Office of Research

Research Development and Support Series

Rigor and Reproducibility: Focus on the NAE Report

Tuesday, February 25, 2020

University Hall, Room 454

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Overview

Introductions

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Our Experts

- **Jacinda Dariotis, Ph.D.,** Professor of Education and Director of Evaluation Services Center
- **Tiffany Grant, Ph.D.,** Assistant Director for Research and Informatics and Associate Librarian
- **Ken Greis, Ph.D.,** Professor of Cancer and Cell Biology and Associate Dean
- **Jane Strasser, Ph.D.,** Sr. AVP, Office of Research Integrity

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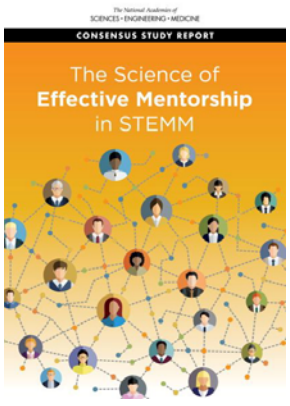
Just Released



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Rigor and Reproducibility

25 February 2020

Ken Greis, Ph.D.
Jacinda Dariotis, Ph.D.
Tiffany Grant, Ph.D.
Jane Strasser, Ph.D.

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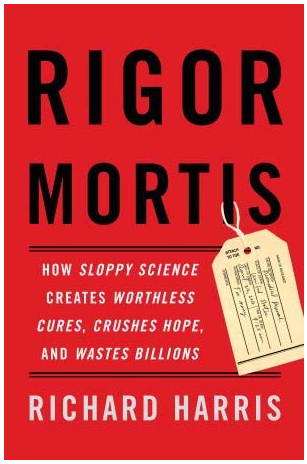
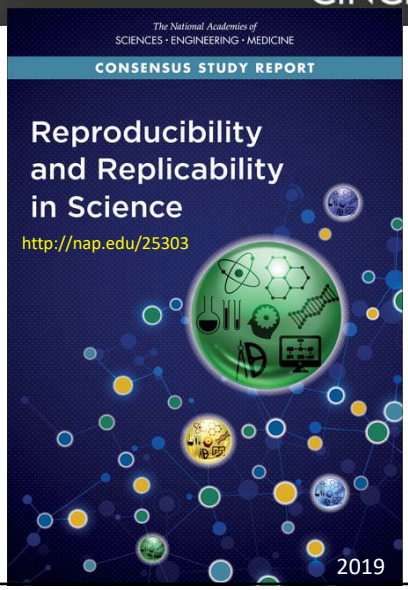


2017



2017

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Who couldn't use $1,000?

Research Transparency Award.

This award is intended to promote and reward actions and methods that ensure the integrity of the research record and data sharing (e.g. standardizing nomenclature, implementing validation procedures, backup systems, and corrections to the research record).

There will be awards in up to 3 categories: 1 for faculty, 1 for students, and 1 for staff. Nominations should include the name and job title of the nominee and a description of the actions taken to promote research transparency. Nominations should not exceed 500 words. Self-nominations are permitted.

Nominations should be submitted to: integrity@uc.edu.

The deadline for submissions is February 28, 2020. Nominations received after that date will not be considered.

Awards will be presented at the annual research awards reception culminating Research and Innovation week.

Awards: **$1k for top prize in each category (faculty, staff student)**

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Rigor & Reproducibility

An Overview

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Some practical insight/impact into Rigor and Reproducibility in Research Reporting in Biomedical Sciences.

Learning objectives:

1. Review some of the basic concepts Responsible Conduct in Research (RCR) and Rigor and Reproducibility
2. Understand the research landscape that has led to a re-evaluation of reporting standards.
3. Become familiar with the new and emerging standards of research reporting as adopted by the NIH, publishing groups, and a variety of scientific societies (e.g. FASEB).

Outline:

1. Review of RCR principles with some examples of common challenges in reporting of data
2. The "New" Problem—Rigor and Reproducibility in Research Reporting
3. Academic pressures that may have contributed to The Problem
4. Introduce new FASEB recommendation and NIH guidelines
5. Real situations: How would you respond? How to minimize problems.

A few short commentaries worth reading

Begley and Ellis. Raise standards for preclinical cancer research (2012) *Nature*, **483**, 531–533, doi:10.1038/483531a

Collins and Tabak. NIH plans to enhance reproducibility (2014) *Nature*, **505**, 612–613, doi:10.1038/505612a

Babic et al. eLife 2019; 8:e41676. DOI: https://doi.org/10.7554/eLife.41676

Other Reference Material:

Enhancing Research Reproducibility: Recommendations from the Federation of American Societies for Experimental Biology Effective January 14, 2016. https://www.faseb.org/Portals/2/PDFs/opa/2016/FASEB_Enhancing%20Research%20Reproducibility.pdf

Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability. Nosek, Spies and Motyl doi: 10.1177/1745691612459058. Perspectives on Psychological Science November 2012 vol. 7 no. 6 615-631

NIH policy: Rigor and Transparency Module 1 https://grants.nih.gov/reproducibility/module_1/presentation.html. 30 min video outlining NIH policy and Practice

Case study on Research Integrity—Michael C. Lauer, NIH Deputy director for extramural research May 22, 2019 (https://youtu.be/ZKwpe77iZws)

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Responsible conduct of research (RCR) review*

Definition: "…the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research." [underline added for emphasis].

Subject Matter:

Regulatory rules

- conflict of interest – personal, professional, and financial
- policies regarding humans and animals subjects in research, and safe laboratory practices
- mentor/mentee responsibilities and relationships
- collaborative research including collaborations with industry

Research Practice

- peer review
- data acquisition and laboratory tools; management, sharing and ownership
- research misconduct and policies for handling misconduct
- responsible authorship and publication
- the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Research Practices can all be lumped into the concept that **someone skilled in the field should be able to accurately reproduce another person's research results**. This implies that:

Accurate record keeping of experimental design, execution, collection of experimental results, data analysis and reporting of the method and results is essential.

*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

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One of the alarms: The Saga of Serum Biomarkers of Ovarian Cancer

1. Petricoin et al. Use of proteomic patterns in serum to identify ovarian cancer. (2002) *THE LANCET* 359, 572-577.

"Findings: [Comparative Mass Spectral profiles of serum samples]…identified a cluster pattern that, in the training set, completely segregated cancer from non-cancer… [with] a sensitivity of 100% (95% CI 93–100), specificity of 95% (87–99), and positive predictive value of 94% (84–99)."

Correlogic, LLC in 2003 licenses OvaCheck to LabCorp and Quest Diagnostic to screen and diagnose Ovarian Cancer from serum samples (even at early stages).

