

Scientist-Specific Solutions to Research Accountability Concerns

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Image: Mark Airs/Getty Images

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Quality Central 

Sharpening the focus on sound science and quality practices

**Career Development Seminar Series:
Promoting and maintaining
a culture of research accountability**

February 13, 2018

Scientist-Specific Solutions to Research Accountability Concerns

1. Jan 26 2018: Scientific Sea-Change? Responding to the clarion calls for improved research rigor.

2. February 13, 2018: Scientist-Specific Solutions to Research Accountability Concerns.

3. April 13, 2018: Managing research data to improve research reproducibility.



Image: Mark Airs/Getty Images

Quality Central 

Sharpening the focus on sound science and quality practices

**Seminar Series:
Promoting and maintaining
a culture of research
accountability**



Research accountability clarion call: a strongly expressed demand or request for action.

Objectives for today:

Discuss individual approaches to research accountability

Explain the use of research quality management systems as a strategic, science centered, systematic and risk-based approach to research and data management.

Propose some first steps that can be taken to improve research documentation practices.

Individual strategies for improving research accountability

Use available resources

Engage with your professional societies

Engage with your collaborators and core laboratories

Incorporate best practices and guidelines

Learn from clinical research

Individual strategies for improving research accountability

Use available resources

NIGMs Clearinghouse
for training modules
to enhance data
reproducibility


NIH Web Portal on
Rigor and
Reproducibility

Journal Checklists

Center for Open
Science

Stanford Meta-
Research Innovation
Center at Stanford

Editorial

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Setting the bar for cell biology best practices

Jean E. Schwarzbauer^a, W. Mark Leader^b, and
David G. Drubin^{c,*}

 Affiliations

The reproducibility of scientific findings is of great importance to all researchers. If our work cannot be reproduced and built upon by our peers and successors, it is of little value to the scientific enterprise.

In a 2015 white paper, the American Society for Cell Biology Reproducibility Task Force noted that scientific journals have an important role in ensuring that the work reported in them is reproducible ([American Society for Cell Biology, 2015](#)). *Molecular Biology of the Cell (MBoC)* has always supported the sound

This Article

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Classifications

Editorial

Article Usage Stats

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The checklist will have 4 sections: **Data Presentation, Methodology and Statistics, Reagents and Model Systems, and Data Accessibility.** Authors will answer 4 questions confirming that their article meets the applicable requirements for each section or, if it does not, to provide an explanation.'

MANAGING YOUR DATA

MANAGING YOUR DATA

Home

Our Services

1. Before Your Research

2. During Your Research

3. After Your Research Ends

Training and Workshops

About Us

Got data? We're here to help you manage, share, and preserve your research data. In addition to our [Data Repository for the U of M](#) curation services, the Libraries will help you navigate available campus resources throughout the data lifecycle:



Before Your Research Begins

- Schedule a [data management plan \(DMP\)](#) consultation ([Request Form](#)) or use our [Explore funding agency requirements](#) for data and learn best practices for getting [IRB approval](#) for sharing data.
- See [more tools for planning for data management](#)



During Your Research

- Attend workshops and explore online [training resources on best practices for data management](#)
- [Get help](#) creating documentation and using metadata standards
- Discover appropriate [U of M services for data, such as data storage](#)
- See [more tools for managing your data during your research](#)



After Your Research Ends

Individual strategies for improving research accountability

Engage with your professional societies



How Can Scientists Enhance Rigor in Conducting Basic Research and Reporting Research Results?

A White Paper from the
American Society for Cell Biology

ascb
an international forum for cell biology™

Join Renew

Membership • Committees/Communities • Advocacy • Educators • Careers • Awards • Publications • Meetings • Science

Reproducibility

the ascb
RReport on Reproducibility

The difficulty in replicating research findings has been at the center of the attention in the specialized and lay press for a number of years and is more recently attracting the attention of the Administration and Congress. Various reports indicate the problem of data replication as cutting across all areas of research, although it has been studied mostly in the clinical and pre-clinical domains. The magnitude of the problem described in respectable published reports, is disturbing and could possibly undermine scientists' credibility.

In 2014, the American Society for Cell Biology (ASCB) convened a task force to examine the issue of reproducibility in life science research, with particular attention to basic research. The Task Force issued a white paper expressing 13 recommendations, which fall into two broad categories: engaging with existing efforts, and initiating new activities.

[Click here to read the Task Force report](#)

f t G+ in p e

ASCB TASK FORCE CHARGE

TASK FORCE MEMBERS

ABRF
The Association of Biomolecular Resource Facilities

Research • Technology • Communication • Education

About ABRF Membership Research Groups ABRF Resources Meetings

Committee for Core Rigor and Reproducibility (CCoRRe)

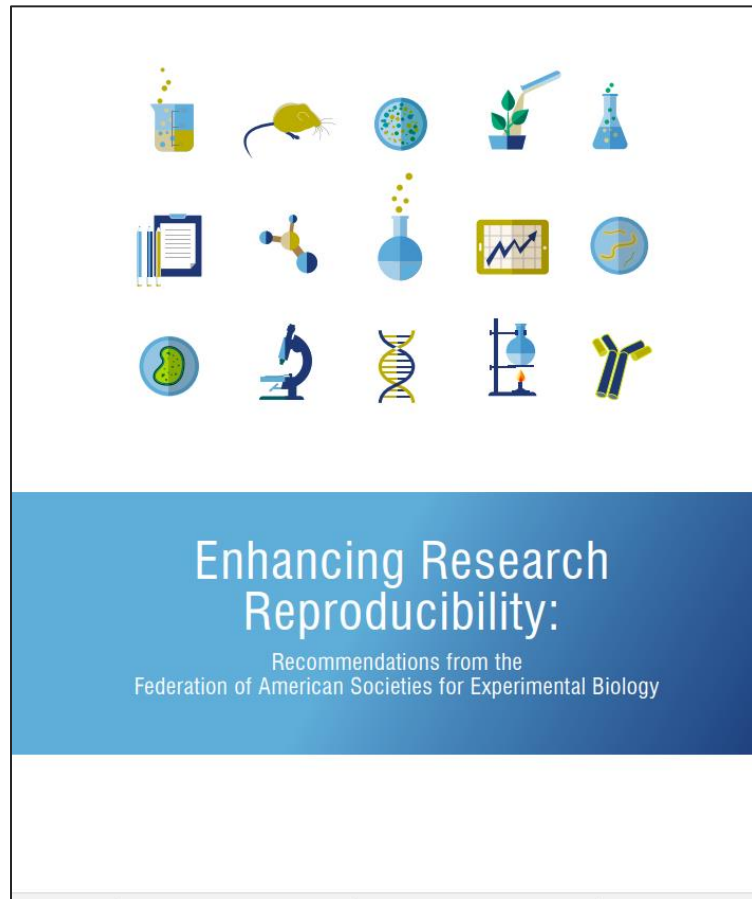
The Mission of the Committee for Core Rigor and Reproducibility (CCoRRe) is to promote resources for the ABRF membership in achieving accurate and reproducible results in their shared resource facilities.

