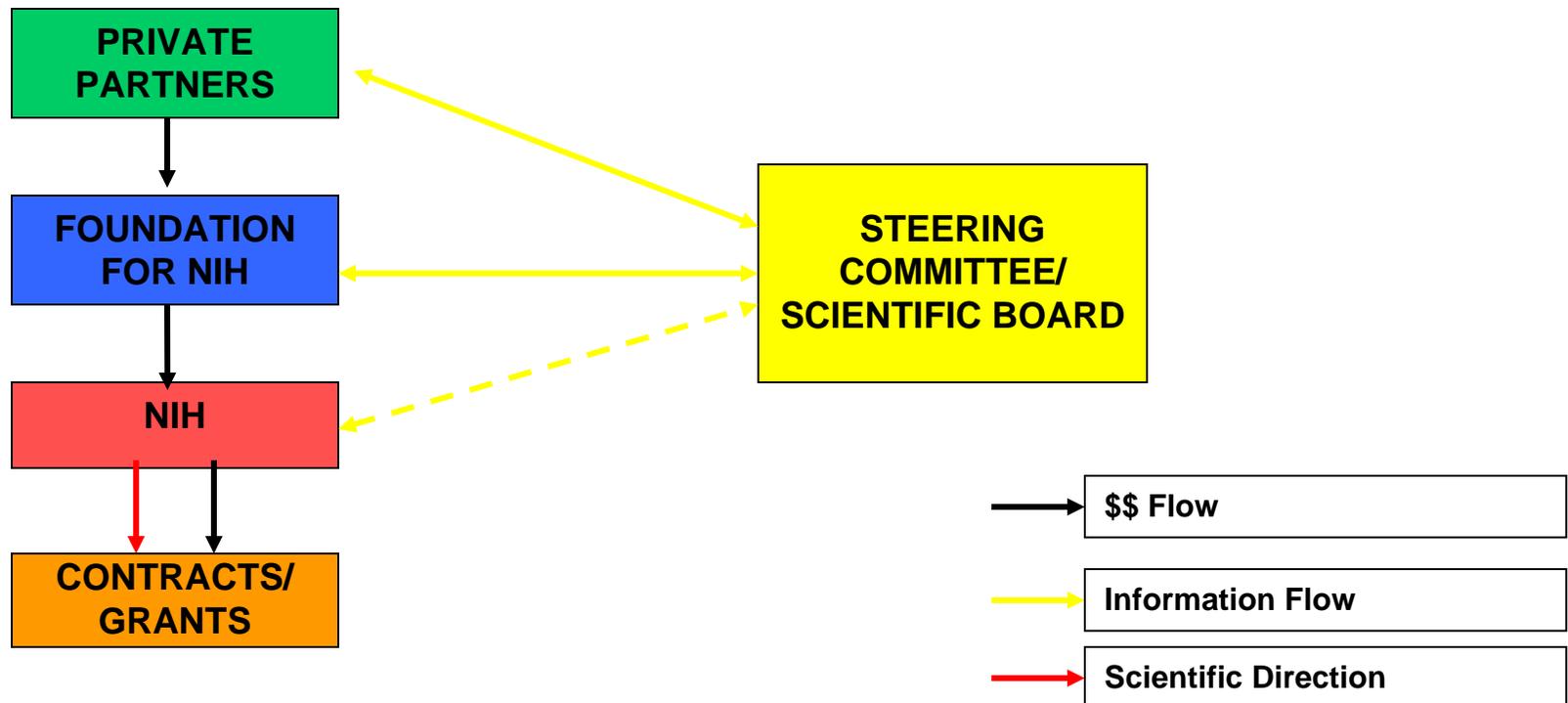
## How the Foundation Works with NIH (continued)

- Developing **partnerships for “on the ground” clinical and public health studies** to collect data that will directly contribute to improved prevention of/intervention against childhood diseases”
  - Head-off Environmental Asthma in Louisiana
- Established **comprehensive research programs**, including the means for solicitation, review, award, administrative and scientific oversight of research grants to academic, for-profit, or governmental organizations:
  - Grand Challenges in Global Health
- Organizing and managing **multi-partner consortia**, bringing together organizations such as governmental agencies, the pharmaceutical industry, voluntary health organizations and professional societies with a common purpose to accelerate scientific discovery:
  - The Biomarkers Consortium



