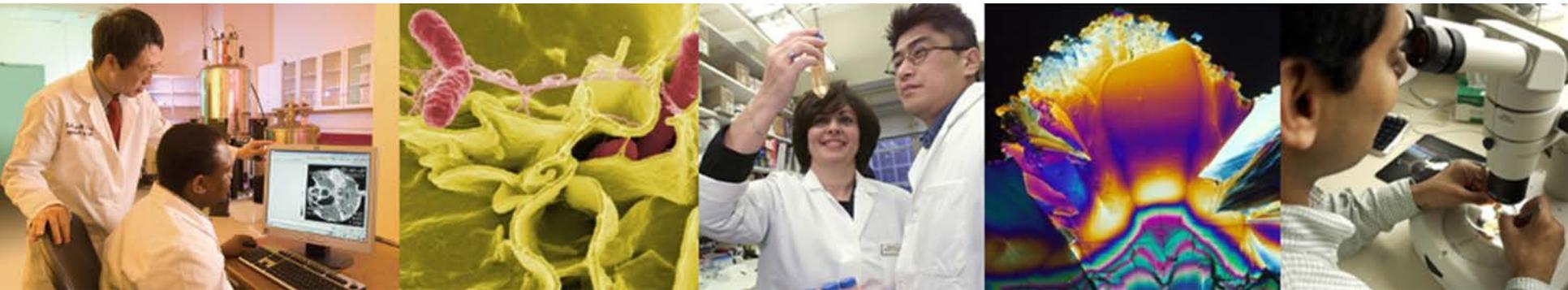


# Update: Enhancing Rigor and Reproducibility of Research Findings

*Advisory Committee to the Director (ACD)  
December 12<sup>th</sup>, 2014*



Lawrence A. Tabak, DDS, PhD  
Deputy Director, NIH  
Department of Health and Human Services



# The Growing Challenge

- Noted by research community; in multiple publications

## Beware the creeping cracks of bias in research areas

Evidence is mounting that research is riddled with unchecked, this could erode public trust, warn

preclinical

Believe it or not: how much can we rely on published data on potential drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah

**False-Positive Psychology: Undisclosed Flexibility in Data Collection and Analysis Allows Presenting Anything as Significant**

## Drug targets slip-sliding away

The starting point for many drug discovery programs is a published report on a new drug target. Assessing the reliability of such papers requires a nuanced

**Reforming Science: Methodological and Cultural Reforms**

The Economist | World politics | Business & finance | Economics | Science & technology | Culture

**Unreliable research**

### Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not

Oct 19th 2013 | From the print edition

Like 11k | Tweet 1,227

### Why animal research needs to improve

Many of the studies that use animals to model human diseases are too small and too prone to bias to be trusted, says Malcolm Macleod.

Jason Ford

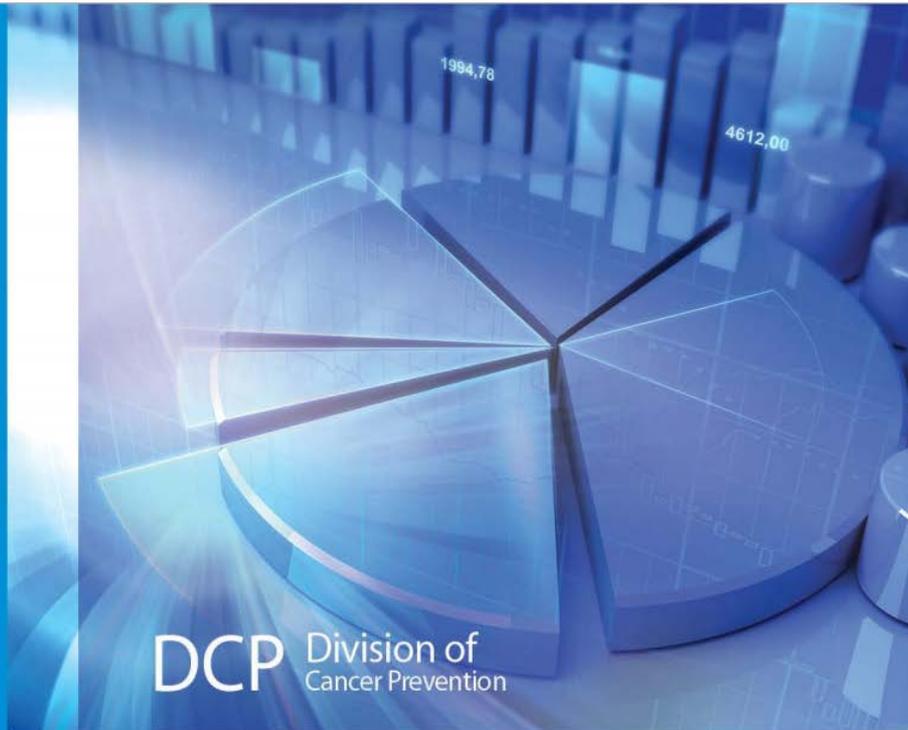
## Raise standards for preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