The mission will be achieved in the near term by developing resources and supporting ABRF studies that help ABRF members provide services to their customers/users that comply with NIH policy directives in rigor and reproducibility. The resources would include developing a website that has educational links and best-practice protocols for the various scientific disciplines of the ABRF membership. The Committee will also identify opportunities for outreach and partnership with other professional societies and scientific journals, which over longer timeframe will create a lasting influence that advances our mission.

Core Lab Reproducibility Survey

The Association of Biomolecular Resource Facilities (ABRF) Committee on Core Rigor and Reproducibility (CCoRRe) is conducting a global worldwide survey to learn how scientific cores or other shared resource facilities generate transparent, rigorous and reproducible research data. The results of this survey will help the

Faseb: Enhancing Research Reproducibility



Overarching Recommendations

**Recommendations Specific to
Research Using Mouse and
Other Animal Models**

**Recommendations Specific to
Research Using Antibodies**

https://www.faseb.org/Portals/2/PDFs/opa/2016/FASEB_Enhancing%20Research%20Reproducibility.pdf

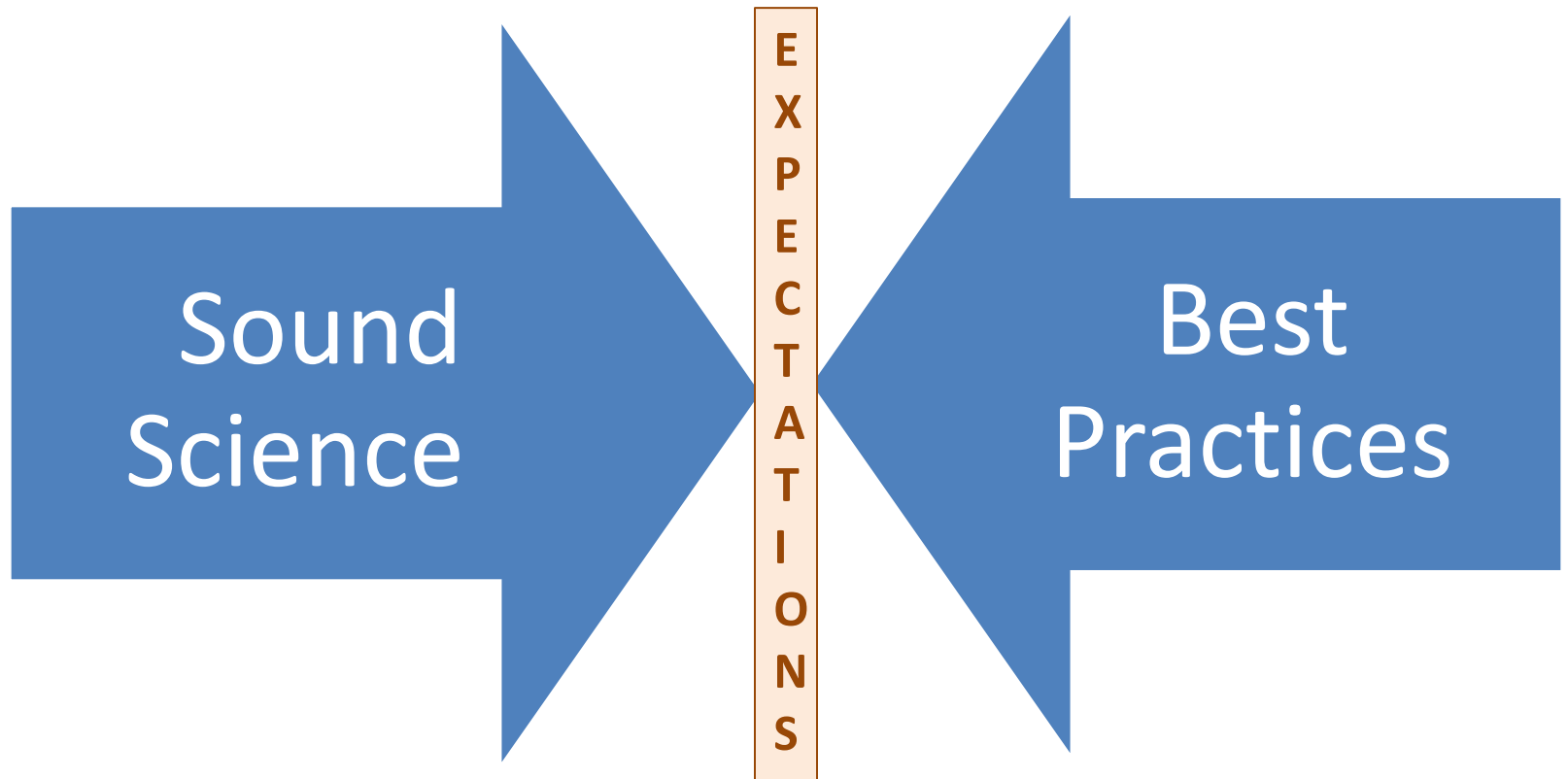
Individual strategies for improving research accountability

Engage with your professional societies



Individual strategies for improving research accountability

Engage with your collaborators and core laboratories



Consistent Procedures, Quality Checkpoints, Research Review

Individual strategies for improving research accountability

Use available resources

Engage with your professional societies

Engage with your collaborators and core laboratories

Incorporate best practices and guidelines

Learn from clinical research

Incorporate best practices and guidelines

NIH Rigor and Transparency Guidelines

Principles and Guidelines for Reporting Preclinical Research

ARRIVE: Animal Research: Reporting of In Vivo Experiments

Biome

Molec

How are we doing?

roducibility

Minimum Information About a Microarray Experiment (MIAME)

STAR Methods (Structured, Transparent, Accessible, Reporting (Cell Press))

**Quality Practices for Biomedical Research/Good Research
Practices/Research Quality Assurance**

Incorporate best practices and guidelines



Randomization, blinding, sample size estimation , and considering sex as a biological variable are considered crucial study design elements to maximize the predictive value of preclinical experiments.

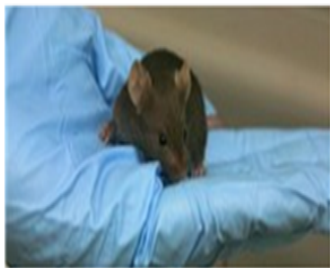
An infographic titled "NEW GRANT GUIDELINES" with the subtitle "what you need to know". It lists four key areas for updating guidelines: 1. PREMISE (The scientific premise forming the basis of the proposed research), 2. DESIGN (Rigorous experimental design for robust and unbiased results), 3. VARIABLES (Consideration of relevant biological variables), and 4. AUTHENTICATION (Authentication of key biological and/or chemical resources). It includes contact information for inquiries and a link to the NIH Notice NOT-OD-16-011.