2. Baggerly KA, et al. Reproducibility of SELDI-TOF protein patterns in serum: comparing datasets from different experiments. Bioinformatics. 2004 Mar 22;20(5):777-85. Rigorous biostatistics models applied to the above data set found:
    1. the results were generally non-reproducible
    2. There was evidence of a major shift in protocol mid-experiment that seems to bias the work.
    3. feature solely associate with the noise region of the spectra were responsible for the correlation.
3. FDA does not approve OvaCheck as a diagnostic test in 2004.

4. Later studies showed that much of the distinguishing noise was related to uncontrolled factors that biased the results: the serum collection tubes, spectral collection variability, and analysis at a single location.

5. Early Detection Research Network (EDRN) established at NCI to address best practices to avoid data bias in biomarker discovery and validation studies.—Robust Biostats and analysis of potential biases are a must!

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The "New" Problem:

- **More than 50% of published studies from academic laboratories cannot be replicated according to venture capital firms for biomedical research**
    - From: **Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability** Brian A. Nosek, Jeffrey R. Spies and Matt Motyl. doi: 10.1177/1745691612459058. Perspectives on Psychological Science November 2012 vol. 7 no. 6 615-631
- **Only about 25% of published preclinical studies based on literature reports could be confirmed by Bayer scientist prior to moving forward with drug studies.**
    - Prinz, F., Schlange, T. & Asadullah, K. *Nature Rev. Drug Discov*. 10, 712 (2011)
- **Only 6 of 53 (11%) of preclinical cancer studies that were published as landmark finding could be reproduced by scientist at Amgen**.
    - Begley and Ellis, (2012*) Nature* 483, 531.

Questions:

On the laboratory scale, how many of you have tried to reproduce a finding and have been unsuccessful?

Why do you think this is the case?

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The Problem continued

Two-thirds of clinical trials are not shared publicly within two years of completion. Study results are neither reported on the government website dedicated to that purpose, clinicaltrials.gov, nor published in a medical journal.

Academic medicine has fostered a culture in which the sharing of results is considered discretionary, rather than mandatory.

Question:

Would you agree to be in a study with the knowledge that the results wouldn't be shared?

http://www.npr.org/sections/health-shots/2016/02/23/467712481/academic-medical-centers-get-an-f-in-sharing-research-results

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What factors may contribute to The Problem?

Group 1: There is a Disconnect Between What Is Good for Scientists and what Is Good for Science

Are there any disincentives to producing high quality unbiased science?

Group 2: Novelty and Positive Results Are Vital for Publishability, but Not always for the full Truth

What do you think is meant by this statement? Is it valid?

Group 3: Science is "self-correcting" over the long term:

Is this valid? What are some of the barriers to this concept?

Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability. Nosek, Spies and Motyl doi: 10.1177/1745691612459058. Perspectives on Psychological Science November 2012 vol. 7 no. 6 615-631

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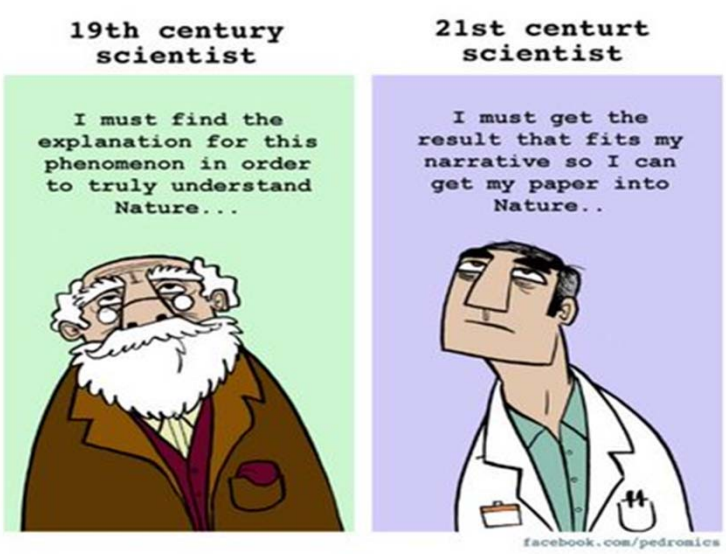

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Enhancing Research Reproducibility:
Recommendations from the Federation of American Societies for Experimental Biology (FASEB).

Background:
Science advances through the publication of novel results, followed by efforts to reproduce them. Such replication of experimental findings distinguishes science from other forms of intellectual inquiry.

Today, as we learn more about the complexity of living organisms, both successful and failed attempts to replicate a given study can provide valuable insights into biological processes. We are also gaining greater understanding of the many factors that can affect the outcomes of experiments.

What are some of the factors that effect Research Reproducibility?

Enhancing Research Reproducibility: Recommendations from the Federation of American Societies for Experimental Biology Effective January 14, 2016. https://www.faseb.org/Portals/2/PDFs/opa/2016/FASEB_Enhancing%20Research%20Reproducibility.pdf

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Enhancing Research Reproducibility: Recommendations from the Federation of American Societies for Experimental Biology (FASEB)

Background: Variability of reagents, model systems, methods, and resources is difficult to avoid—particularly in biology—and can have a sizeable effect on experimental outcomes.

Conclusions: 12 recommendations were put forth that address common terminology, details of materials and methods, training on keeping proper records, experimental and statistical design and methods as well as the choice and use of appropriate cell and animal models, and finally report of both positive and negative data.

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FASEB REPORT RECCOMENDATIONS

1. Scientists, policy makers, and journalists should use precisely defined terms and definitions when discussing research rigor and transparency to promote uniform understanding.

a. Replicability: the ability to duplicate (i.e., repeat) a prior result using the same source materials and methodologies. This term should only be used when referring to repeating the results of a specific experiment rather than an entire study

b. Reproducibility: the ability to achieve similar or nearly identical results using comparable materials and methodologies. This term may be used when specific findings from a study are obtained by an independent group of researchers

c. Generalizability: the ability to apply a specific result or finding more broadly across settings, systems, or other conditions

d. Translatability: the ability to apply research discoveries from experimental models to human health applications

e. Rigor: the use of unbiased and stringent methodologies to analyze, interpret, and report experimental findings

f. Transparency: the reporting of experimental materials and methods in a manner that provides enough information for others to independently assess and/or
reproduce experimental findings

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What is the difference between Technical Replicates and Biological Replicates?

When would you used these different types?

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What are other issues that affect the quality / rigor of science?

Approaches

a) leveraging chance by running many low-powered studies, rather than a few high-powered ones;
b) uncritically dismissing "failed" studies as pilot tests or because of methodological flaws but uncritically accepting "successful" studies as methodologically sound;
c) selectively reporting studies with positive or "clean" results and not studies with negative results;
d) stopping data collection as soon as a reliable effect is obtained;
e) continuing data collection until a reliable effect is obtained;
f) including multiple independent or dependent variables and reporting the subset that "worked"
g) maintaining flexibility in design and analytic models, including the attempt of a variety of data exclusion or transformation methods, and reporting a subset
h) reporting a discovery as if it had been the result of a confirmatory test
i) once a reliable effect is obtained, not doing a direct replication

From: **Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability** Brian A. Nosek, Jeffrey R. Spies and Matt Motyl doi: 10.1177/1745691612459058. Perspectives on Psychological Science November 2012 vol. 7 no. 6 615-631

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What are other issues that affect the quality / rigor of science?