## A call for transparent reporting to optimize the predictive value of preclinical research

Story C. Landis<sup>1</sup>, Susan G. Amara<sup>2</sup>, Khusru Asadullah<sup>3</sup>, Chris P. Austin<sup>4</sup>, Robi Blumenstein<sup>5</sup>, Eileen W. Bradley<sup>6</sup>, Ronald G. Crystal<sup>7</sup>, Robert B. Darnell<sup>8</sup>, Robert J. Ferrante<sup>9</sup>, Howard Fillit<sup>10</sup>, Robert Finkelstein<sup>1</sup>, Marc Fisher<sup>11</sup>, Howard E. Gendelman<sup>12</sup>, Robert M. Golub<sup>13</sup>, John L. Goudreau<sup>14</sup>, Robert A. Gross<sup>15</sup>, Amelie K. Gubitzi<sup>1</sup>, Sharon E. Hesterlee<sup>16</sup>, David W. Howells<sup>17</sup>, John Huguenard<sup>18</sup>, Katrina Kelner<sup>19</sup>, Walter Koroshetz<sup>1</sup>, Dimitri Krainc<sup>20</sup>, Stanley E. Lazic<sup>21</sup>, Michael S. Levine<sup>22</sup>, Malcolm R. Macleod<sup>23</sup>, John M. McCall<sup>24</sup>, Richard T. Moxley III<sup>25</sup>, Kalyani Narasimhan<sup>26</sup>, Linda J. Noble<sup>27</sup>, Steve Perrin<sup>28</sup>, John D. Porter<sup>1</sup>, Oswald Steward<sup>29</sup>, Ellis Unger<sup>30</sup>, Ursula Utz<sup>1</sup> & Shai D. Silberberg<sup>1</sup>

The US National Institute of Neurological Disorders and Stroke convened major stakeholders in June 2012 to discuss how to improve the methodological reporting of animal studies in grant applications and publications. The main workshop recommendation is that at a minimum studies should report on sample-size estimation, whether and how animals were randomized, whether investigators were blind to the treatment, and the handling of data. We recognize that achieving a meaningful improvement in the quality of reporting will require a concerted effort by investigators, reviewers, funding agencies and journal editors. Requiring better reporting of animal studies will raise awareness of the importance of rigorous study design to accelerate scientific progress.



**NCI-FDA-NIST Workshop on Standards in Molecular Diagnostics for the Discovery and Validation of Clinically Useful Cancer Biomarkers:**

***Recommendations from the***  
**National Cancer Institute**  
**U.S. Food and Drug Administration**  
**National Institute of Standards and Technology**

Workshop: December 7, 2012  
REPORT

**December 7, 2012:**

- Workshop held by NCI, in partnership with FDA and NIST
- Focused on:
  - “State of the science” in standardization of molecular diagnostics
  - Survey of what has been successful and what remains challenging
  - Presentations of real and mock submissions to the FDA
  - Discussions of future priorities

# NIH plans to enhance reproducibility

**Francis S. Collins** and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

**A** growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring<sup>1,2</sup>. As leaders of the US National Institutes of Health (NIH), we share this concern and here explore some of the significant interventions that we are planning.

Science has long been regarded as 'self-correcting', given that it is founded on the replication of prior work. Over the long term, that principle remains true. In the

shorter term, however, the checks and balances that once ensured scientific fidelity have been hobbled. This has compromised the ability of today's researchers to reproduce others' findings.

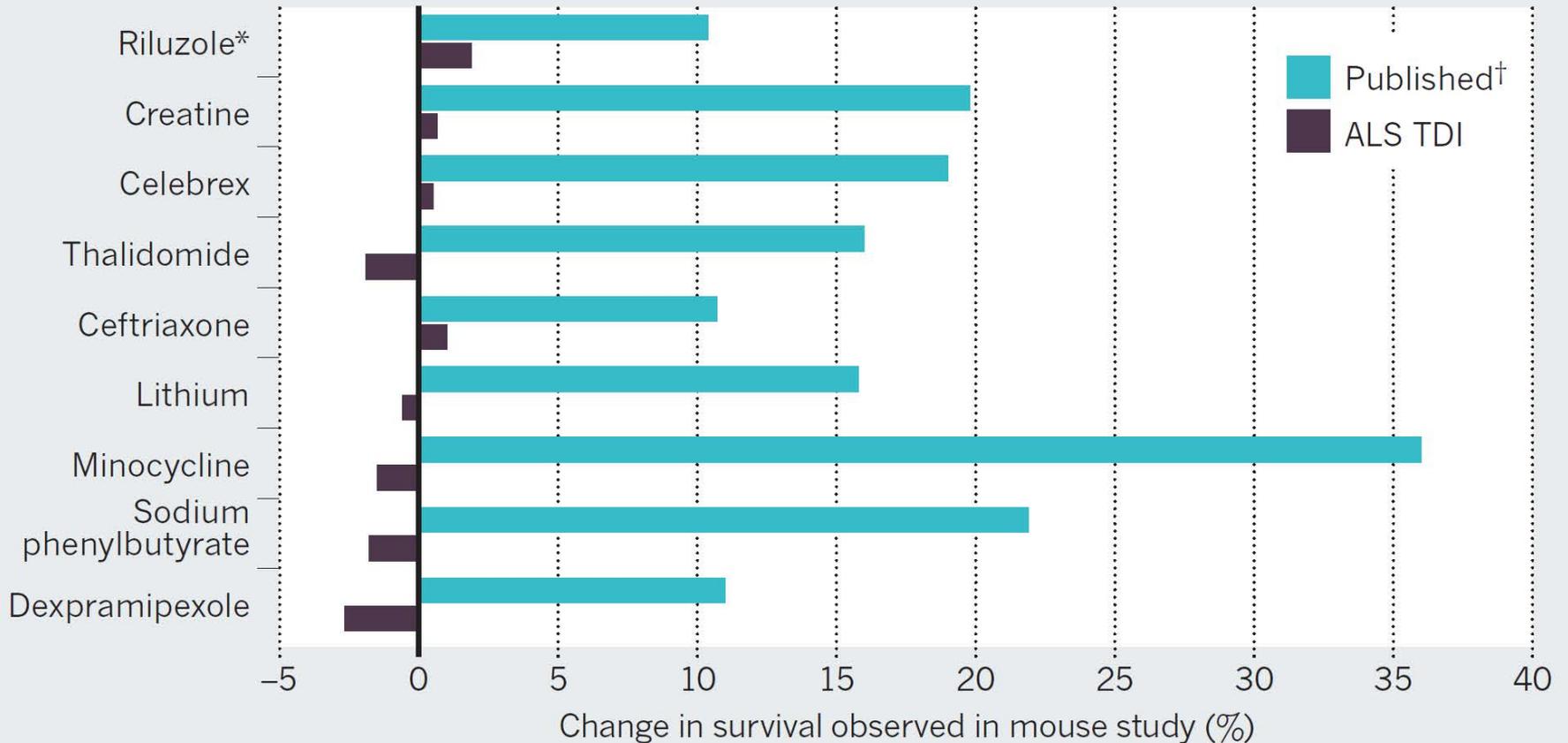
Let's be clear: with rare exceptions, we have no evidence to suggest that irreproducibility is about scientific misconduct. In 2011, the Office of Research Integrity of the US Department of Health and Human Services pursued only 12 such cases<sup>3</sup>. Even if this represents only a fraction of the actual problem, such papers are vastly