NEW GRANT GUIDELINES
what you need to know

WHY UPDATE THE GUIDELINES?
The updates focus on four areas deemed important for enhancing rigor and transparency:

- 1 PREMISE**
The scientific premise forming the basis of the proposed research
- 2 DESIGN**
Rigorous experimental design for robust and unbiased results
- 3 VARIABLES**
Consideration of relevant biological variables
- 4 AUTHENTICATION**
Authentication of key biological and/or chemical resources

Send inquiries to reproducibility@nih.gov
See also NIH Notice NOT-OD-16-011
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html>



Preclinical Studies Don't Regularly Adhere to Best Practices

By Kerry Grens

Animal experiments published in a handful of cardiovascular journals mostly ignore NIH guidelines.

8 May 2017

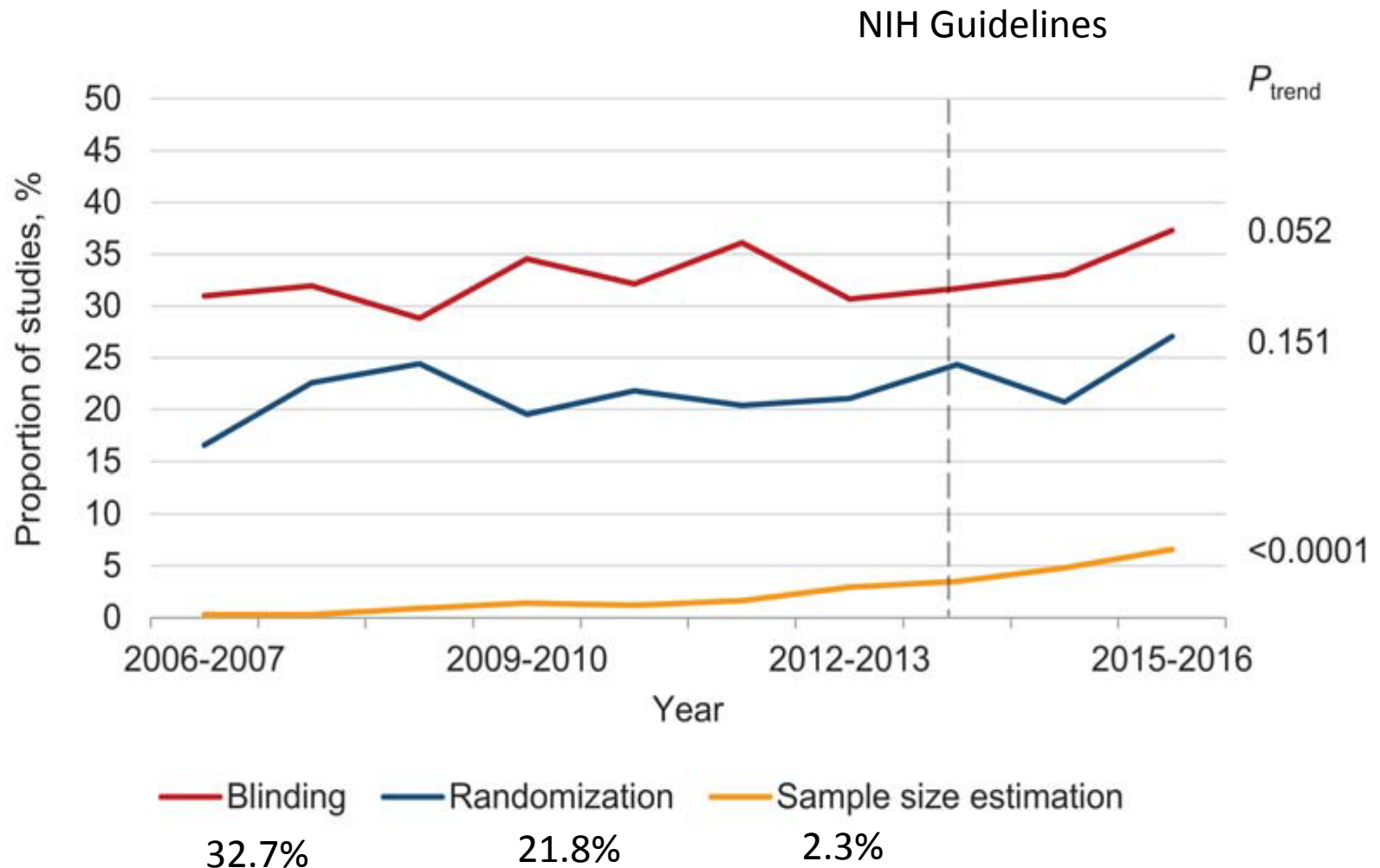
[The Scientist](#) » [News & Opinion](#) » [Daily News](#)

Conclusions:

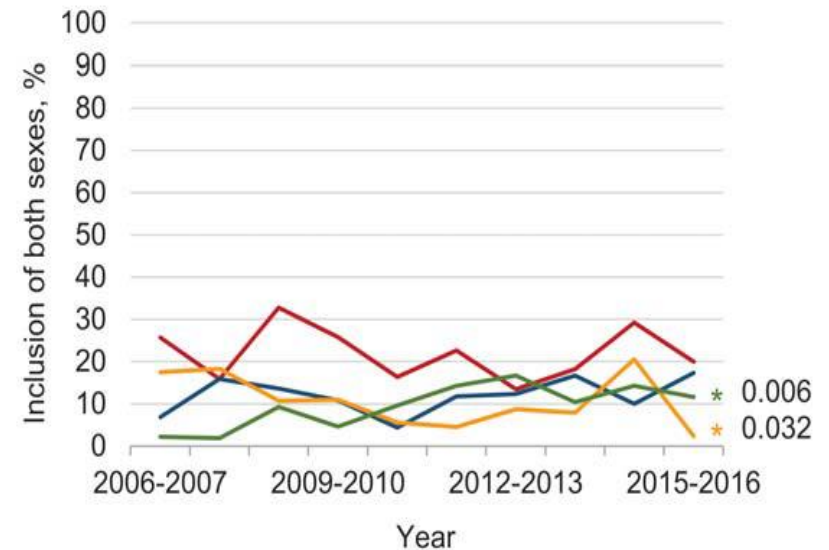
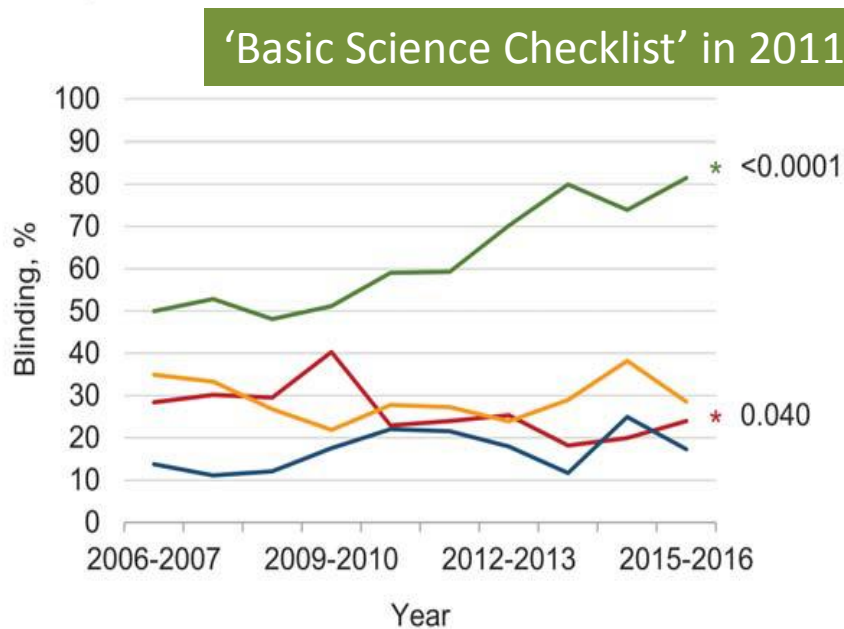
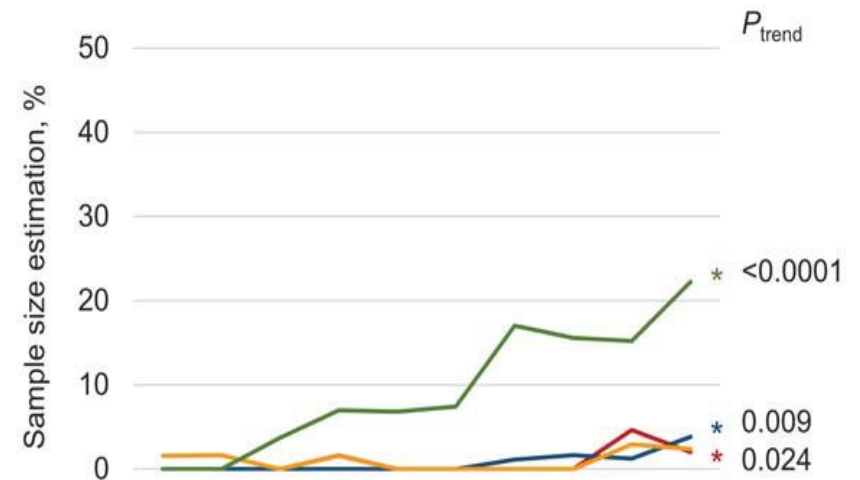
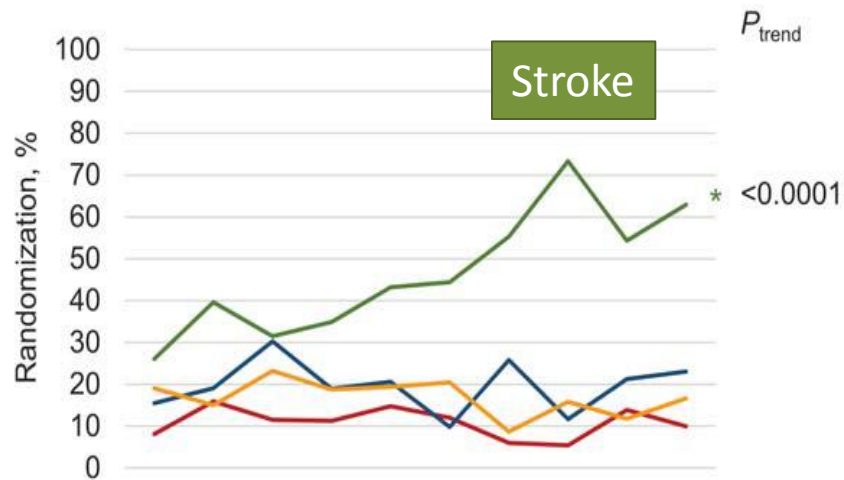
‘Methodological shortcomings are prevalent in preclinical cardiovascular research, have not substantially improved over the past 10 years, and may be overlooked when basing subsequent studies.

Stroke research quality has uniquely improved in recent years, warranting a closer examination for interventions to model in other cardiovascular fields.’

Temporal patterns in randomization, blinding and sample size estimation in preclinical cardiovascular studies.



Patterns in preclinical research for the most commonly studied CV diseases.



— Atherosclerosis — Hypertension — CM/HF — Stroke

Stroke

JOURNAL OF THE AMERICAN HEART ASSOCIATION

Sub Group Analysis: practices before and after the publication of NIH guidelines and policies for reporting preclinical research and the implementation of a 'Basic Science Checklist' by the Stroke journal.

Stroke

JOURNAL OF THE AMERICAN HEART ASSOCIATION

‘No difference in the prevalence of the study design elements before and after the NIH principles and guidelines for reporting preclinical research were published in 2014’.

Sub group analyses: (CVD and animal model-adjusted comparisons of study design elements before and after presentation of checklist)

‘significant improvements in all measures of methodological quality (range of adjusted odds ratios 2.4-8.2, $p < 0.0001$ for all study design elements).

‘identified stroke as the CVD studied as an independent positive predictor of one or more study design element in every journal.’

Editorials

Reporting Standards for Preclinical Studies of Stroke Therapy

Farhaan Vahidy, MD, PhD; Wolf-Rüdiger Schäbitz, MD; Marc Fisher, MD; Jaroslaw Aronowski, MD, PhD

The unmet need for development of new stroke therapies is enormous. Evidence generated from positive, null, or negative preclinical studies for various therapeutic agents is crucial to enhancing scientific progress. The scientific community shares a societal responsibility to practice and promote meticulous conduct and reporting of all experimental studies. A systematic survey conducted by the UK government-sponsored National Center for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs) reported that only 59% of biomedical animal studies stated the hypotheses and objectives, and <87% did not use randomization.¹ This, in part, led to the

emphasize and communicate the crux of methodological and reporting issues.^{10,11}

To improve quality of preclinical studies, a relatively simple checklist requesting reporting of randomization procedures, blinding, a priori definition of inclusion and exclusion, and so on was implemented in 2011. This basic science checklist is currently part of the submission process, and the document is evaluated by editors and reviewers but has not been published so far. A recent analysis revealed that the checklist implementation has led to improvements in reporting of key characteristics of the overall scientific quality.¹² However, relevant components

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Learn from clinical research

**Quality Practices for Biomedical Research/Good
Research Practices/Research Quality Assurance**

Lessons to learn from clinical research

L Pedro-Roig, Emmerich CH. Medical Writing; Dec 2017; 26:4

The reproducibility crisis in preclinical research – lessons to learn from clinical research