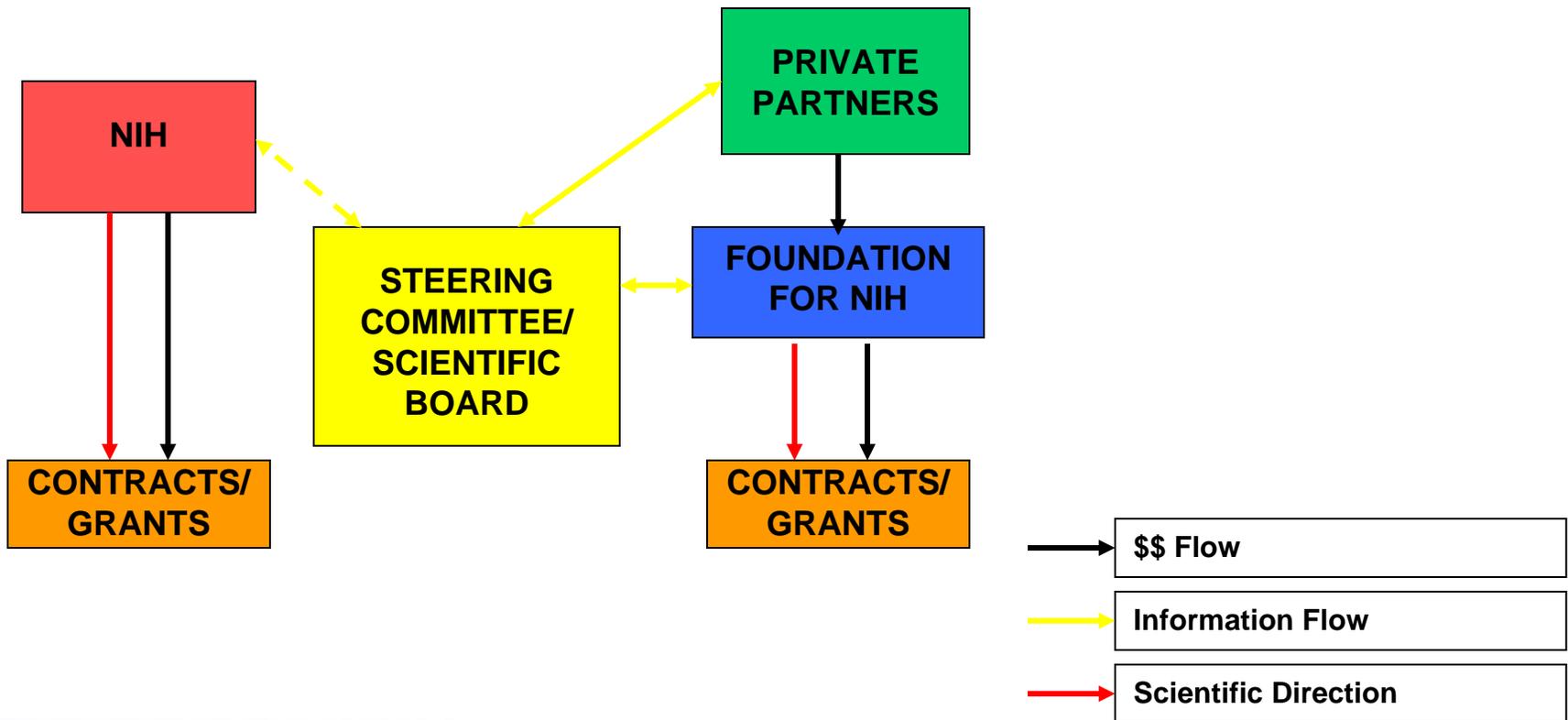
## Model 1: NIH-Managed

Private Funds to FNIH Pooled with NIH Funding



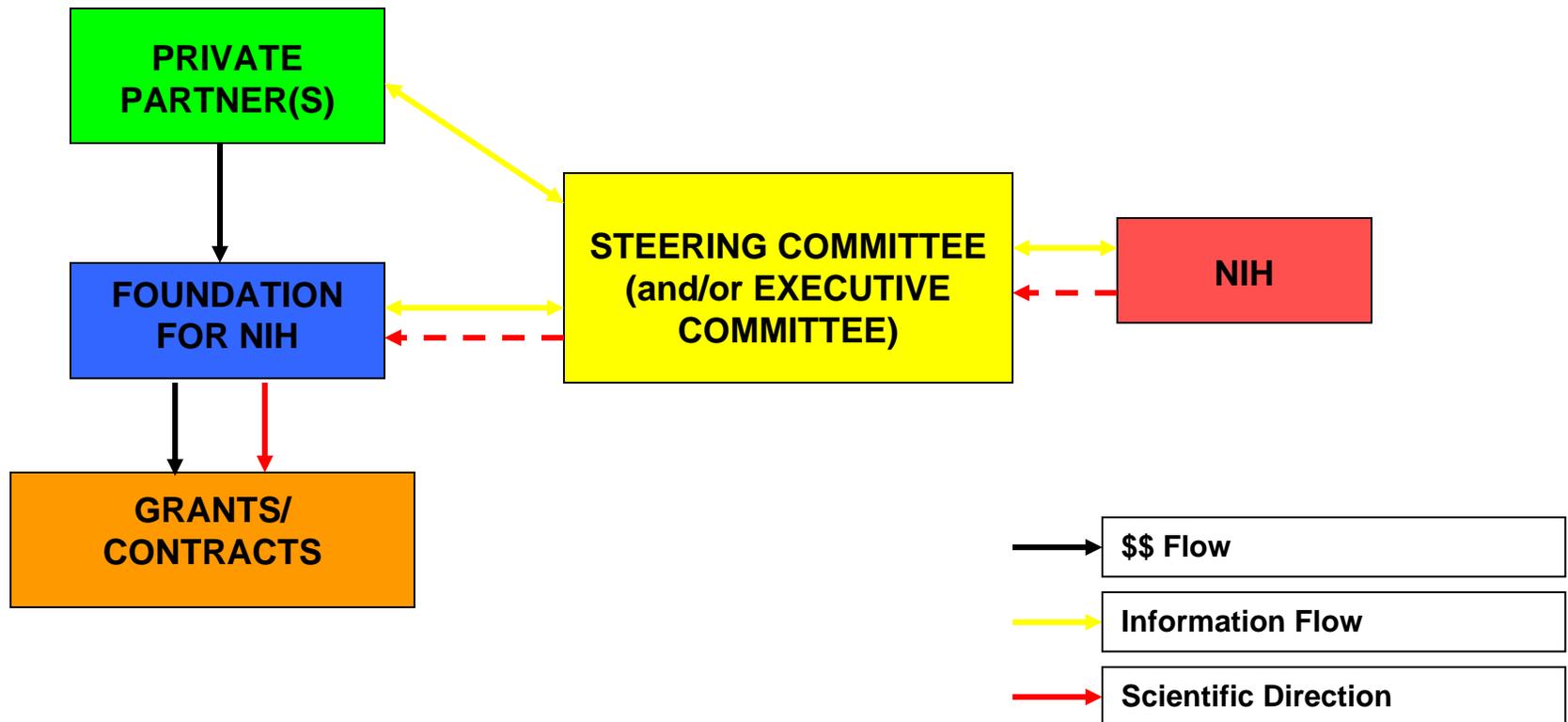


## Model 2: Parallel NIH and FNIH Funding Supplementing NIH's Efforts





## Model 3: FNIH-Managed NIH in Advisory Capacity





## Process of Forming a Partnership

- Identify new initiative
- Hold first discussion with core group of potential partners
- Discuss budget, project description, and timeline using the Request for Collaboration form
- Seek preliminary approval from the NIH IC and the Chairman of the FNIH Board
- Draft project “charter” outlining roles and responsibilities for each partnership group (example: NIH, FDA, private funders, academic partners, etc.)
- Broaden discussions to include larger group of potential partners/funders
- Refine budget, project description, project charter, and timeline and complete Request for Collaboration and share with FNIH Board and NIH
- Establish Memorandum of Understanding between FNIH and NIH
- Secure funding commitments and establish Letters of Agreement between FNIH and each private-sector funder
- Negotiate award agreements with any grantees/contractors



# Major Public-Private Partnerships

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<b>Grand Challenges in Global Health</b> Partner: Bill & Melinda Gates Foundation	<b>\$200M</b>