# Challenges to Ensuring Rigor and Transparency in Reporting Science: Science and “Self-Correction”

- Science often viewed as “self-correcting”; immune from reproducibility problems
  - Principle remains true over the long-term
- Checks and balances for reproducibility in the short- and medium-term are hobbled by interrelated factors
  - Results in compromised ability to reproduce findings of others, particularly in preclinical research studies involving animal models of disease

## DUE DILIGENCE, OVERDUE

Results of rigorous animal tests by the Amyotrophic Lateral Sclerosis Therapy Development Institute (ALS TDI) are less promising than those published. All these compounds have disappointed in human testing.



\*Although riluzole is the only drug currently approved by the US Food and Drug Administration for ALS, our work showed no survival benefit.

†References for published studies can be found in supplementary information at [go.nature.com/hf4jf6](http://go.nature.com/hf4jf6).

# Challenges to Ensuring Rigor and Transparency in Reporting Science: Factors that “Short Circuit” Self-Correction

- Current “hyper-competitive” environment is fueled, in part, by:
  - historically low funding rates
  - over-dependence on “high profile” publications when grants are reviewed; institutions are making appointment, promotion, and tenure decisions
- Publication practices that contribute:
  - Difficulty in publishing negative findings
  - Overemphasis on the “exciting, big picture” finding sometimes results in publications leaving out necessary details of experiments

# Challenges to Ensuring Rigor and Transparency in Reporting Science: Factors that “Short Circuit” Self-Correction (cont.)

- Poor training leading to:
  - Inadequate experimental design – fundamental quality characteristics not reported/performed (e.g. blinded assessment, randomization, sample size calculations)
  - Inappropriate use of statistics (“p-hacking”)
  - Incomplete reporting of resources used and/or unexpected variability in resources

# NIH Response

# Trans-NIH actions

## *Implementation of pilots*

Pilot Focus	Approaches	Types of Efforts Being Developed
Training	<ul style="list-style-type: none"><li>• Develop materials for training module to enhance transparency and reproducibility of scientific reporting</li></ul>	<ul style="list-style-type: none"><li>• RFI of courses in experimental design</li><li>• RFA GM-15-006 to develop training modules—Ten ICs to support up to 21 awards at \$150K each</li><li>• Video training tools</li><li>• Intramural workshops speaking to pitfalls with cutting edge technologies</li></ul>

# Development of Training Materials

- NIGMS funding opportunity (multiple ICs have signed on) supporting the development of training modules to enhance reproducibility
  - [RFA-GM-15-006](#): Closed on November 21<sup>st</sup>, 2014
  - 10 ICs, \$3.1M, ~20 awards
- NIH training materials on experimental design, rigor, and reproducibility
  - Release of modules expected in early 2015; will be made publicly available

# Exclusive Preview!

- Sample Size and Exclusion Criteria



# Development of Training Materials

- IRP workshops on data interpretation considerations for various experimental techniques
  - [First workshop held on November 24<sup>th</sup>](#), 2014, 5 sessions covering imaging, FRET, FACS, and cell-based models
  - Publicly available at:  
<http://videocast.nih.gov/summary.asp?Live=15277&bhcp=1>
- Future sessions:
  - Structural Biology: March 2015
  - Genomics: April/May 2015

# Trans-NIH actions

## *Implementation of pilots*

Pilot Focus	Approaches	Types of Efforts Being Developed
Training	<ul style="list-style-type: none"> <li>• Develop materials for training module to enhance transparency and reproducibility of scientific reporting</li> </ul>	<ul style="list-style-type: none"> <li>• RFI of courses in experimental design</li> <li>• RFA GM-15-006 to develop training modules—Ten ICs to support up to 21 awards at \$150K each</li> <li>• Video training tools</li> <li>• Intramural workshops speaking to pitfalls with cutting edge technologies</li> </ul>
Enhance grant application review	<ul style="list-style-type: none"> <li>• Reviewer checklists on standards/scientific rigor</li> <li>• Evaluation of scientific premise/grant applications</li> <li>• Support replication studies</li> <li>• Consider sex as a biological variable</li> <li>• Identification of cell lines</li> </ul>	<ul style="list-style-type: none"> <li>• Study section pilots</li> <li>• New FOAs with additional review criteria regarding scientific premise</li> <li>• Pilot use of contract service; replication centers being contemplated</li> <li>• RFI</li> </ul>

