Registered Reports:
Peer reviewed study pre-registration

Implications for reporting of human clinical trials

Chris Chambers

Professor of Cognitive Neuroscience
Cardiff University Brain Research Imaging Centre (CUBRIC)
School of Psychology, Cardiff University
Email: chambersc1@cardiff.ac.uk
Twitter: @chrisdc77

Science has an incentive problem

What's best for science

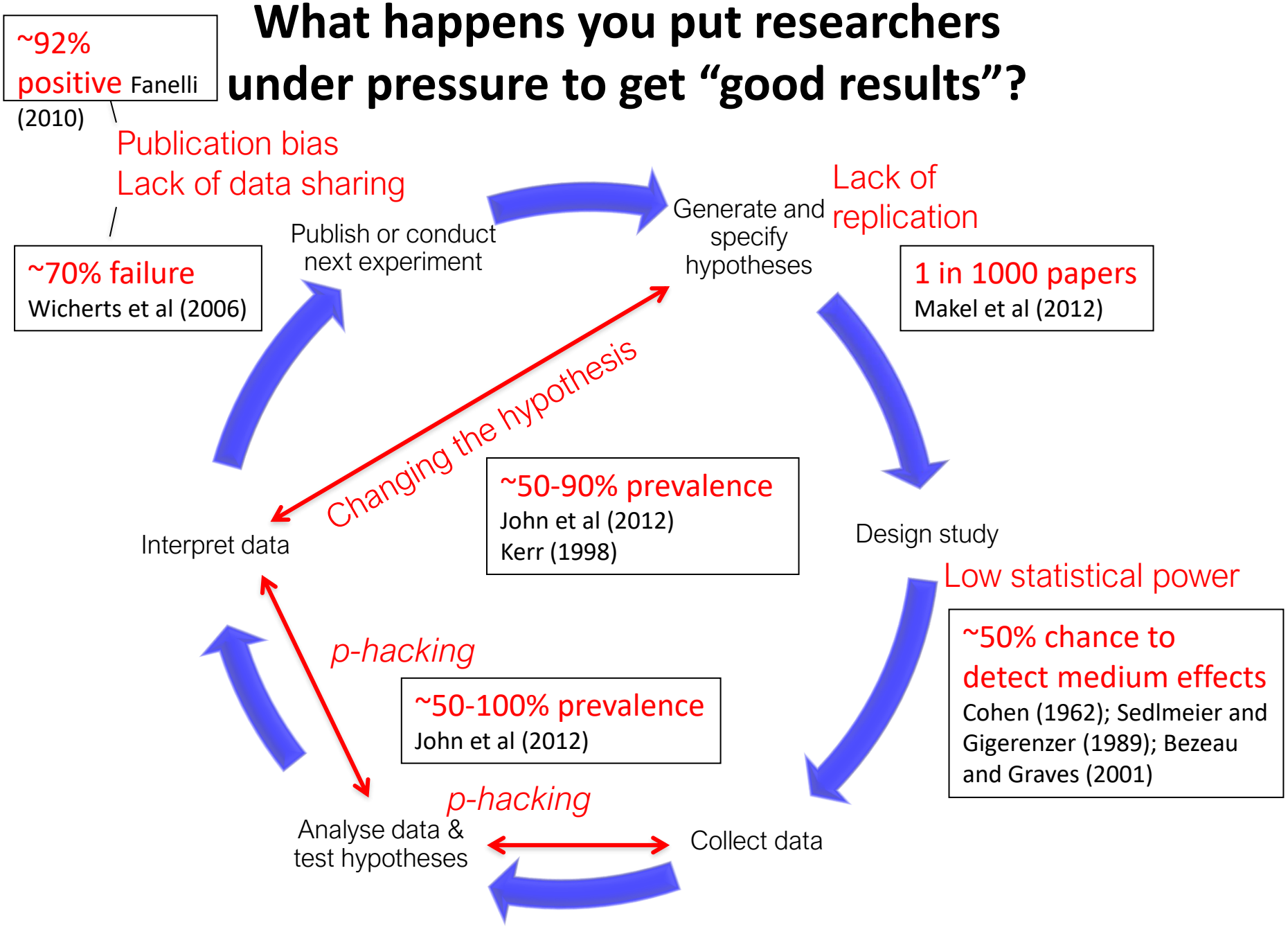
High quality research, published regardless of outcome