Laia Pedro-Roig¹ and
Christopher H. Emmerich²

¹ Trilog
Frank
² PAAS

crisis.¹ The published literature is a common
source for potential new drugs tested by the

promotion, or tenure). Journal editors
and grant reviewers look for the p
simple, clear, and complete.³ The
tempt investigators to characterize

for
or
sig
Ca

GBSI
Global Biological Standards Institute



**The Case for Standards in
Life Science Research**

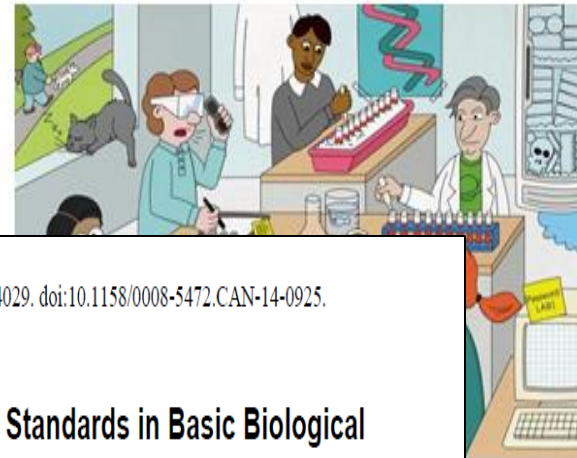
Seizing Opportunities at a Time of Critical Need

NATURE | NEWS FEATURE; 27 JAN 16

MONYA BAKER

QUALITY TIME

IT MAY NOT BE SEXY, BUT QUALITY ASSURANCE IS BECOMING A
CRUCIAL PART OF LAB LIFE.



Published in final edited form as:

Cancer Res. 2014 August 1; 74(15): 4024–4029. doi:10.1158/0008-5472.CAN-14-0925.

The Increasing Urgency for Standards in Basic Biological Research

Leonard P. Freedman and

Global Biological Standards Institute, Washington, DC, USA

James Inglese

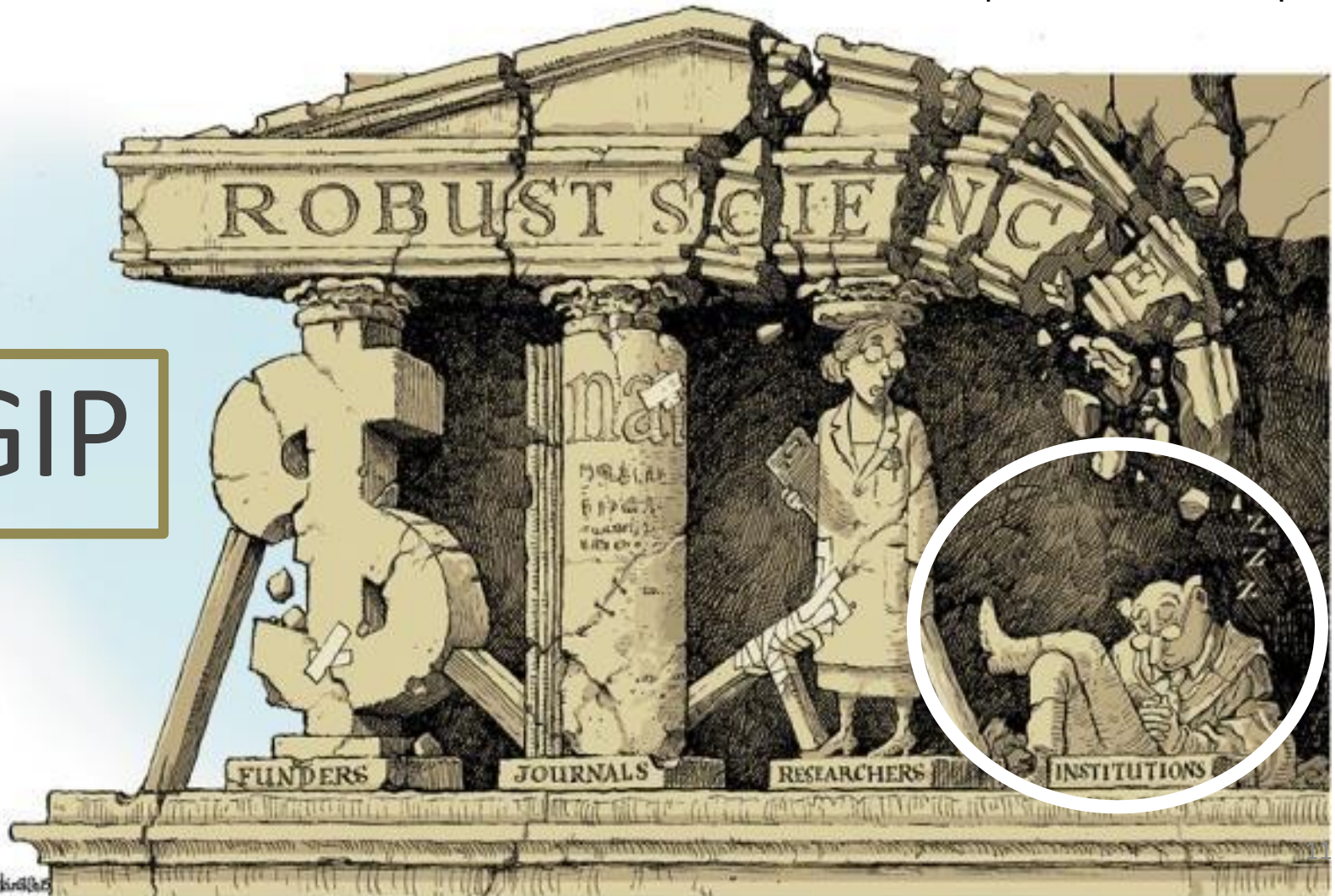
Division of Pre-clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health, Bethesda, MD, USA

Robust research: Institutions must do their part for reproducibility

[C. Glenn Begley](#), [Alastair M. Buchan](#) & [Ulrich Dirnagl](#)