# Scientific Rigor: Review Criteria

- **Significance:**

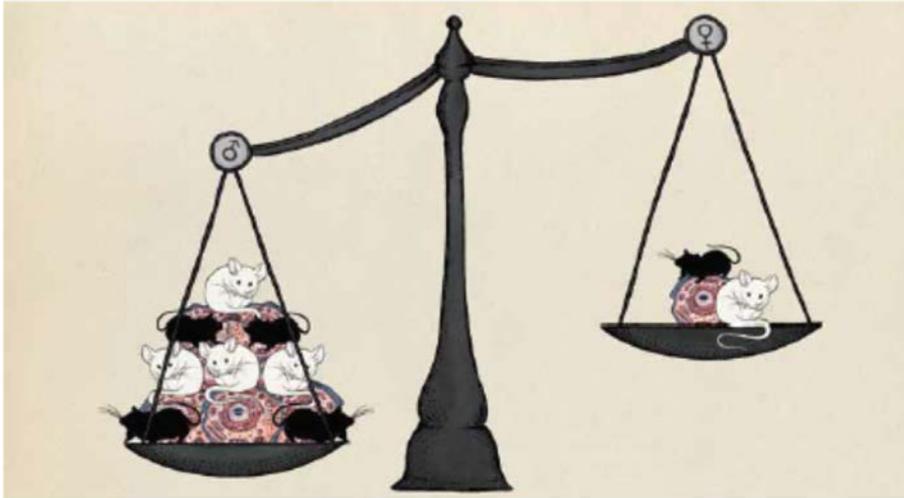
- Is the scientific premise of the project grounded in evidence from rigorously designed studies?

- **Approach:**

- Have the investigators presented adequate plans to ensure the scientific rigor of experimental design, methodology, analysis, and interpretation by including strategies to ensure a robust and unbiased approach and to address biological variables, such as sex, as appropriate for the work proposed?

COMMENT

May 14, 2014



## NIH to balance sex in cell and animal studies

Janine A. Clayton and Francis S. Collins unveil policies to ensure that preclinical research funded by the US National Institutes of Health considers females and males.

Clayton JA, Collins FS.  
*Nature*. 2014 May 15;509(7500):282-3.

## NIH Takes Steps to Address Sex Differences in Preclinical Research

May 14, 2014

Over the past two decades, we have learned a great deal about how men and women respond differently to medications. This knowledge came after a concerted effort in the NIH-funded clinical research participants are cell and animal research to increase the number of women in just over half of NIH-funded clinical unfortunately, experimental design in ways followed suit. An over-reliance on the sex of cells, can lead to should be guiding clinical studies, and ultimately, clinical practice. NIH is taking action to address this shortfall as outlined by Janine A. Clayton, M.D., Director of the NIH Office of Research on Women's Health, and me in the *Nature* Comment below.

Francis S. Collins, M.D., Ph.D.  
Director, National Institutes of Health

### Director's Page

Filling the Gaps: NIH Enacts New Policies to Address Sex Differences

Posted May 14, 2014

Today in *Nature*, National Institutes of Health (NIH) Director Dr. Francis Collins and I announce that NIH will be requiring applicants to report their cell and animal