Rigor, the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.

1. Insufficient, inappropriate controls
2. Lack of investigator blinding, sample randomization
3. Improper statistical analysis
4. Bad reagents (cells, antibodies)

From: **Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability** Brian A. Nosek, Jeffrey R. Spies and Matt Motyl. doi: 10.1177/1745691612459058
Perspectives on Psychological Science November 2012 vol. 7 no. 6 615-631

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Reagent Validation

1. Bad reagents (e.g. antibodies, enzymes)
   - What is the source, purity, activity, cross-reactivity?
   - How do you know if they are good/valid?

2. Cell lines or other biological models?
   - What are the critical features that need to be verified for your studies?

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FASEB REPORT BAD REAGENTS - Antibodies

Recommendation for Individual Investigators

Uniform reporting of research findings for experiments using antibodies. Core suggestions include:

a) Images should show as much of a blot or tissue section as reasonable to demonstrate findings. Show all key experimental samples, appropriate positive and negative controls, and size markers

b) Methods sections should include descriptions of sample preparation and blocking procedures (e.g., tissue retrieval, fixation, and processing parameters)

c) Details regarding reagents and equipment used should be described in the methods section

d) Results should include descriptions of the positive and negative controls used, including justification of appropriateness for technique, experimental system, and research query.

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FASEB REPORT BAD REAGENTS - Antibodies

Recommendations for All Stakeholders

2. ALL lab personnel may not fully appreciate the underlying **science or limitations of commercially available antibodies or antibody based kits.**

Vendor-supplied technical information may help investigators select reagents, but is insufficient for validation. Stakeholders (researchers, funding agencies, product vendors, and journals) should determine information needed for high quality technical bulletins. This might (or might not) include:

- immunogenic sequence
- epitope sequence
- cross-species reactivity
- methodologies for which the antibody is validated.

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FASEB REPORT BAD REAGENTS - Antibodies
Recommendations for All Stakeholders

1. Adopt a standard format for citing antibodies in grant applications and publications. At minimum:

- complete product name
- catalog number
- Vendor
- lot number
- antibody type (monoclonal, polyclonal, or recombinant)
- Target
- dilution/concentration.

How might you validate your antibodies prior to using them in your experiment?

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Real situations and examples for discussion:

1. Wrong Cell Line—True story
2. Multiple replicates and reporting
3. Large Data Sets and reporting

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1) Non-validated Cell Line (true story): The MDA-435 Cell line saga

Cancer Cell line MDA-435 was isolated in the late 70s as a breast cancer cell line and used extensively in research including one of the original NCI-60 cell lines used to screen drug against a variety of cancers

Through comparative mRNA expression profiling studies of various cancers in early 2000's, it was actually shown to be a near identical match to a common Melanoma cell line (M-14)—the cells in the ATCC (American Type Culture Collection) were even incorrect, but has been used for years as a breast cancer model.

May investigators were unwilling to abandoned their years of research results from this cell line and it has shown up in nearly a 1000 breast cancer papers since it was first reported as been misidentified by 2005.
https://slate.com/technology/2017/04/the-impostor-cell-line-that-set-back-breast-cancer-research.html

Tools to help address these issues:
Registry of Misidentified cell line established by ICLAC as a source for cell lines of concerns.

As of October 2018, they have formation on 529 suspect cell lines --https://iclac.org/databases/cross-contaminations/
Common contaminant that were thought to be other cell include HeLa, T-24 and M14 cells

VALIDATE YOUR CELL LINES and MODEL SYSTEM REGULARLY

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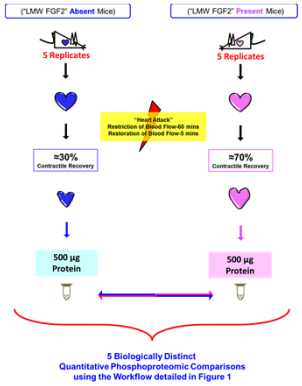
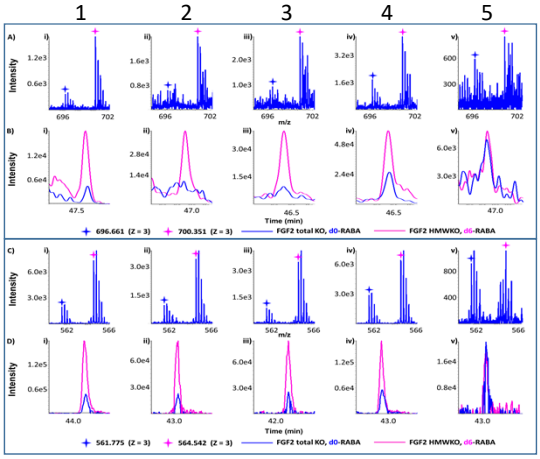
2) Multiple replicates—Which ones to present?

Differential Phosphorylation in Mouse Hearts (+/-) a cardio- protective growth factor





Which data should be included in the poster and/or in the manuscript?

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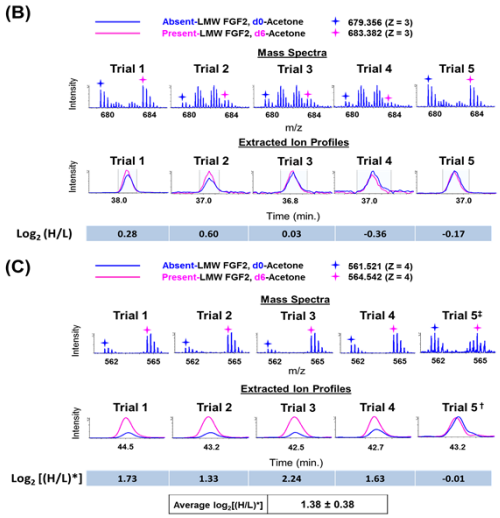
Quantitative Validation

Positive internal control

Differential Phospho



Wijeratne, et al. *J. Proteome Res.* 2013, 12, 4268−4279

Show them all! Biological response differences is a variability that must be represented

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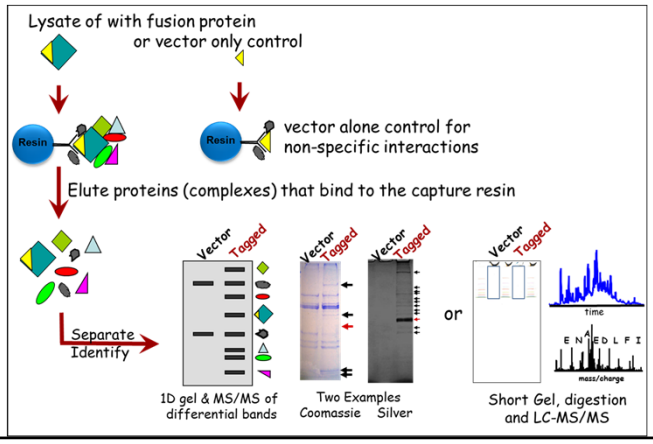
3) Reporting of differential expression (e.g. RNAseq, proteomics, metabolomics).