Nature | Comment 01 Sep 2015

GIP



Good Institutional Practices

Use of established standards

Routine discussion and critique of research methods

Incident, error, occurrence flagging, reviewing

Training and standards

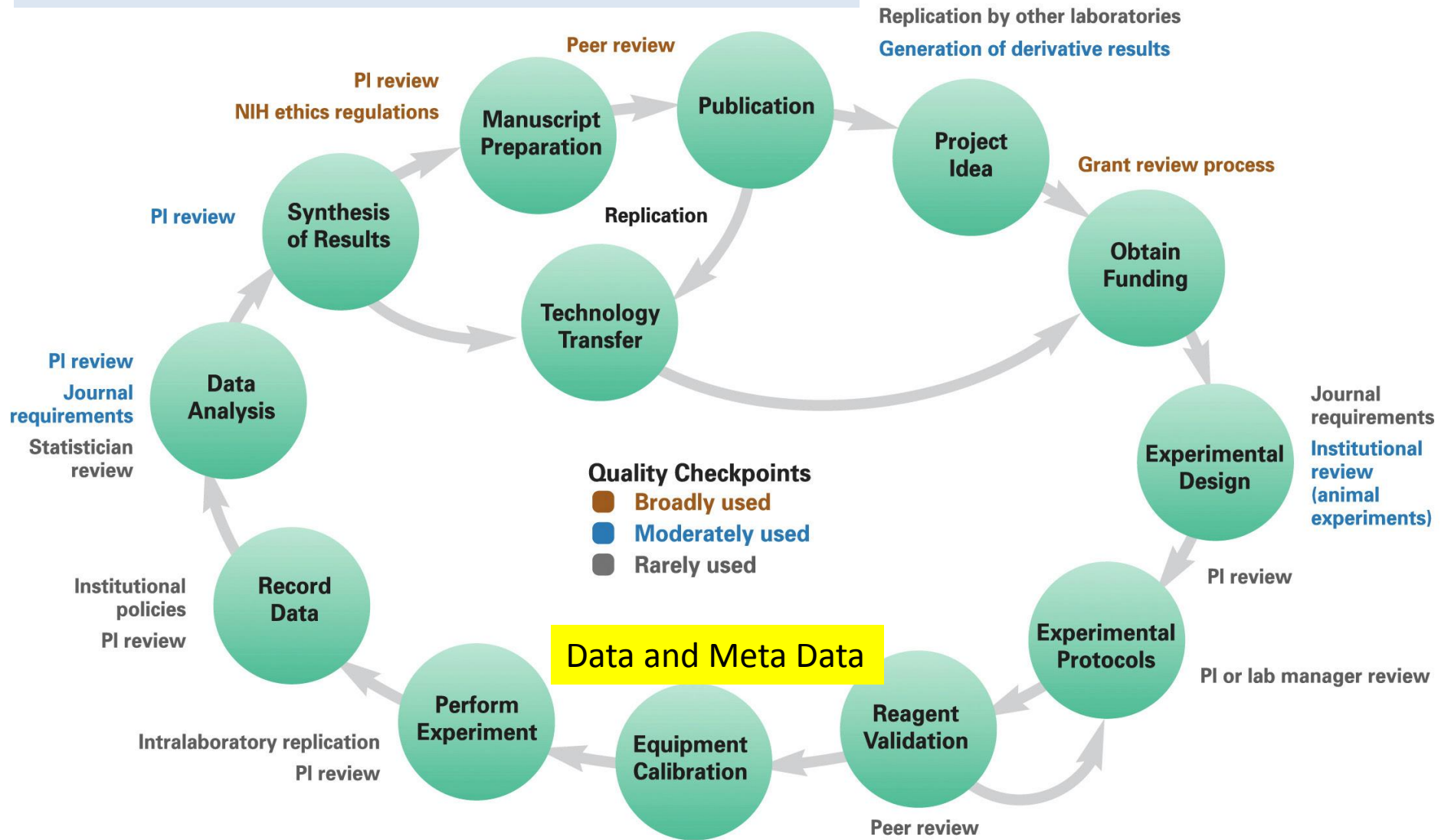
Records and Quality Management

Appropriate incentive and evaluation systems

Enforcement
Monitoring
Audit

“We propose that research institutions that receive public funding should apply the same kind of oversight and support to ensure research integrity as is routinely applied for animal husbandry, biosafety and clinical work.”

Research Life Cycle: Quality Check Points



Green circles indicate common steps in the life science research process. Adjacent color-coded text describes current/traditional quality checkpoints.

Good Quality Practices: A critical gap?

Data and Metadata

Who, what, where, when, how, why

Equipment

Personnel training

Supplies

Documentation

Methods

Facility and environment

Research records



Research accountability clarion call:
a strongly expressed
demand or request for action.

Objectives for today:

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Explain the use of research quality management systems as a strategic, science centered, systematic and risk-based approach to research and data management.

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What does research on research show?

Survey of NIH funded, early career scientists who say they have engaged in the behavior within the previous 3 years, n= 3247

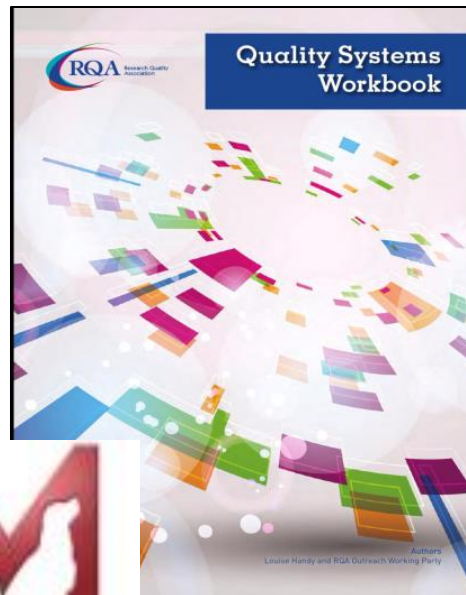
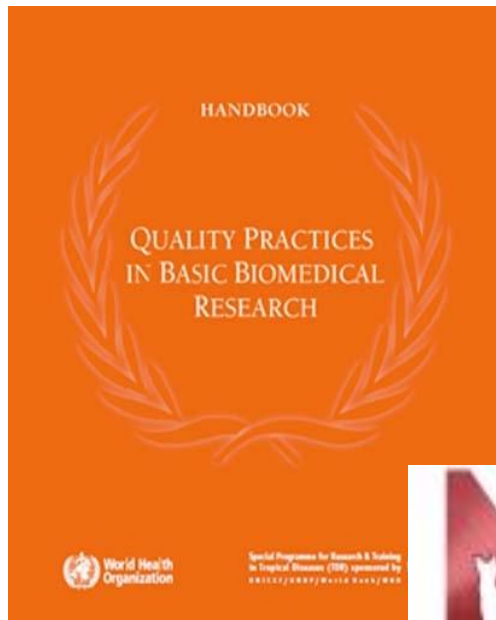
Behaviors	All early/ mid career
Changing design, methodology or results of a study in response to pressure from a funding group.	12.5
Using inadequate or inappropriate research design	13.5
Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	15.3
Inadequate record keeping related to research projects *	27.5