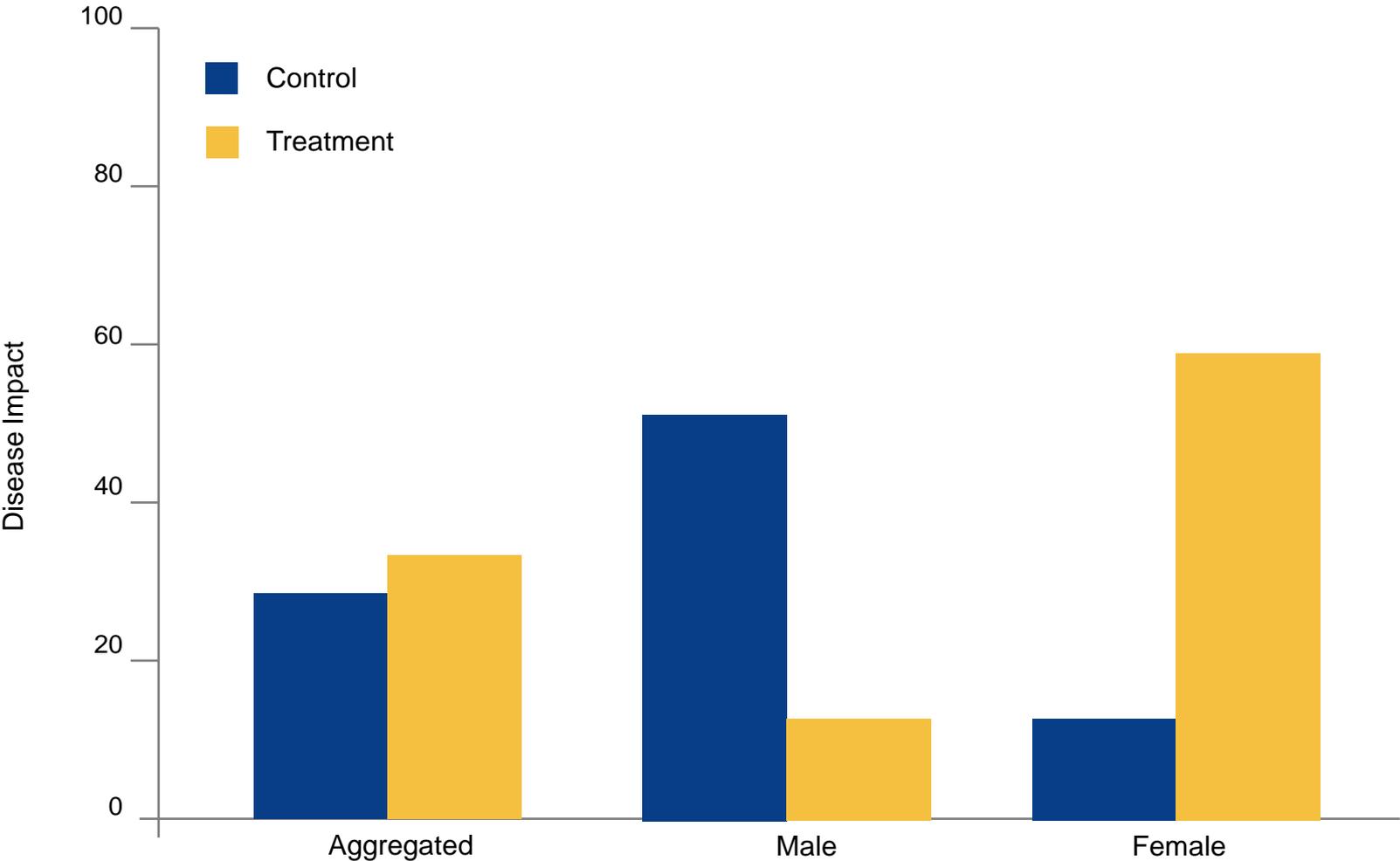
experimental design. By developing this policy, we are promoting a balanced approach to addressing male and female differences in cells and animals – just as we did years ago with women and men in NIH-funded clinical trials.



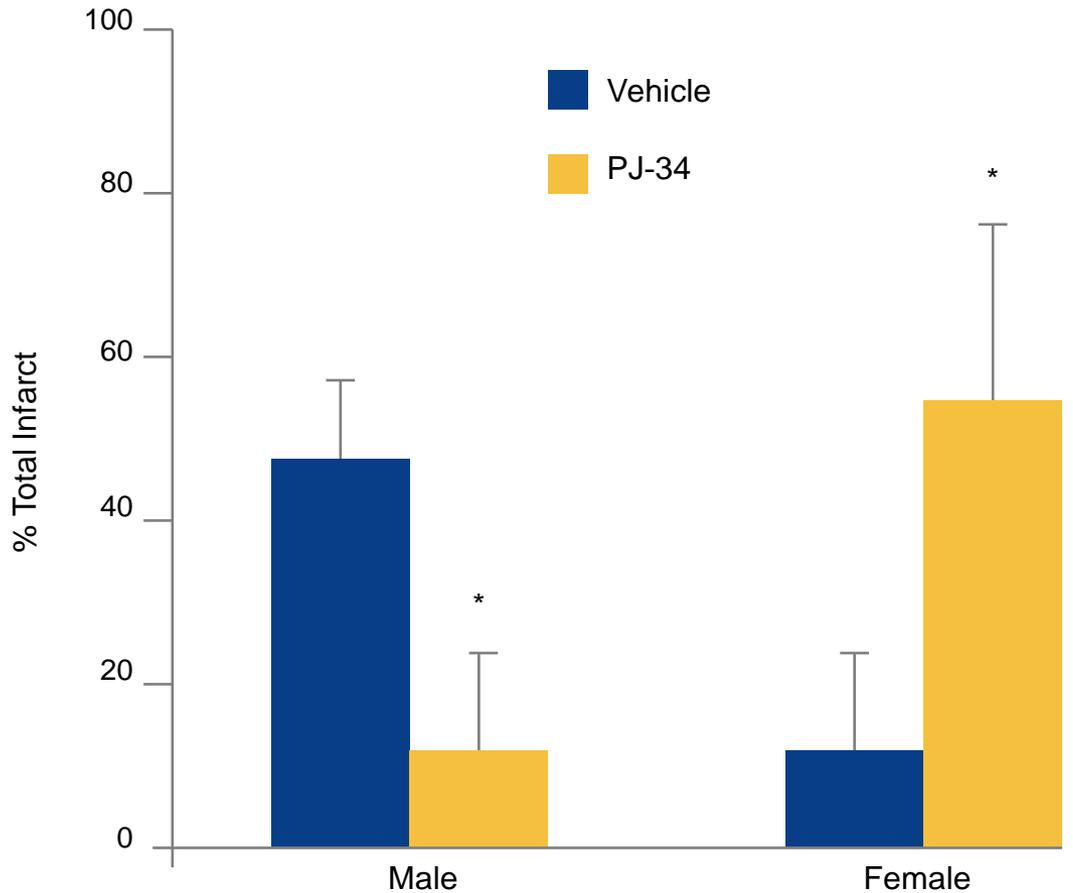
Janine Austin Clayton, M.D.



