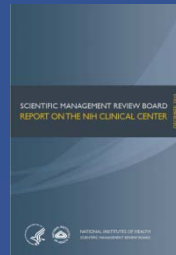




# SMRB RECOMMENDATIONS TO DATE



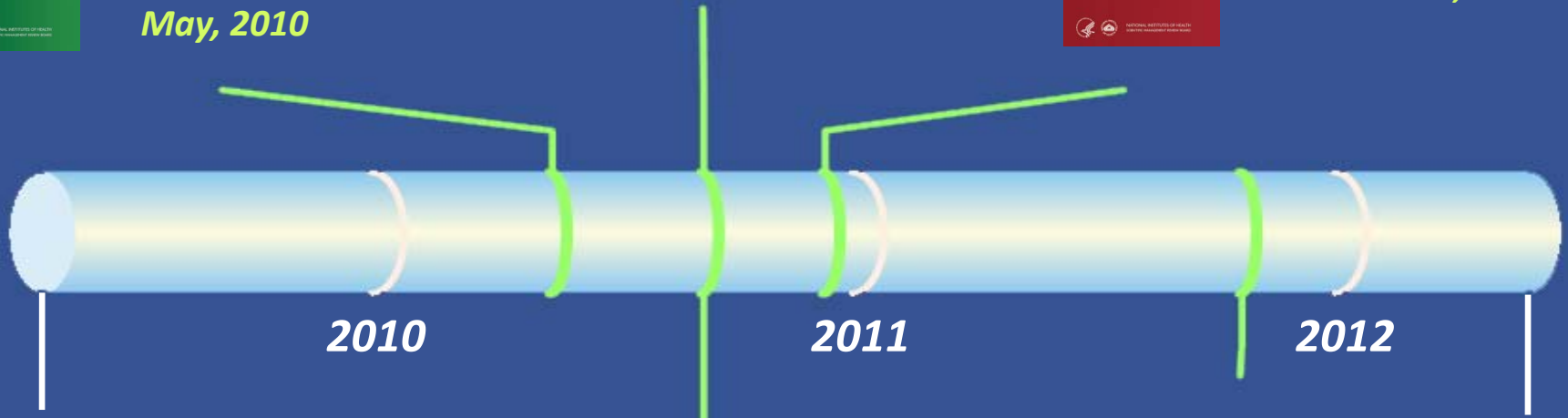
**DOCE  
Framework  
Established**  
*May, 2010*



**CC  
Recommendations**  
*September, 2010*



**TMAT  
Recommendations**  
*December, 2011*



**2010**

**2011**

**2012**

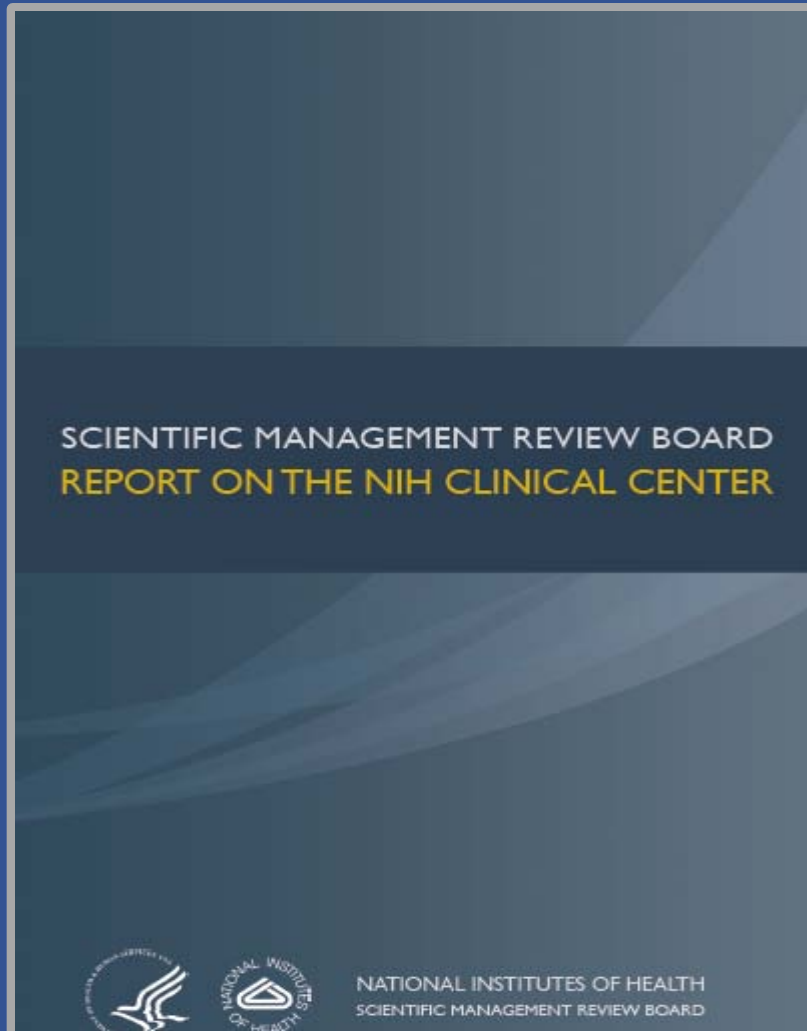
**1<sup>st</sup> SMRB  
Meeting**  
*April, 2009*