Scientists behaving badly

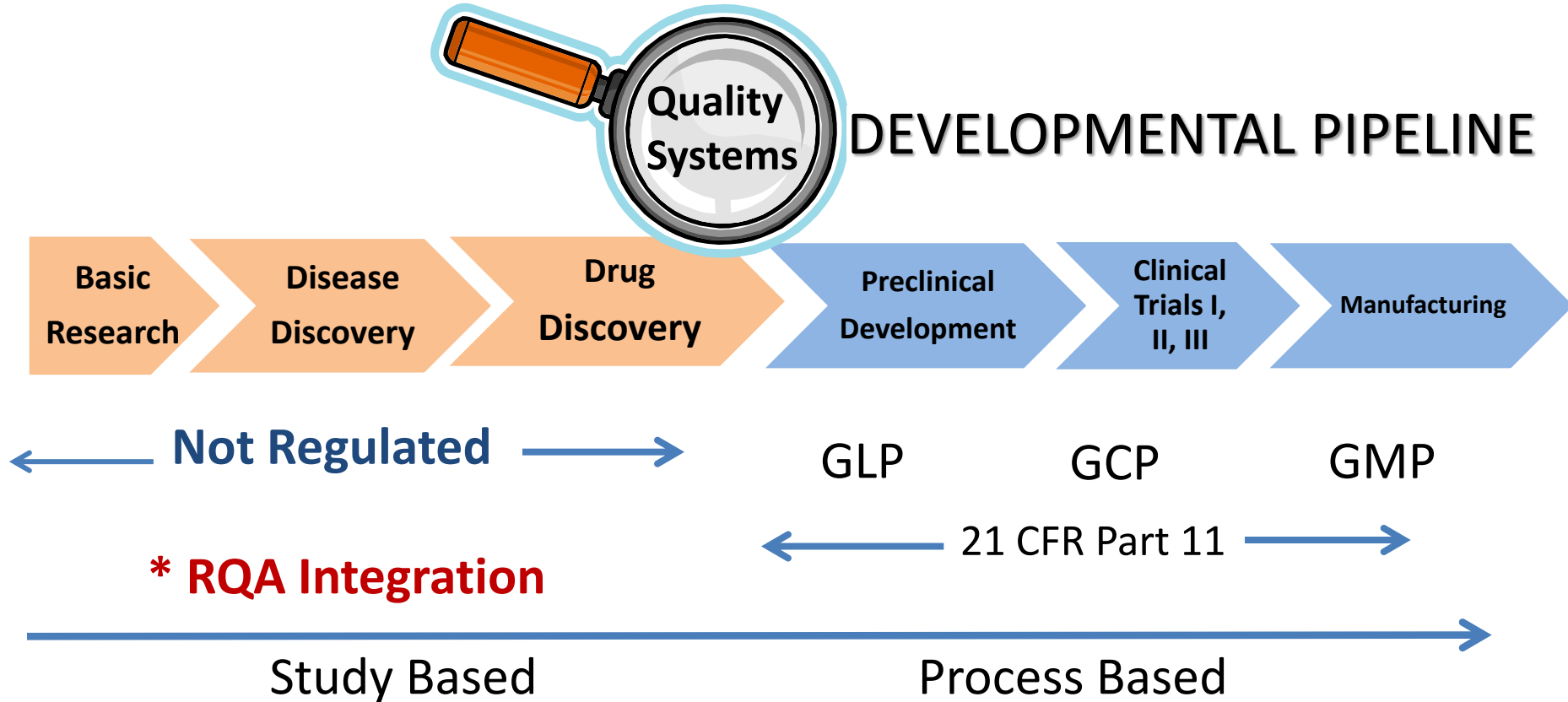
Nature 435, June 2005

BC Martinson, MS Anderson et al

Learning from clinical research: the case for standards in life science research



Scientific QA: The Research Continuum



Quality Assurance
Management Systems are
designed to:

Improve and maintain the precision and accuracy
of a **product**






and establish routine performance

A photograph of a green lamppost in the foreground with a red banner attached. The banner has the text 'UNIVERSITY OF MINNESOTA' and 'Driven to Discover' in gold. In the background, a large, classical-style building with many columns is visible, surrounded by trees with autumn foliage. The sky is blue.

UNIVERSITY
OF MINNESOTA
Driven to Discover

The **products** we
produce are
research
data, inference
and publications

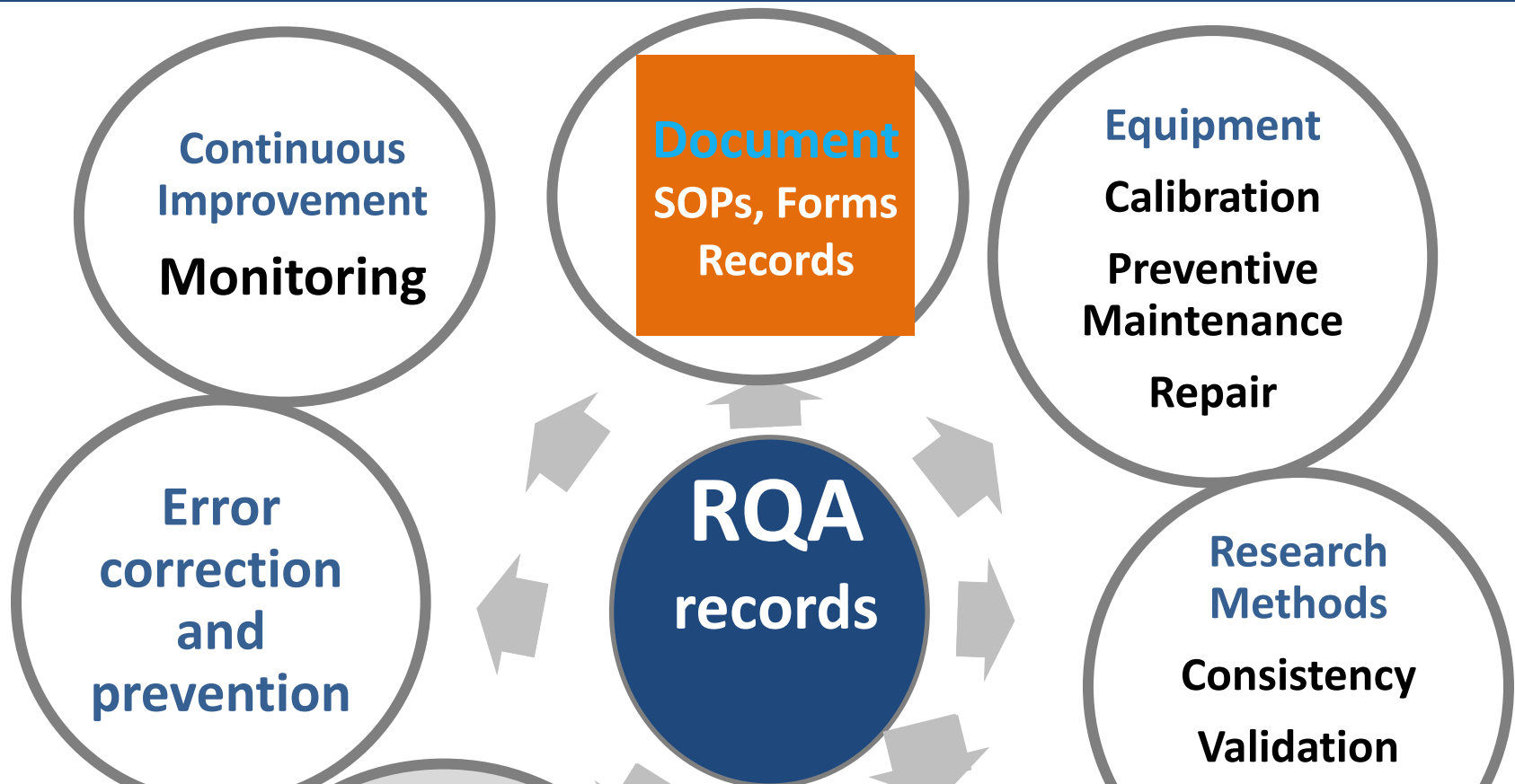
A group of graduates in caps and gowns are silhouetted against a bright orange sunset sky. They are holding hands and raising their arms in celebration. The sun is a bright, glowing orb in the center of the frame, partially obscured by the graduates. The graduates are standing on a grassy hill.