Example: Differential IP to identify protein interacting partners



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From full data tables to validated targets. How to present in manuscript?

IP for His-tagged "Protein Y" to identify interacting partners by mass spectrometry.

Results:

Fusion protein	Table showing 34 proteins identified
Vector control	Table showing 6 proteins identified
Net	Table of 28 proteins candidates that "interact" with Protein Y.

Subsequent validation of a selected "Protein X" from this list as being necessary for the biological function.

Results section in paper: "Protein interactions studies with his-tagged Protein Y followed by mass spectrometry identified Protein X." No other information on the other 27 (or 34) proteins is provided.

Is this type of selective reporting of the results allowable? In what context?

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Some ideas captured from the groups exercises

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Disincentives to producing high quality unbiased science

- Hiring, promotion, salary, graduation based on output
- Winner takes all – first to publish
- "Coolness" factor rewarded (Cold fusion, DNA with arsenic instead of phosphorous, others?)
- No publication of negative results
- Lack of money prohibits great rigor (need to cut corners?)
- Page charges/limits often results in minimal method reported
- Secrecy to protect scientific advantage, intellectual property

Who should pay for preclinical validation studies? (Pharma/biotech, universities, states, Feds)

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Novelty and Positive Results Are Vital for Publishability, but Not for Truth

1. **Publish on soundness**, not importance. PLoS ONE does this, but still ranked in the top 25% of general biological science journals.
2. **Remove publication barriers**. Peer review serves as gatekeeper and evaluator, post-publication peer review separates these concepts.
   - Shifts peer review from assessing publishability to whether the ideas should be taken seriously and/or is evaluated appropriately—Does this add value to the research knowledge?
   - Removes barrier to publishing replications and negative results.
   - Changes mindset of publication as the end of the process, and instead emphasize its impact on other research and the whole scientific community
3. Develop **metrics** to identify what is worth replicating
4. **Crowd source replication** efforts to reduce burden

Scientific Utopia II. Restructuring Incentives and Practices to Promote Truth Over Publishability Brian A. Nosek, Jeffrey R. Spies and Matt Motyl. doi: 10.1177/1745691612459058

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Science is Self correcting over the long term?

Generally true, but many barriers exist in today's research environment.

Barriers:

1. Grants and publication controlled by establishment
    - How can we all impact this through peer review?
2. Little room for truly exploratory research
3. Increased emphasis on making provocative statements (marketing)
4. The cost to disprove "established" models.
5. Expectation that all observations be completely explained or they are not ready to be published in high impact journals.
    - The changing emphasis of discussion section in manuscripts.

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What is the difference between Technical Replicates and Biological Replicates?

When would you used these different types?

• **Technical replicates** are repeated measurements of the same sample that represent independent measures of the random noise associated with protocols or equipment.

• **Biological replicates** are parallel measurements of biologically distinct samples that capture random biological variation, which may itself be a subject of study or a source of noise.

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A couple other NIH grant summary tools

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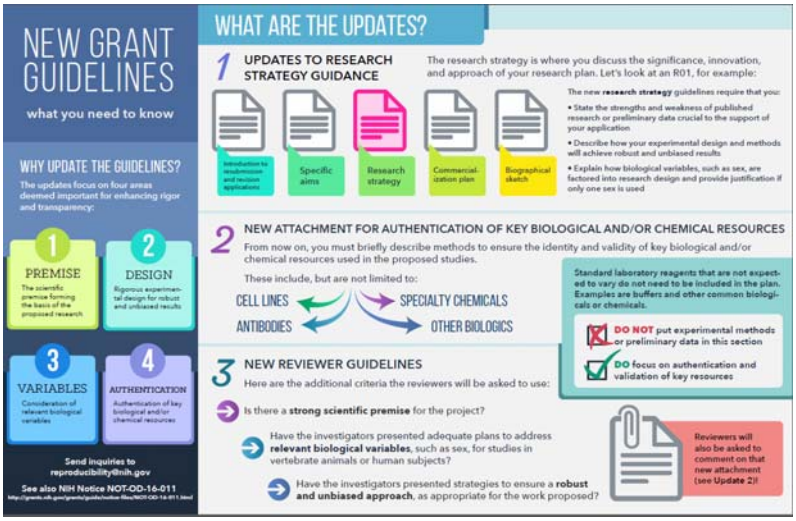
NIH Summary for Grant Submission



https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html

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Rigor and Reproducibility in NIH Applications: Resource Chart

NIH Grants Policy Website: http://grants.nih.gov/reproducibility/index.htm; **NIH Website:** https://www.nih.gov/research-training/rigor-reproducibility

4 AREAS OF FOCUS	WHAT DOES IT MEAN?	Where in the Grant?
Scientific Premise	The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.	**Research Strategy** ➢ Significance
Scientific Rigor (design)	**Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.	**Research Strategy** ➢ Approach
Biological Variability	**Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.	**Research Strategy** ➢ Approach
Authentication	**Key biological and/or chemical resources** include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not be generated with NIH funds and: • may differ from laboratory to laboratory or over time; • may have qualities and/or qualifications that could influence the research data; • are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan.	**Other Research Plan Section** ➢ Include as an attachment ➢ Do not include in the Research Strategy.

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Rigor & Reproducibility

An Overview

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Disclaimers

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- Presentation emphasis
  - Social Science
  - Public Health
  - Social emotional learning
- Assumption: familiar with definitions of experimental, quasi-experimental, and non-experimental designs
- Methodologist, biostatistician, evaluator
- Director, Evaluation Services Center & Institute for Interdisciplinary Data Science
- Professor, Research Methods, School of Education

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Rigorous Experimental Design

Scientific rigor is the strict application of the scientific method to ensure **robust and unbiased experimental design, methodology, analysis, interpretation and reporting** of results. This **includes full transparency in reporting** experimental details so that others may reproduce and extend the findings. NIH expects applicants to describe how they will achieve robust and unbiased results when describing the experimental design and proposed methods. Robust results are obtained using methods designed to avoid bias and can be reproduced under well-controlled and reported experimental conditions.