**SUAA  
Recommendations**  
*September, 2010*

**11<sup>th</sup> SMRB  
Meeting**  
*May, 2012*

# SMRB Recommendations: NIH Clinical Center



**CHARGE:** Provide an analysis of and recommendations regarding the fiscal sustainability and utilization of the NIH Clinical Center.

**RECOMMENDATIONS:** The NIH Clinical Center [should] have an expanded vision and role; a streamlined governance structure; and a stable, adequate budget for fiscal viability and sustainability.

Available at <http://smrb.od.nih.gov/>

# SMRB Recommendations: NIH Clinical Center

## *Clinical Center Governing Board*

- Charged with serving as a Board of Trustees to provide:
  - Strategic and operational oversight with the objective of facilitating high quality, cost effective clinical research
  - Budget recommendations that promote stable funding, consistent with the intent of the SMRB



# SMRB Recommendations: NIH Clinical Center

## *CC-Extramural Collaborations Committee*

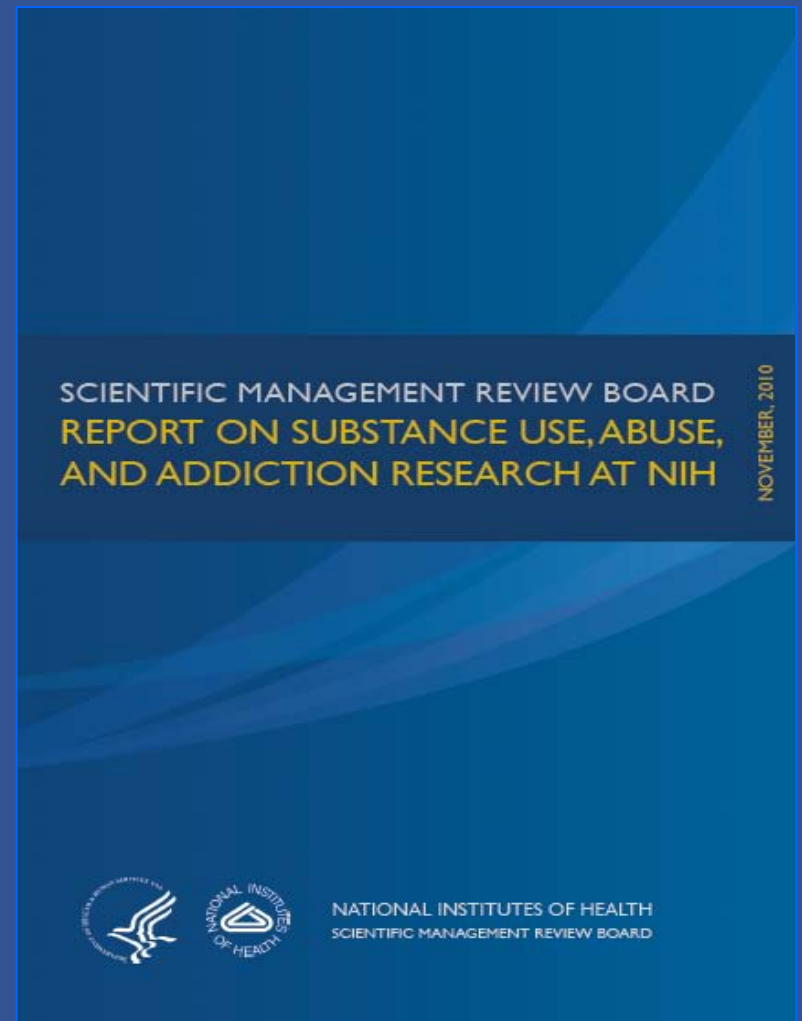
- Charged with developing a FOA that promotes clinical research collaborations between intramural and extramural investigators
- **June, 2012:** Issued Notice of Intent to published
- **August 2012:** FOA to be published
- **November, 2012:** Scheduled receipt date for applications
- **July-August, 2013:** Awards to be issued



# SMRB Recommendations: Substance Use, Abuse, and Addiction Research at NIH

**CHARGE:** Consider whether changes within NIH could further optimize research into substance use, abuse, and addiction.