And the next generation of biomedical scientists



Quality Assurance support is rarely found in
academic basic research settings

Quality Management Systems Generate Evidence



Credible evidence supports data traceability and integrity which leads to trust and confidence in research outcomes

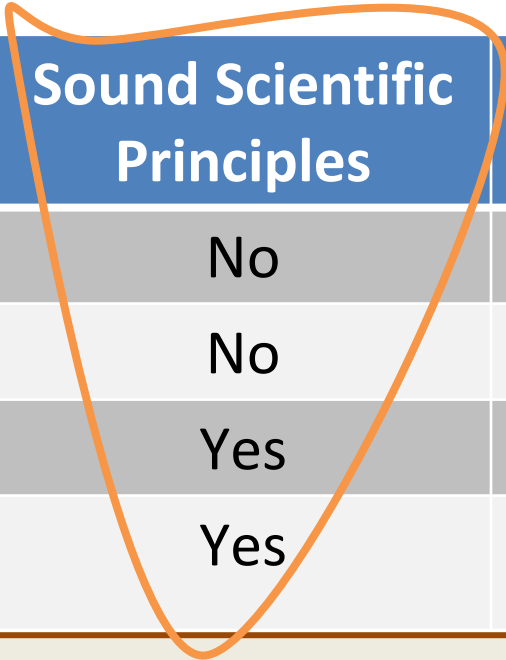
Traceability

Competency

**Research Quality Assurance is all about
research records and documentation practices**

How sound scientific principles and good quality practices contribute to the credibility of results

(WHO: Quality Practices in Biomedical Research Handbook, 2006)



	Sound Scientific Principles	Good Quality Practices	Credibility of Results
Study 1	No	No	No
Study 2	No	Yes	No
Study 3	Yes	No	No
Study 4	Yes	Yes	Yes

Both are critical for reproducible research

Promote
Best
Practices
and Sound
Science

Demonstrate
Research
Quality

Improve
Research
Rigor

Why integrate

**Scientist Driven Response to
Research Reproducibility Concerns
Can be adopted as an:
Individual, Group, Institution or System Approach**

Drive Research
Standards

and train
our
Scientists



Research accountability clarion call: a strongly expressed demand or request for action.

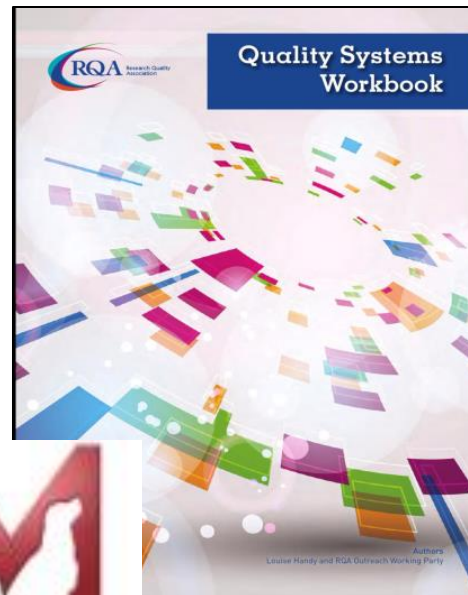
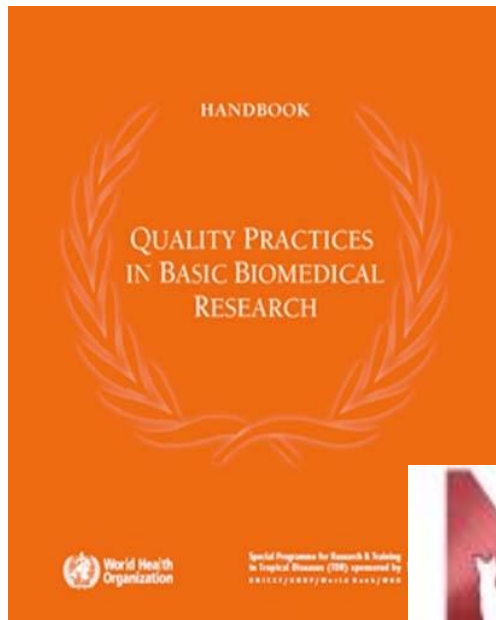
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Basic QA Rule 1: If it wasn't documented, it wasn't done



Where to start?

'ALCOA' + C



Good Documentation Principles [FDA]

Attributable

Legible

Contemporaneous

Original

Accurate

Complete

A good question

The data curating process is time-consuming.

I have been involved in preparing the data for curation which typically occurs AFTER funding for the project has ended.

Where are the resources for the additional effort required for research accountability tasks when grant funding barely covers the cost of data analysis?

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Image: Mark Airs/Getty Images

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**Seminar Series:
Promoting and maintaining
a culture of research
accountability**

Research Integrity and Trustworthy Science: Challenges & Solutions

Thursday, March 8, 2018
8:30am-1pm
Coffman Theater
University of Minnesota



Presented by the Office of the Vice President for Research; Consortium on Law and Values in Health, Environment & the Life Sciences; and Masonic Cancer Center
Part of Research Ethics Week, March 5-9, 2018

Prof. John P.A. Ioannidis, MD, DSc Stanford University

Prof. C.K. Gunsalus, JD

National Center for Professional and Research Ethics (NCPRE);
University of Illinois

Prof. Barbara Spellman, JD, PhD

University of Virginia

*This conference is part of **Research Ethics Week** (March 5-9, 2018), during which the University of Minnesota will focus on professional development and best practices to ensure safety and integrity in research.*



April 19, 2018
College of Veterinary Medicine
Ivan Oransky from Retraction Watch

Quality Central

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