- Use of Standards
- Sample size estimation (power analysis, justification)
- Randomization
- Blinding
- Appropriate replicates
- Controlling for inter-operator variability
- Statistical methods planned
- Inclusion and exclusion criteria
- Subject retention and attrition
- Plan to handle missing data
- Other

https://www.nih.gov/research-training/rigor-reproducibility

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Topics Plaguing R & R

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- The allure of the "most rigorous design" & EBPs
- Reasons for lack of R & R (Barriers & Solutions)
  - Unspecified Problem or Program/ "Wicked" problems
  - Fallacy of the Pilot Study
  - Implementation Quality
  - Mistakes/ Errors/ Lapse in Judgment
- Best Practices
  - Project Management
  - Process Evaluation
  - Choose Team Members

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Take-Home Messages

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- Methodologist or Biostatistician and Evaluators may be your new BFFs – make them team members
- Standards of Evidence should be known and aspired to
- Design should match the study purpose & constraints (feasibility!)
- Quality of the evidence matters!
  - No statistical adjustments can make up for a poor design!
  - No design can make up for poor planning
    - Not even experimental designs
  - Validity is study dependent!
    - Context matters
- Document, document, document…

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The Allure of the…

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Allure of the Most Rigorous Design

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- Best plans (sometimes)
- Choose the most rigorous design
  - Why?
    - RFP says so…
    - The almighty…

EBP-value

(Evidence-Based Program/ Practice/ Policy)

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EBPs & Standards of Evidence

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- Evidence-based is more than "research-based"
- Standards of Evidence
  - Will vary by field/ discipline
  - Used to guide studies & assess quality of previous studies
  - Gottfredson et al. (2015) – prevention science standards
    - Statement [efficacy] [note: categories vary for effectiveness & scale-up]
    - Intervention description; Measures and their properties; Theory testing
    - Valid causal inference; Statistical analysis; Efficacy claims; Reporting
  - Koplan (1999) – 4 categories of 30 total standards (CDC)

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Levels of Evidence

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Level of evidence (LOE)	Description
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trial) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results.
Level II	Evidence obtained from at least one well-designed RCT (e.g. large multi-site RCT).
Level III	Evidence obtained from well-designed controlled trials without randomization (i.e. quasi-experimental).
Level IV	Evidence from well-designed case-control or cohort studies.
Level V	Evidence from systematic reviews of descriptive and qualitative studies (meta-synthesis).
Level VI	Evidence from a single descriptive or qualitative study.
Level VII	Evidence from the opinion of authorities and/or reports of expert committees.

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Evidence Hierarchy/ Pyramid

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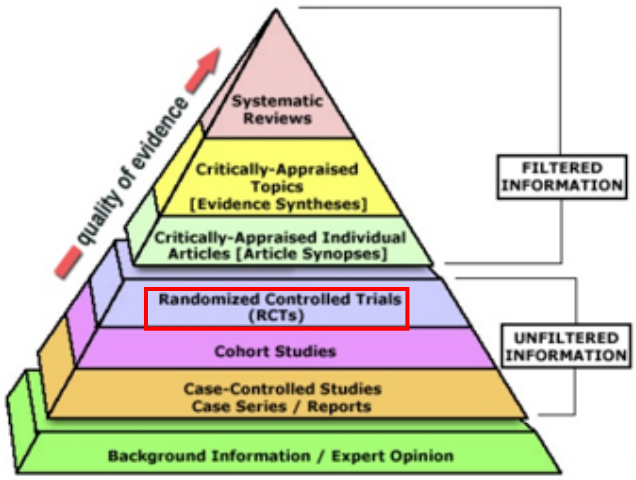

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RCT Considerations

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Barriers

- The Gold Standard (e.g., RCT) is not feasible, appropriate, or conducted with fidelity
  - Randomization is not possible (e.g., schools)
  - Fidelity issues: Cannot assume implementers/ stakeholders have the same priorities as researchers
    - Hint: randomization, contamination, etc. are not their primary concern
    - Desire for inclusion (outside of the plan)… need for (any) participants
  - Example study on mindfulness
    - Study and survey fatigue

Solutions

- Include all stakeholders in the design decision-making process
- Discuss its principles, components, and other aspects in advance and during study
- Have additional team members responsible for randomizing, checking, etc.
- Other suggestions?

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EBPs for Various Disciplines

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- Burns, P. B., Rohrich, R. J., & Chung, K. C. (2011). The levels of evidence and their role in evidence-based medicine. *Plastic and reconstructive surgery*, *128*(1), 305.
- Murad, M. H., Asi, N., Alsawas, M., & Alahdab, F. (2016). New evidence pyramid. *BMJ Evidence-Based Medicine*, *21*(4), 125-127.
- https://www.blueprintsprograms.org/
- https://casel.org/guide/
- https://ies.ed.gov/ncee/wwc/
  - https://ies.ed.gov/ncee/wwc/handbooks
- https://nicic.gov/evidence-based-practices-ebp
- https://crimesolutions.gov/
- https://www.ojjdp.gov/mpg/Home/About/#mpg

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Standards of Evidence References

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- Flay, B. R., Biglan, A., Boruch, R. F., Castro, F. G., Gottfredson, D., Kellam, S., ... & Ji, P. (2005). Standards of evidence: Criteria for efficacy, effectiveness and dissemination. *Prevention science*, *6*(3), 151-175.
- Gottfredson, D. C., Cook, T. D., Gardner, F. E., Gorman-Smith, D., Howe, G. W., Sandler, I. N., & Zafft, K. M. (2015). Standards of evidence for efficacy, effectiveness, and scale-up research in prevention science: Next generation. *Prevention science, 16*(7), 893-926.
- Koplan, J. P., Milstein, R., & Wetterhall, S. (1999). Framework for program evaluation in public health. *MMWR: Recommendations and Reports*, *48*, 1-40.
- Blueprints Programs: http://www.blueprintsprograms.com/
- Collaborative for Academic, Social, and Emotional Learning (CASEL): www.casel.org/guide

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Reasons for Compromised R & R

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Vague problem/ program – "Wicked" problems

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Barriers

- Undeveloped theory of change
- No conceptual model
- No logic model
- Poor quality research questions
- Activities are not well defined or documented

Solutions

- Consult the literature – learn from what others have done
- Develop a TOC, conceptual model, logic model
- Develop good research questions (PICO, SPICE, ECLIPSE, etc.)
- Detail program/ practice activities (what is being implemented?)

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PICO – Research Questions

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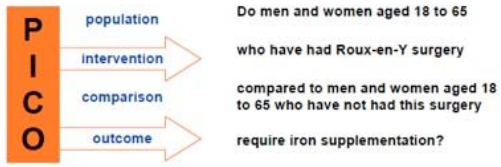

Problem	Intervention	Comparison	Outcome
For smokers who want to give up smoking,	does nicotine replacement therapy,	when compared with individuals relying on advice only,	increase their chance of giving up smoking?

PICO question

- Population: Health care workers and patients
- Interventions: Proper hand washing and PPE
- Comparison: No proper hand washing and use of PPE
- Outcome: Decrease spread of nosocomial infections
- PICO question: For Patients, does the use of proper hand washing and PPE by health care workers reduce the risk of nosocomial infection compared with improper hand washing and use of PPE?