What's best for scientists

Producing a lot of "good results"

see Nosek, Spies & Motyl (2012). *Perspectives on Psychological Science, 7(6)*: 615–631

What happens you put researchers under pressure to get "good results"?



Reproducibility and reliability of biomedical research: improving research practice

Symposium report, October 2015

The Academy of Medical Sciences

BBSRC bioscience for the future

MRC Medical Research Council

wellcome trust

https://acmedsci.ac.uk/policy/policy-projects/reproducibility-and-reliability-of-biomedical-research

Same problems affect clinical trials

COMPARE
TRACKING SWITCHED OUTCOMES IN CLINICAL TRIALS

METHODS | RESULTS | TEAM | FAQ | BLOG

Here's what we found.

67	9	354	357
TRIALS CHECKED	TRIALS WERE PERFECT	OUTCOMES NOT REPORTED	NEW OUTCOMES SILENTLY ADDED

On average, each trial reported just 58.2% of its specified outcomes. And on average, each trial silently added 5.3 new outcomes.

Hidden outcome switching common in clinical trials, despite trial registration

RESEARCH NOTE

REVISED **Funding source and primary outcome changes in clinical trials registered on ClinicalTrials.gov are associated with the reporting of a statistically significant primary outcome: a cross-sectional study [version 2; referees: 2 approved]**

Sreeram V Ramagopalan[1], Andrew P. Skingsley[2], Lahiru Handunnetthi[3], Daniel Magnus[4], Michelle Klingel[5], Julia Pakpoor[3], Ben Goldacre[5]

Hidden outcome switching associated with positive results (p-hacking)

Why is this happening?

Because we place too much importance on the **results** of research and not enough on the **processes** that produce them

Results make science exciting but judging the quality of science (and scientists) according to the results is “soft” science

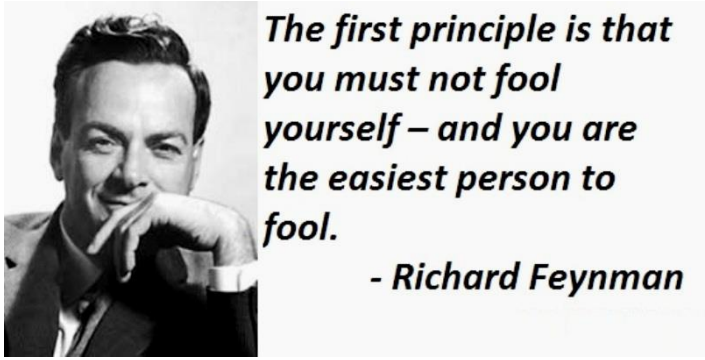
Fixing this requires a change in mindset

Philosophy:

What gives hypothesis-testing its scientific value is

- the QUESTION it asks
- the QUALITY of the method it uses
- never the RESULT it produces

If we accept this philosophy then editorial decisions at journals should be *blind* to results



Registered Reports

CORTEX 49 (2013) 609–610

ELSEVIER

Available online at www.sciencedirect.com

SciVerse ScienceDirect

Journal homepage: www.elsevier.com/locate/cortex

Editorial

Registered Reports: A new publishing initiative at *Cortex*

Christopher D. Chambers

Cardiff University Brain Research Imaging Centre (CUBRIC), School of Psychology, Cardiff University, United Kingdom

Four central aspects of the Registered Reports model:

- Researchers decide hypotheses, experimental procedures, and main analyses *before* data collection
- Part of the peer review process takes place before experiments are conducted
- Passing this stage of review virtually guarantees publication
- Original studies and high-value replications are welcome

How it works

Authors submit **STAGE 1** manuscript with Introduction, Proposed Methods & Analyses, and Pilot Data (if applicable)

↓

Stage 1 peer review

↓

If reviews are positive then journal offers **in-principle acceptance (IPA)**, regardless of study outcome (*protocol not published yet*)

Are the hypotheses well founded?