# Biological/Disease Impact of Experimental Design



# Real Life



The effects of the selective poly-ADP ribose polymerase (PARP-1) inhibitor PJ-34 in wild-type (WT) mice of both genders. Treatment with PJ-34 at ischemic onset reduced total infarction in male mice compared with saline-treated controls (\*  $P < 0.001$ ). A significant increase in ischemic damage was seen in PJ-34-treated females compared with control (\*  $P < 0.001$ ).

# Reproducibility in Cell Culture Studies

- >400 misidentified cell lines have been cataloged, dating back to the 1960s.
- ~70% of researchers surveyed in 2004 had never checked the identity of their cell lines.
- Major repositories report that 14-30% of cell lines submitted are contaminated.
- In a 2013 survey, <50% of cell lines had an unambiguous identifier and source in publications.
- NIGMS currently exploring options for standards for cell line authentication and methods for cell authentication.

**NEWSFOCUS**



**Cases of Mistaken Identity**

**For decades, biologists working with contaminated or misidentified cell lines have wasted time and money and produced spurious results; journals and funding agencies say it's not their job to solve this problem**

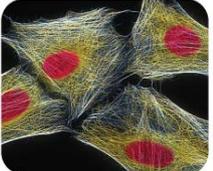
**IN THE 1980S, WHEN HE WAS A** postdoctoral fellow at the Scripps Research Institute in San Diego, California, Reinhard Kofler received what was supposed to be a human cancer cell line from a collaborator. "We cultured it, we cloned genes into it," he recalls, then "[we] genotyped it and realized it was 100% mouse."

After scores of similar experiences with misidentified cells, Kofler and his colleagues at the Tyrolean Cancer Research Institute in Innsbruck, Austria, now authenticate every line as soon as it arrives at the institute. And periodically afterward, they use a simple, cheap, quick, and reliable DNA fingerprinting technique to verify that each cell line continues to be what it should be. "It's an absolute must now," says Kofler. His lab "repeatedly" encounters problems with cell line contamination, and without this constant vigilance, Kofler says, "I wouldn't be confident about our work."

Buehring of the University of California, Berkeley, and her colleagues, showed that less than 50% of researchers regularly verify the identities of their cell lines using any of the standard techniques such as DNA fingerprinting. "Everybody is in denial" about the widespread problem of cell line cross contamination, says Charles Patrick Reynolds of the University of Southern California and the Children's Hospital Los Angeles' Institute for Pediatric Clinical Research, who establishes new pediatric cancer cell lines and tests potential cancer drugs on existing lines.

Indeed, many studies have shown that a surprisingly large number of cell lines have become contaminated, often by older, more well-established cancerous cells. For example, according to a 1999 paper by Roderick MacLeod and his colleagues at the German Cell Bank (DSMZ) in Braunschweig, 18% of 252 lines donated to the bank were misidentified or contaminated. The extent of the problem "always seems to come as a surprise for people," says John Masters of University College London, president of the European Tissue Culture Society.

And even though biologists read and hear about cross contamination, "people just think that this is not a problem in my lab," says Reynolds. If contaminated cell lines are used merely as "test tubes" to express proteins, a lab's work may not be affected. But, say Masters and others,



Downloaded from www.sciencemag.org on April 11, 2014

# Reproducibility in Cell Culture Studies

## Possible action areas:

- Add a section to applications analogous to model organism sharing plans on plans for validation of key reagents, including cell lines
- Facilitate the development and dissemination of consensus standards for authentication, handling, controls, and reporting
- Promote development of more efficient and cost-effective tools for characterizing cell lines and reagents
- Promote development of defined, controllable and affordable cell culture media and reagents

# Trans-NIH actions

## *Implementation of pilots (cont.)*

Pilot Focus	Approaches	Types of Efforts Being Developed
Post-publication review	<ul style="list-style-type: none"><li>• Provide “safe-space” for scholarly discourse of published work</li></ul>	<ul style="list-style-type: none"><li>• NGOs experimenting in this space, e.g., Reproducibility initiative by ScienceExchange – to validate findings via independent replication)</li><li>• PubMed Commons</li></ul>

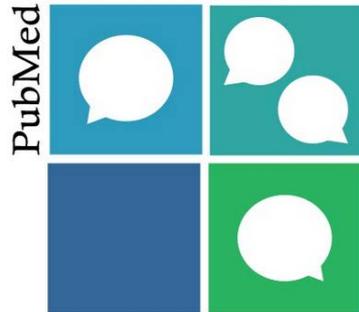
# PubMed Commons

## NIH DIRECTOR'S BLOG

### PubMed Commons: Catalyzing Scientist-To-Scientist Interactions

Posted on August 5, 2014 by Dr. Francis Collins

## COMMONS BLOG



Today's scientists find it tough to keep up with all of the latest journal articles, innovative methods, and interesting projects of colleagues in their fields. That's understandable, because there are tens of thousands of journals, hundreds of conferences in major fields, dozens of emerging

The screenshot shows the PubMed Commons website. At the top left is the PubMed logo and 'US National Library of Medicine National Institutes of Health'. A search bar is on the top right. The main heading is 'COMMONS' with the tagline 'A forum for scientific discourse'. Below this is a row of six colored squares (teal, dark blue, teal, green, dark blue, dark teal) with speech bubble icons. A 'Pilot' badge is on the last square. The text below reads: 'PubMed Commons enables authors to share opinions and information about scientific publications in PubMed'. There are links for 'Get Started', 'Guidelines', and 'FAQ'. The main content area features 'Top comments now' with two entries: 1. 'Troponin Elevations Only Detected With a High-sensitivity Assay: Clinical Correlations and Prognostic Significance.' by Korley FK, Acad Emerg Med 2014, with 2 comments. 2. 'Cognitive conflicts in major depression: Between desired change and personal coherence.' by Feixas G, Br J Clin Psychol 2014, with 2 comments. On the right side, there is a 'PubMed Commons Blog' section with the title 'Refining &amp; revising research on the public record' and a small image of a person in a lab. Below that is a 'Follow us' section with a Twitter icon. At the bottom right, there is a 'What people are reading' section with several trending articles.