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Fallacy of the Pilot Study

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- But the pilot had significant findings…
  - Sample selection effects – volunteer, early-adopters
  - Quality of implementation – higher
  - Considered exploratory, no correction for multiple tests
  - Scaling up: change dosage or other aspects
  - Other reasons?
- Solutions
  - Include safeguards and quality checks
  - Do not change the protocol, measures, implementers or other aspects when scaling up or replicating
  - Other suggestions?

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Implementation Quality Concerns

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Barriers

- Processes and procedures are not well documented (especially mid-stream changes)
- More training is needed (assumptions are made about skills at the start)
- No, limited, or untimely feedback loops for implementation quality assurance
- Insufficient resources
- Contextual changes

Solutions

- Develop standard documents BEFORE study begins – program management best practices
- Budget for personnel
- Assess program/ project implementation (process evaluation) with timely feedback
- Implementation science
- Other suggestions?

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Mistakes/ Errors/ Lapse in Judgment

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- Happens to everyone, even very senior researchers
  - Caution:
    - No statistical adjustments can make up for a poor design!
    - No design can make up for poor planning
- Researchers think they can cover all aspects (do it all internally)
- Examples
  - Using wrong measures
  - Participants complete assessments together when intended to complete individually
  - Wanting to “do a good job”
  - Beware of paying by the interview or assessment
  - Other examples?

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Best Practices

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Project Management

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- Manuals, codebooks, measures books, checklists, timelines, decision-trees/ go-no go rules
  - Updated with changes that occur
  - Hint: Lessons learned or protocol papers
- Initial training, boosters, etc.
- Quality checks
- Regular meetings
- Other suggestions?

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Process Evaluation

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- Plan a process evaluation (preferably by external entity)
- Assess program/ project implementation
  - Activities / services being delivered to the intended people? [reach]
  - Program deliver services [dose delivered]
  - Program utilization [dose received]
  - Program organization [functioning]
  - Deviations/ adaptations from planned activities [fidelity]
  - Participant experience with program (e.g., satisfaction)

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Team Members

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- Strategically choose team members
  - Content experts from pertinent disciplines
  - Methodologist/ biostatistician
  - Evaluator
  - Implementation expert
  - Project coordinator/ manager
  - Etc.

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Take-Home Messages

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- Methodologist or Biostatistician and Evaluators may be your new BFFs – make them team members
- Standards of Evidence should be known and aspired to
- Design should match the study purpose & constraints (feasibility!)
- Quality of the evidence matters!
  - No statistical adjustments can make up for a poor design!
  - No design can make up for poor planning
    - Not even experimental designs
  - Validity is study dependent!
    - Context matters
- Document, document, document…

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Need Help?
Jacinda.Dariotis@uc.edu
www.uc.edu/evaluationservices

Thank You!

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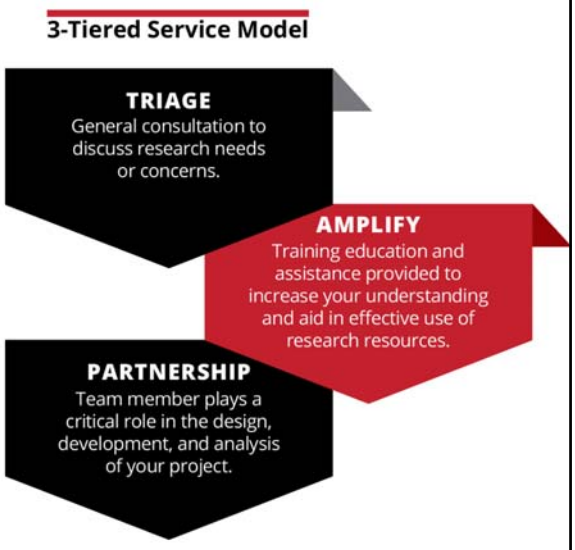
UC Libraries
Research & Data Services

Tools and Resources for Research R&R

UC Libraries R&DS

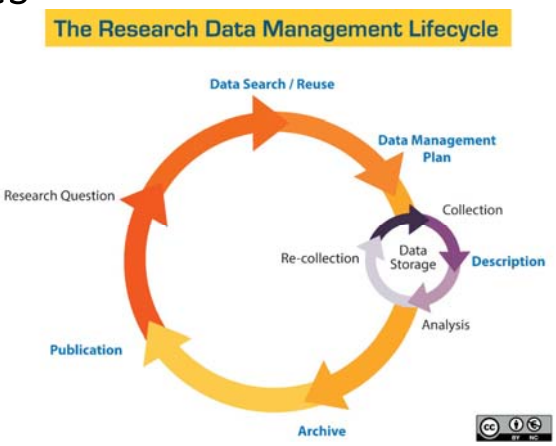
- Seeks to inspire the creation of knowledge and enhances research productivity across the UC research community through the development and implementation of interdisciplinary research data services that enables research and promotes synergistic collaborations between UCL and UC researchers.

- Areas of Focus
  - Research Data Services
  - Data Management
  - Data Analytics
  - Biomedical Informatics
  - Geographic Information Systems



Data Tools and Resources

- Goal: Create efficiencies for researchers
- Data Management Planning Guide
  - http://guides.libraries.uc.edu/datamanagementplanning
- UCL and UC Sponsored Tools, *selected*
  - DMPTool
  - ORCID
  - Open Science Framework
  - REDCap
  - Scholar@UC



DMPTool

DMPTool
Build your Data Management Plan

- Open-source online application that helps researchers create data management plans
- Provides a click-through wizard for creating a DMP that complies with funder requirements.
  - Direct links to funder websites
  - Help text for answering questions
  - Resources for best practices surrounding data management
- https://dmptool.org/

ORCID

- **ORCID** stands for **O**pen **R**esearcher and **C**ontributor **ID**
  - A persistent digital identifier that you own and control, and that distinguishes you from every other researcher.
- A **unique identifier** that allows you to associate your works with your name.
  - **Removes author ambiguity** especially for individuals with common names or for people who change their name through the course of their career.
- You can register directly on the website http://orcid.org
  - Registering is free and takes around 30 seconds.

- https://orcid.org/0000-0001-7036-8247

Open Science Framework

- Open source web application that connects and supports the research workflow, enabling scientists to increase the efficiency and effectiveness of their research.

- Through the OSF, researchers can organize projects, track activities, share with collaborators, and publish parts or the project in entirety using permalinks.
  - Many 3rd party tools and services can be used within the OSF.
  - Researchers can also track analytics for their public projects.