**RECOMMENDATIONS:** Establish a new institute that encompasses all substance use, abuse, and addiction-related research and dissolve the independent existence of NIAAA and NIDA.

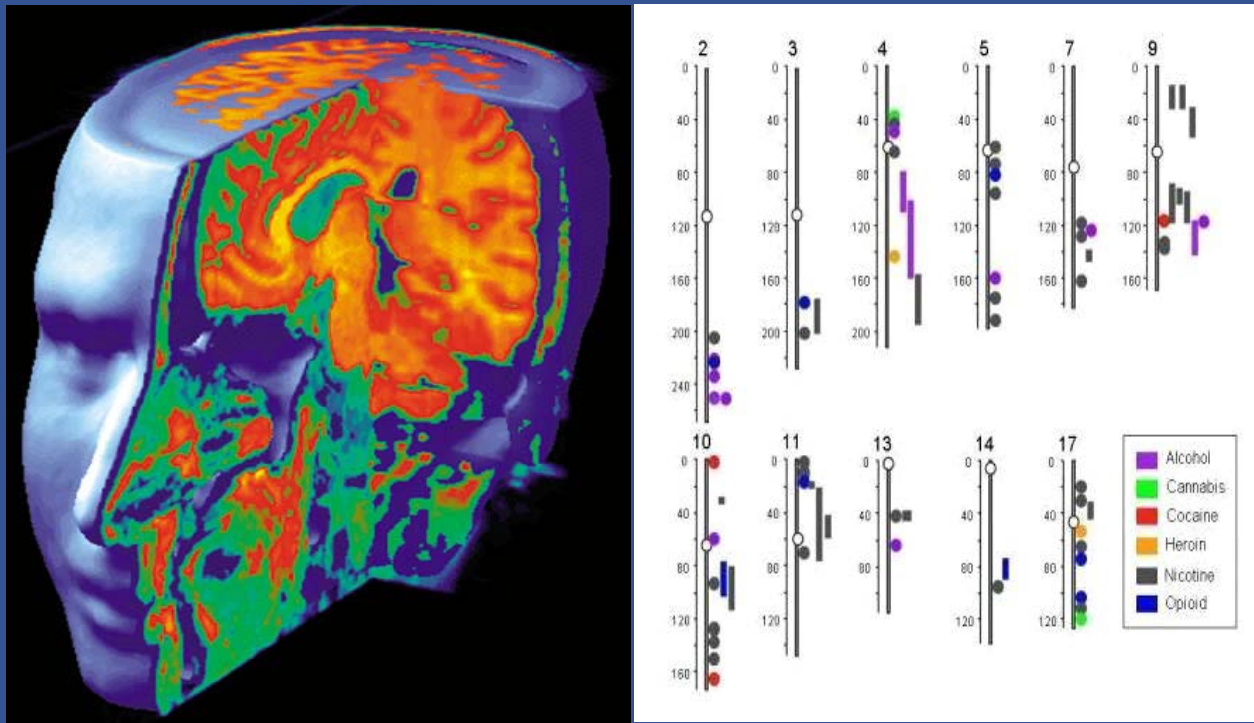


Available at <http://smrb.od.nih.gov/>

# NIH Update: Substance Use, Abuse, and Addiction Research at NIH

“The formation of a single, new Institute devoted to such research makes scientific sense and would enhance NIH's efforts to address the substance abuse and addiction problems that take such a terrible toll on our society.”

*- Statement of NIH Director Francis Collins, MD, PhD, November 18, 2010*



# NIH Update: Substance Use, Abuse, and Addiction Research at NIH

- **January–March, 2011:** NIH Task Force formed to gather data and consult with IC scientific staff
- **April 2011:** NIH Task Force developed draft principles to guide reorganization
- **By Fall, 2012:** NIH Task Force & Strategic Planning Committee:
  - Complete SUAA portfolio analysis and develop a portfolio integration plan for public comment
  - Develop Scientific Strategic Plan including input from stakeholders
    - February, 8 2012 to May 11, 2012: Requests for Information (RFI)
      - Received 494 responses
    - April 2, 2012: Conducted a Web Meeting on the RFI
    - June/July 2012: Meetings with targeted sets of stakeholders



# NIH Update: Substance Use, Abuse, and Addiction Research at NIH

- **Fall, 2012**
  - Release of Portfolio Integration Plan and public comment period
  - Release of Scientific Strategic Plan and public comment period
- **December 2012:** Final Recommendations to NIH Director
- **January/February 2013:**
  - Include in President's FY 2014 Budget
  - Begin implementing portions of Scientific Strategic Plan that are not dependent on reorganization
- **October 2013 (FY 2014):** Launch the new National Institute of Substance Use and Addiction Disorders (*working name*)

# SMRB Recommendations: Translational Medicine and Therapeutics

**CHARGE:** Design a NIH network - including a description of its attributes, activities, and functional capabilities - for advancing therapeutics development

**RECOMMENDATIONS:** Create a new NIH Center with the mission of supporting and strengthening translational medicine; evaluate its impact on other relevant programs at NIH, including NCRR.