### PubMed Commons Blog

#### Refining & revising research on the public record

August 27, 2014

The life of a research project often doesn't end when a publication appears in a journal. PubMed Commons members are posting updated and complementary information to keep work current.

[See full blog post](#)



### Follow us

### What people are reading

#### Trending articles - those with recent increases in activity

Last updated: August 29 09:04 a.m.

[Bidirectional switch of the valence associated with a hippocampal contextual memory engram](#)

Nature 2014

[Effects of sexual arousal on lymphocyte subset circulation and cytokine production in man](#)

Neuroimmunomodulation 2014.

[RNA switch at enhancers.](#)

Nat Genet 2014.

[Ribosome Profiling Reveals Pervasive Translation Outside of Annotated Protein-Coding Genes.](#)

Cell Rep 2014

[Cardiovascular risk and events in 17 low-, middle-, and high-income countries.](#)

PLoS Med 2014.

[Gary Ward](#) 2013 Dec 10 10:14 p.m. 3 of 3 people found this helpful

Notes further areas of interest, complementary approach to help validate conclusions

*T. gondii*, using a conditional dimerizable Cre recombinase (DiCre) system. Given essential genes can be disrupted for phenotypic characterization. In a coding proteins previously believed to be essential for parasite invasion, the case of the *myoA* knockout parasites, it would be interesting to see rates with the myosin motor complex (e.g., as assessed by a GAP45 IP) in

ence is presented to suggest that the actin knockouts remain capable of invasion and the authors suggest that the most important defect is instead in apicoplast segregation. Have the authors attempted to isolate and maintain an *act1* knockout clone in the presence of isopentenyl pyrophosphate (IPP)? Blood-stage *Plasmodium falciparum* can survive independently of the apicoplast as long as this isoprenoid precursor is provided (Yeh *et al. PLOS Biol* [2011] 9(8): e1001138). It would be interesting to look at the *T. gondii act1* knockout's ability (or perhaps inability) to invade and invade under

The picture that emerges from these ground-breaking studies is that myosin A model would posit, but that there is another previously unrecognized way for the

Posted by Gary Ward on behalf of the University of Vermont *Toxoplasma Journal* Kelsen, Shruthi Krishnamurthy, Jacqueline Leung, Pramod Rompikuntal, Luke

Reply Permalink Share Report

[Markus Meissner](#) 2014 Jan 22 07:52 a.m. 3 of 3 people found this helpful

Hello Vermont JC. Thank you for the comment and the intriguing question about the composition of the remaining motor complex in absence of MyoA and we currently perform these experiments. You might be interested in our current study, submitted as prepub (Egarter *et al.*, 2014 bioRxiv 01/2014; DOI:10.1101/001800) that addresses some of your questions. With regards to maintaining the *act1* KO in presence of IPP we planned this experiment until we were assured from experts working on the apicoplast in *Toxoplasma gondii* that IPP cannot complement apicoplast loss in this parasite (Sheiner *et al.* personal communication). I also agree with your conclusion that there must be an actin-myosin-MIC2 independent invasion mechanism and it will be very interesting to see if it plays a major role in wild type parasites as well. Future will tell.

Permalink Share Report

Was this helpful? [yes](#) | [no](#)

[Lilach Sheiner](#) 2014 Jan 22 08:24 a.m. 2 of 2 people found this helpful

Credit for IPP experiment: Boris Striepen and Carrie Brooks.

Permalink Share Report

Was this helpful? [yes](#) | [no](#)

Author replies  
Provides information for preprint, notes that proposed experiment doesn't work in this parasite

Conditional genome engineering in *Toxoplasma gondii* uncovers alternative invasion mechanisms

Nature Methods 2013

# Trans-NIH actions

## *Implementation of pilots (cont.)*

Pilot Focus	Approaches	Types of Efforts Being Developed
Post-publication review	<ul style="list-style-type: none"> <li>• Provide “safe-space” for scholarly discourse of published work</li> </ul>	<ul style="list-style-type: none"> <li>• NGOs experimenting in this space, e.g., Reproducibility initiative by ScienceExchange – to validate findings via independent replication)</li> <li>• PubMed Commons</li> </ul>
Reduce "perverse incentives"	<ul style="list-style-type: none"> <li>• Explore options with longer period of support</li> <li>• Change bio-sketch (coordinated by the Office of Extramural Research)</li> </ul>	<ul style="list-style-type: none"> <li>• NIH Pioneer Awards</li> <li>• NCI’s Outstanding Investigator Award</li> <li>• NIGMS’s Maximizing Investigators’ Research Award (in development)</li> <li>• RFI; pilots</li> </ul>

# Changes to the NIH Biosketch

- Pilot underway with OER coordinating efforts
- Roll-out of the modified biosketch for all grant applications received for FY 2016 funding and beyond (applications submitted in mid-2015)
- Also complements SciENcv, the federal-wide system that provides comprehensive CV information for applicants and reduces the administrative burden associated with grant applications