<b>Collaboration for AIDS Vaccine Discovery (CAVD)</b> Partners: VRC/NIAID, Bill & Melinda Gates Foundation	<b>\$33M</b>
<b>Genetic Association Information Network (GAIN)</b> Partners: NHGRI, NLM & Pfizer, Affymetrix, Broad Institute, Perlegen, Abbott Laboratories	<b>\$28.4M</b>
<b>Alzheimer's Disease Neuroimaging Initiative (ADNI)</b> Partners: NIA & Pfizer, Eli Lilly, Merck, Novartis, GlaxoSmithKline, Bristol-Myers Squibb, AstraZeneca, Eisai, Elan, Merck, Wyeth, Innogenetics, GE Healthcare, Alzheimer's Association, Alzheimer's Drug Discovery Foundation	<b>\$23M</b>
<b>Osteoarthritis Initiative (OAI)</b> Partners: NIAMS & Pfizer, Novartis, Merck, GlaxoSmithKline	<b>\$20.9M</b>
<b>Avon-NCI Progress for Patients Award Program</b> Partners: NCI & Avon Foundation	<b>\$15.5M</b>
<b>The Edmond J. Safra Family Lodge</b> Partners: NIH Clinical Center & Edmond J. Safra Philanthropic Foundation, Merck, Bristol-Myers Squibb, and others	<b>\$9.6M</b>
<b>Schizophrenia Metabolic Initiative</b> Partners: NIMH & Bristol-Myers Squibb	<b>\$8M</b>
<b>Human Papilloma Virus Clinical Trial</b> Partners: NCI & GlaxoSmithKline	<b>\$7.4M</b>
<b>The Biomarkers Consortium</b> Partners: NIH, FDA, CMS, PhRMA, BIO, pharmaceutical/biotech companies, non-profits	<b>\$2.1M</b>