Available at <http://smrb.od.nih.gov/>

# NIH Update: Translational Medicine and Therapeutics - *NIH NCRR Task Force*

- Task Force concurred with SMRB, concluding that many programs remaining in NCRR following the CTSA's transfer would benefit from enhanced scientific adjacency in other ICs
- **January, 2011:** Straw model, informed by input from NCRR leadership and NCRR subject matter experts – released for comment
- **February, 2011:** Task Force reported results of its analysis to the SMRB
- **March, 2011:** Final recommendations issued to NIH Director
- **December, 2011:** NCRR officially dissolved by the enactment of the Consolidated Appropriations Act of 2012 (P.L. 112-74)

# NIH Update: Translational Medicine and Therapeutics – NIH NCRR Task Force

| PLACEMENT                                       | PROGRAM   |
|---|---|
| NCATS   | <ul style="list-style-type: none"> <li>• Clinical and Translational Science Awards (CTSA)</li> </ul>  |
| NHLBI   | <ul style="list-style-type: none"> <li>• Gene Vector Repository</li> </ul>  |
| NIBIB   | <ul style="list-style-type: none"> <li>• Imaging and Point-of-Care Biomedical Technology Research Centers (BTRC) grants</li> <li>• Biomedical Imaging and Point-of-Care research grants for Technology Research and Development and SBIR/STTR grants</li> </ul> |
| NIGMS   | <ul style="list-style-type: none"> <li>• Institutional Development Awards (IDeA)</li> <li>• All other BTRC grants</li> <li>• All other research grants for Technology Research and Development, and the SBIR/STTR and BIRN network grants</li> </ul>            |
| NIMHD   | <ul style="list-style-type: none"> <li>• Research Centers in Minority Institutions program (RCMI)</li> </ul>  |
| OD - Office of Research Infrastructure Programs | <ul style="list-style-type: none"> <li>• Comparative Medicine Program</li> <li>• Extramural Construction and Animal Facilities Improvement</li> <li>• Shared and High-End Instrumentation</li> <li>• Science Education Partnership Awards (SEPA)</li> </ul>     |

# NIH Update: Translational Medicine and Therapeutics

## Creation of the new National Center for Advancing Translational Sciences (NCATS)

- Established on December 23, 2011
- Part of Consolidated Appropriations Act 2012 (PL 112-74)



# NCATS: Pursuing Opportunities for Disruptive Innovation



*“To catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.”*

<http://ncats.nih.gov/>



# **NCATS: Imported Programs and Initiatives**

## **Clinical and Translational Science Activities**

- Clinical and Translational Science Awards

## **Rare Diseases Research and Therapeutics**

- Therapeutics for Rare and Neglected Diseases
- Office of Rare Diseases Research

## **Re-engineering Translational Sciences**

- NIH Chemical Genomics Center
- Bridging Interventional Development Gaps
- Toxicology in the 21st Century

# NCATS: New Initiatives Underway

## ■ Tissue Chip for Drug Screening



- *Constriction Point:* Low concordance between animal-human tox.
- *Innovative Approach:* Develop chip mimicking human physiology for better prediction of drug safety and efficacy

## ■ Rescuing and Repurposing

- *Constriction Point:* Lengthy, complex process for gaining access to compounds
- *Innovative Approach:* Match pharma compounds with NIH scientists' ideas for new uses



## ■ Target Validation



- *Constriction Point:* No systematic process for identifying targets
- *Innovative Approach:* Develop new tools and methods to efficiently identify druggable targets

**New CAN authorities will enable us to do these cool things more nimbly!**

# NCATS: Moving Forward

- Replace Acting Leadership
- Convene Advisory Council and CAN Board
- Issue new RFAs in June for
  - CTSAs
  - Therapeutic Discoveries Program
- Conduct IOM studies:
  - CAN review by Drug Development Forum (June 4-5, 2012)
  - CTSA review (late 2012)

# SMRB Recommendations





# NIH...

## Turning Discovery Into Health