# Trans-NIH actions

## Leveraging ongoing activities

IC	Activity	Purpose
NIDDK	Mouse Metabolic Phenotyping Centers	Provides scientific community with high quality, standardized phenotyping services
NIAID	ImmPort and TrialShare	Provides access to clinical trials data
NIA	Interventions Testing Program Studies	Provides multi-site replication of preclinical studies
OD	BD2K initiatives in providing access to data	Will provide access to data sets including “negative findings”
NLM	Indexing and PubMed Commons	Links retractions, errata, and comments, discussions, and letters-to-the editor

# Stakeholder Engagement

- Workshop in June 2014 with Journal Editors to identify common opportunity areas
  - Endorsement of consensus principles by more than 135 journals

## ABOUT NIH

### About NIH

Mission

Impact of NIH Research

The NIH Director

Organization

Budget

History

Jobs at NIH

Image Bank

Frequently Asked Questions

The NIH Almanac

Virtual Tour of NIH

Visitor Information

Visitor Tours

Visitor Parking

Campus Shuttle

NIH...Turning Discovery  
Into Health®

NIH Publications List

Small Business  
Opportunities

## Principles and Guidelines for Reporting Preclinical Research

The signatories represent journals that publish preclinical biological research — an area of research that encompasses both exploratory studies and hypothesis-testing studies, with many different designs. The reproducibility of these studies is expected to vary. The journals agree to adhere to the following principles with the aim of facilitating the interpretation and repetition of experiments as they have been conducted in the published study. These measures and principles do not obviate the need for replication and reproduction in subsequent investigations to establish the robustness of published results across multiple biological systems.

### 1. Rigorous statistical analysis

A section outlining the journal's policies for statistical analysis should be included in the Information for Authors, and the journal should have a mechanism to check the statistical accuracy of submissions.

### 2. Transparency in reporting

Journals should have methods sections (including encouraging efficient examination by reviewers)

Journals should use a checklist during editorial processing to ensure the review process

### Background

NIH held a joint workshop in June 2014 with the Nature Publishing Group and Science on the issue of reproducibility and rigor of research findings, with journal editors representing over 30 basic/preclinical science journals in which NIH-funded investigators have most often published. The workshop focused on the common opportunities in the scientific publishing arena to enhance rigor and further support research that is reproducible, robust, and transparent.

The journal editors at that workshop came to consensus on a set of principles to facilitate these goals, which a number of journals have agreed to endorse. These principles and the journals that have agreed to endorse them are shown below.

### Related Links

Endorsements - Principles and Guidelines for Reporting Preclinical Research

Landis, et al Paper on Transparent Reporting of Preclinical Research

Workshop on Science

**nature**

**CellPress**  
**THE JOURNAL OF BIOLOGICAL CHEMISTRY**

**PLOS ONE**

**Science**

**AAAS**

**Circulation**

*The Journal of Neuroscience*

And more than 125 more!

**JCB**

[www.nih.gov/about/reporting-preclinical-research.htm](http://www.nih.gov/about/reporting-preclinical-research.htm)

# Stakeholder Engagement

- Workshop in June 2014 with Journal Editors to identify common opportunity areas
  - Endorsement of consensus principles by more than 135 journals
- Workshop in July 2014 with PhRMA to identify areas of common interest with industry
  - PhRMA obtaining feedback from its Biomedical Advisory Committee (BMAC) and working with NIH to determine interest in further collaborations
- Obtaining input on barriers to reproducibility re: research reagents
  - [Request for Information](#) open until December 22, 2014
- Meetings with professional societies and institutions

# Stakeholder Engagement

## Meetings with/Presentations to (select list):

- ❖ Society for Neuroscience (SfN) – November 16<sup>th</sup>, 2014, led by NINDS, Francis Collins, Keynote Speaker
- ❖ National Health Medical Research Council – November 12<sup>th</sup>, 2014 (virtual presentation to Australia)
- ❖ Virginia Commonwealth University – September 22<sup>nd</sup>, 2014
- ❖ Life Sciences Subcommittee of Committee on Science – May 28<sup>th</sup>, 2014
- ❖ Clinical Research Forum and Association for Clinical and Translational Sciences (ACTS) – joint meeting in April 2014
- ❖ American Society for Pharmacology & Experimental Therapeutics (ASPET) – April 2014
- ❖ Coalition for the Life Sciences (CLS) – March 2014
- ❖ Health Research Alliance (HRA) – January 2014

# Additional Guidelines and Efforts to Consider

- Reporting guidelines, such as [Animal research: Reporting of In Vivo Experiments \(ARRIVE\)](#), or [Consolidated Standards of Reporting Trials \(CONSORT\)](#)
- Broader coordination efforts related to reproducibility, such as [Enhancing the QUALity and Transparency Of health Research \(EQUATOR\)](#)

# Many thanks...

- Story Landis
- Shai Silberberg
- Harold Varmus
- Janine Clayton
- Jon Lorsch
- Eric Green
- Sally Rockey
- Michael Gottesman
- Della Hann
- Paul Liu
- Mike Rogers
- Jim Deatherage
- Judy Hewitt
- Bill Duval
- Liza Bundesen
- Tara Schwetz

Rashada Alexander



# NIH...

[Lawrence.Tabak@nih.gov](mailto:Lawrence.Tabak@nih.gov)

# Turning Discovery Into Health