# Active Cancer Projects, NCI

<u>Research Initiatives</u>	<u>Funds to Date</u>
<p><b>Avon-NCI Progress for Patients Awards Program</b> Partners: NCI &amp; Avon Foundation</p>	<b>\$13M</b>
<p><b>Biotechnology Resource for Innovation &amp; Development in Genomedicine (BRIDGE)</b> Partners: NCI, Avon Foundation, &amp; an individual donor</p>	<b>\$1.5M</b>
<p><b>Cooperative Breast Cancer Tissue Resource (CBCTR)</b> Partners: NCI &amp; Breast Cancer Research foundation</p>	<b>\$500K</b>
<p><b>Endotoxin</b> Partners: NCI, CC &amp; GlaxoSmithKline</p>	<b>\$1.8M</b>
<p><b>FDG-PET Lung and Lymphoma Trials</b> Partners: NCI, Amgen, AstraZeneca, Bristol-Myers Squibb, Genentech, GSK, Johnson &amp; Johnson, Leukemia &amp; Lymphoma Society, Merck &amp; Company, Inc</p>	<b>\$7.5M</b>
<p><b>HPV-GSK Clinical Trial</b> Partners: NCI &amp; GlaxoSmithKline</p>	<b>\$7.3M</b>
<p><b>Imaging Database Resources Initiative</b> Partners: NCI, Agfa, Carestream Health, Fuji, GE, iCAD, Siemens, Philips, Riverain</p>	<b>\$1.2M</b>
<p><b>The Biomarkers Consortium projects</b> The Cancer Steering Committee, chaired by Anna Barker, PhD (NCI), and Barbara Weber, MD (GSK), focuses on selecting, developing, and validating biomarkers of relevance to cancer and related disorders.</p>	<b>TBD</b>



# Active Cancer Projects, NCI

<u>Education Programs, Fellowships, Awards</u>	<u>Funds to Date</u>
<b>Adolescent and Young Adult Oncology PRG</b> Partner: NCI & Lance Armstrong Foundation	<b>\$328K</b>
<b>Adam Berry Memorial Fund</b> Partner: NCI, Australian Academy of Sciences, & an individual donor	<b>\$13K</b>
<b>Collaborative Summit on Breast Cancer Research</b> Partners: NCI, Avon Foundation, & Susan G. Komen for the Cure (organizing partners also included AACR, American Cancer Society, ASCO Foundation, The Breast Cancer Research Foundation, National Breast Cancer Coalition Fund, & Polo Ralph Lauren Foundation Pink Pony)	<b>\$245K</b>
<b>Sally Rosen Kaplan Fellowship for Women Scientists in Cancer Research</b> Partners: NCI and Kaplan estate	<b>\$788K</b>
<b>Overcoming Barriers to Early Phase Clinical Trials</b> Partners: NCI, Bristol-Myers Squibb, Eli Lilly, GSK, Novartis & Sanofi-Aventis	<b>\$2.8M</b>
<b>Targeted Cancer Therapies Tutorials</b> Partners: NCI & Genentech	<b>\$350K</b>

.....And numerous other projects in development



## Moving Forward

- The Foundation for NIH helps underwrite biomedical research enterprise by providing a platform on which world-class partners, public and private, can come together to integrate and leverage the resources and insights special to each to build research value and outcomes not readily attainable in separate efforts.
- Many new research initiatives have been possible because of this new capacity
- NIH priorities are our points of reference
- FNIH has established strong scientific, managerial, administrative and logistic capabilities
- FNIH provides a neutral forum and preferred partner for federal and private sector collaborations to achieve shared goals
- FNIH provides an extremely flexible infrastructure and agile staff to deliver solutions needed by partners and donors
- FNIH looks forward to establishing new programs where our partnerships with NIH and the private sector add important value