The Open Science Framework

https://osf.uc.edu/

Features

Managing Projects

- Creating a Project
- Creating Components
- Adding Contributors
- Uploading files
- Logs
- Using the project organizer
- Bookmarks

Sharing Projects

- Privacy controls
- View-only links
- Applying a license
- Citations with persistent IDs
- Metrics
- Tags - files and projects

Collaborating

- Wikis
- Notifications
- Commenting
- Forking and Linking projects
- User profile data

Connecting Add-ons

- ORCID
- Box
- AWS
- Github
- Mendeley
- Zotero
- R
- Dataverse
- Google Drive

Files and Version Control

- Drag and drop interface
- Revisions and versions
- Folders
- Download Counts
- File checkout

Registering Projects

- What are registrations
- Explanation of Registration Templates
- Embargoes
- DOIs/ARKs
- Retractions

Security and Privacy

- 2-factor authentication
- Backup scheme
- Security information (FAQs)
- Institutional login

Developed by the Center for Open Science – works for any discipline

REDCap: Research Electronic Data Capture

REDCap™ Research Electronic Data Capture

- **Developed to provide scientific research teams intuitive and reusable tools for collecting, storing and disseminating project-specific clinical and translational research data.**
- **REDCap provides user-friendly web-based:**
  - **Case report forms**
  - **Real-time data entry validation**
  - **Audit trails**
  - **Calendar scheduling to track**
    - **Critical study events such as blood-draws, participant visits, etc.**
- **Designated users can assign different levels of access for each member of the research team.**
  - Supports concurrent access by multiple users from anywhere via web browser
- **REDCap services are provided through the CCTST to its members.**

Scholar @UC

- The mission of Scholar@UC is to:
  - Preserve the permanent intellectual output of UC
  - Advance discovery and innovation
  - Foster scholarship and learning through the transformation of data into knowledge
  - Collect a corpus of works that can be used for teaching and
  - Inspire derivative works
  - Enhance discoverability and access to these resources
- A digital repository that enables the University of Cincinnati community to share its research and scholarly work with a worldwide audience.
- Faculty and staff can use Scholar@UC to collect their work in one location and create a durable and citeable record of their papers, presentations, publications, datasets, or other scholarly creations.
- https://scholar.uc.edu/

Contact us

- UC Libraries Research & Data Services website
  - https://libraries.uc.edu/research-teaching-support/research-data-services.html
- Email address: askdata@uc.edu

Office of Research Resources

Office of Research Web Site (research.uc.edu)

Office of Research How2 (researchhow2.uc.edu)

Research Directory (researchdirectory.uc.edu) – Ohio Department of Higher Education – Ohio Innovation Exchange (OIEx)

SPIN (research.uc.edu/funding/spin)

Limited Submissions (via web portal (rsrch-webserver.uc.edu/)) Two types – faculty research nominations and research proposals; Selection process dependent on type.

Office of Research *Findings* Please sign up to receive this monthly newsletter (https://research.us16.list-manage.com/subscribe?u=48c9bcb343e73c93605e53eee&id=6527e50384)

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Office of Research Resources – NEW!!

Early Career Funding Opportunities – under Funding on main Office of Research webpage (http://researchhow2.uc.edu/search?indexCatalogue=researchhow2-dev&searchQuery=Early+Career+Funding+Opportunities&wordsMode=0)

Office of Research Annual Report – IMPACT

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Faculty Enrichment Center Partner Consultation Hours

Research Development Services (RDS)
RDS consultation hours will provide consulting, one-on-one meetings, and assistance with access to research tools. During this time, Office of Research staff will facilitate access and use of tools, education materials, research support offices, external consultants, and trainings.
1st & 3rd Tuesdays, 1:00 - 4:00pm Room 540C
sarah.clift@uc.edu

UC Press & Cincinnati Library Publishing Services (CLIPS)
UC Press/CLIPS office hours will provide consulting on how to create a manuscript proposal, publishing contract consultation and review, copyright/permissions guidance, TOME grant information, ideas on how to create digitally interactive publications, open educational resources and open access publications.
2nd Mondays, 11:00am - 1:00pm Room 540B & 3rd
Thursdays, 3:00 - 4:00pm Room 540C mark.konecny@uc.edu

The Human Research Protection Program (HRPP)
HRPP consultation hours will provide consulting for UC faculty and staff with questions about Institutional Review Board (IRB) submissions.
1st & 3rd Tuesdays, 11:00am - 1:00pm Room 540C
devan.vaughn@uc.edu

Video Captioning for Accommodations Accessibility Resources will provide consulting and assistance for closed captioning for faculty whose course has an active accommodation for captioning or for faculty interested in making their course video content accessible with closed captioning.
2nd & 4th Tuesdays 12 - 3pm, 1st and 3rd Fridays 12 - 3pm,
Room 540C lanek7@ucmail.uc.edu

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Faculty Enrichment Center Partner Consultation Hours

Advanced Research Computing (ARC) ARC consultation hours will facilitate access to and use of research computing tools, services, educational materials and training.
3rd Tuesdays, 9:00am - 12:00pm & 4th Fridays 9am - 1pm Room 540C
ARC_Info@uc.edu

Academic Personnel
Academic Personnel will provide consulting and advisory services to Unit Heads on AAUP collective bargaining agreement issues and related faculty concerns.
1st Wednesdays, 10:00am -12:00pm & 3rd Thursdays, 1 - 3pm Room 545N
kasey.underwood@uc.edu

Virtual & Augmented Reality in the Creative Innovation Room - The UCSIM | Center for Simulations & Virtual Environments Research
Provides demonstrations and consultation to help faculty learn more about how to use virtual and augmented Reality for teaching and research. UCSIM staff are available for walk-in demonstrations or other hours by appointment. ***Mondays, 10:00am- 12:00pm & Thursdays,***
12:30pm- 3:00pm Room 540A
ucsim@uc.edu

The Statistics Consulting Center (SCC)
Statistics consulting services will be provided free of charge to faculty and their graduate students engaged in research by the Statistics Consulting Center (SCC) in the Division of Statistics and Data Science of the Department of Mathematical Sciences.
By Appointments ONLY
Monday 10:10 am - 12:10 pm & 1:40 pm - 3:40 pm
Wednesday 10:10 am - 12:10 pm
Thursday 10:00 am - 12:00 pm
Walk-in clinic ONLY Wednesday 1:40 pm - 3:40 pm
Schedule at https://www.artsci.uc.edu/statconsulting
Room 540C askstat@uc.edu

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Research Development and Support Series

2/25/2020 – Research Development & Support Series – Rigor and Reproducibility: Focus on the NAE report
1pm – 2:30pm, University Hall 454
3/2/2020 – Research Development & Support Series – Multi-PIs and Center Grants
3/6/2020 – Research Development & Support Series – Talking to Your Program Officers
3/16/2020 – Research Development & Support Series – Grant Writer's Workshop (full day) ($75 cost associated with attendance)
8am – 4:30pm, West Campus
3/22 – 27/2020 – Research and Innovation Week
Various locations and events
3/26/2020 – Hutton Ethics Lecture (with other Ethics Lectures)
9am – 10:30 pm Professional Ethics and the Responsible Conduct of Research, CEAS Ethics Lecture and Reception – Dr. Michael C. Loui, ERC 427
Noon – 1pm Hutton Ethics Lectureship – Citizen Science and Human Genomic Research: Ethical and Social Implications, Dr. Eric T. Juengst, UC Gardner Neuroscience Institute – Auditorium, RSVP by March 20th, lunch provided
2pm – 3:30pm Ethics: The Secret to Effective Leadership? – Dr. Andrew Cullison, Lindner Hall 1220

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Research Development and Support Series

3/30/2020 – Research Development & Support Series – Outreach, Education and Infrastructure Panel, 10:30am – Noon, Faculty Enrichment Center, Langsam Library Room 540F
3/30/2020 – Research Development & Support Series – Early Career Workshop (half day, afternoon)
1pm – 5pm, **Lindner Center Athletics Building between Nippert and 5/3rd** , Room 450 (This is NOT the new Business Building)
4/8/2020 – Research Development & Support Series – Moving your NSF Biosketch to SciENcv, 2 – 3:30 pm, Langsam Library, Room 475
4/20/2020 – Undergraduate Scholarly Showcase (Office of Research is a sponsor again this year)
9am – 4pm, TUC
4/29/2020 – Research Development & Support Series – Building Your Team – Team Science, 11:30 – 1 pm, Faculty Enrichment Center, Langsam Library Room 540F

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Extra Slides

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Documentation should include:

1. Who generated the record
2. What they did
3. When they did it
4. Why the did it
5. What the overall goal/project was
6. How they did it (protocol/methodology)
7. What materials were used
8. The results
9. The analysis
10. The interpretation
11. The next step(s)

Remember to check for data entry errors

Can you audit (are changes in the database saved so you can identify if/when an error occurred?/do you have version controls?)?

Modified from "Guidelines for Scientific Record Keeping in the Intramural Research Program at NIH" Michael Gottesman, MD. 2008

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The research record includes:

Lab notes, spreadsheets, databases

- Equipment/access logs, etc.
- Posters
- Seminars
- Funding proposals
- Progress reports
- Manuscripts

ARCHIVE: final raw data set, documented program that prepared the data set, documented program that conducted the analysis, output from the program (the analysis)

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Documentation should be:

1. Reasonably permanent
   - Paper (organized!)
   - Electronic (with back up)

2. Appropriately secured

3. Meet the FAIR standard
   - Findable
   - Accessible
   - Interoperable
   - Reusable

Good mentoring including consistent review of raw data reduces the likelihood of misconduct

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BOX 9-1
Best Practices Checklist for Researchers

Research Integrity
- Maintain high standards in own work.
- Understand policies.
- Raise questions and problems promptly and professionally.
- Strive to be a generous and collegial colleague.

Data Handling
- Develop data management and sharing plan at the outset of a project.
- Incorporate appropriate data management expertise in the project team.
- Understand and follow data collection, management, and sharing standards, policies, and regulations of the discipline, institution, funder, journal, and relevant government agencies.

Authorship and Communication
- Ensure that general and disciplinary standards are followed for research publications.
- Acknowledge the roles and contributions of authors.
- Be transparent when communicating with all audiences.

Mentoring and Supervision
- Model and instruct on research best practices.
- Regularly check work of subordinates and ensure adherence to best practices.
- Clarify expectations.

Peer Review
- Provide complete and timely review.
- Maintain confidentiality.
- Disclose conflicts, and eliminate or manage them as appropriate.

Research Compliance
- Protect human subjects and laboratory animals.
- Follow environmental and other safety regulations.
- Do not engage in misuse.
- Disclose and manage conflicts of interest.

Fostering Integrity. National Academies of Sciences, Engineering, and Medicine. 2017. www.nap.edu

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BOX 9-3
Best Practices Checklist for Journals

Practicing Transparency

- Adopt up-to-date policies and instructions.
- Publish retractions/corrections and reasons in articles, in tables of contents, and as metadata in a timely fashion.
- Provide a link to data and code that support articles, and facilitate long-term access.
- Require full descriptions of methods in methods sections or electronic supplements.
- Provide for postpublication review and commentary.
- Be transparent in negotiating with authors and in adjudicating disputes.
- Establish a conflict of interest policy covering editorial staff.
- Provide open access consistent with business viability.

Adopt Policies that Ensure Openness Regarding:

- Data, code, and records of any image alterations.
- Author funding and conflicts of interest.
- Peer reviewer conflicts of interest.

Author Contributions

- Describe author roles.

Training and Education

- Facilitate training for editors, reviewers, and authors.

Collaboration

- Participate in science, engineering, technology, and medical publishing efforts to develop tools and approaches to foster integrity.

Fostering Integrity. National Academies of Sciences, Engineering, and Medicine. 2017. www.nap.edu

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Box 9-4: Best Practices Checklist for Research Sponsors and Users of Research

Aligning Policies with Research Integrity

- Maintain clear policies on research misconduct, and implement them consistently.
- Increase awareness of how policies and practices affect research integrity and quality, and act on that knowledge.
- Work to harmonize policies and practices across agencies, sectors, and national borders.

Public Access to Data and Code

- Develop data and code access policies for extramural grants appropriate to the research being funded, and make fulfillment of these policies a condition of future funding.
- Cover the costs borne by researchers and institutions to make data and code available.
- Practice transparency of data and code for intramural programs.
- Promote responsible sharing of data in areas such as clinical trials.
- Practice impartiality and transparency in utilizing research for the development of policy and regulations.

Fostering Integrity. National Academies of Sciences, Engineering, and Medicine. 2017. www.nap.edu

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Home - Data Management Planning - Research Guides at University of Cincinnati http://guides.libraries.uc.edu/datamanagementplanning

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Libraries / Research Guides / Health Sciences Library / Data Management Planning / Home

Data Management Planning

Search | Submit Query

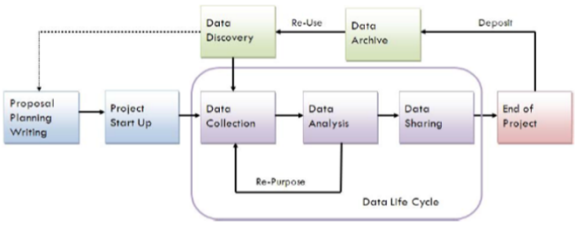
This guide on data management planning and data discovery focuses on STEM fields.

- Home
- Why Manage Your Data?
- Mandates & Requirements
- Writing a Data Plan
- Documentation & Metadata
- Sharing, Storage, & Backup
- UC Services

Welcome!

Welcome to UCL's resource guide for Data Management Planning!

Data Management Planning Process



Source: http://dmconsult.library.virginia.edu/files/2013/03/DataLifeCycle1.jpg

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