Are the methods and proposed analyses feasible and sufficiently detailed?

Is the study well powered? (≥90%)

Have the authors included sufficient positive controls to confirm that the study will provide a fair test?

How it works

Authors do the research

↓

Authors resubmit completed **STAGE 2** manuscript:

- **Introduction** and **Methods** (virtually unchanged)
- **Results (new)**: Registered confirmatory analyses + unregistered exploratory analyses
- **Discussion (new)**
- **Data deposited in a public archive**

↓

Stage 2 peer review

↓

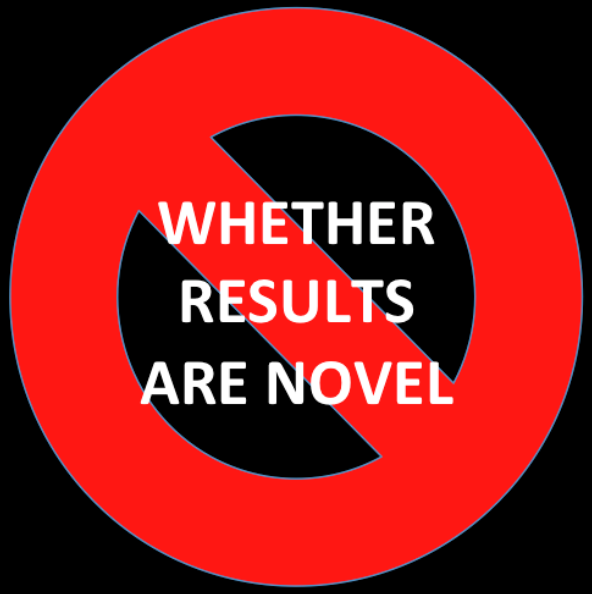
Manuscript published!

Did the authors follow the approved protocol?

Did positive controls succeed?

Are the conclusions justified by the data?

None of these things matter



Published examples at *Cortex*

Registered report

The effects of AMPA blockade on the spectral profile of human early visual cortex recordings studied with non-invasive MEG

Suresh D. Muthukumaraswamy [a,b,], Bethany Routley [c], Wouter Droog [d], Krish D. Singh [c] and Khalid Hamandi [c,e]*

Registered report

The functional subdivision of the visual brain: Is there a real illusion effect on action? A multi-lab replication study

Karl K. Kopiske [a,f,], Nicola Bruno [b], Constanze Hesse [c], Thomas Schenk [d] and Volker H. Franz [a,e]*

Registered report

Mu suppression – A good measure of the human mirror neuron system?

Hannah M. Hobson[*] and Dorothy V.M. Bishop

– Reproducible –
- detailed, repeatable methods
- high statistical power (2-3x above normal)

– Transparent –
- accompanied by open data & materials
- outcomes of confirmatory and exploratory analyses distinguished

– Credible –
- no publication bias
- no hindsight bias
- no selective reporting

http://www.journals.elsevier.com/cortex/virtual-special-issues/virtual-special-issue-registered-reports

See also:
Social Psychology special issue: http://econtent.hogrefe.com/toc/zsp/45/3
Perspectives on Psychological Science: http://www.psychologicalscience.org/index.php/replication/ongoing-projects

theguardian

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News > Science > Peer review and scientific publishing

Trust in science would be improved by study pre-registration

Open letter: We must encourage scientific journals to accept studies before the results are in

Chris Chambers, **Marcus Munafo** and more than 80 signatories
theguardian.com, Wednesday 5 June 2013 12.45 BST

Jump to comments (43)

The quest: a better understanding of nature. Photograph: Sebastian Kaulitzki/Alamy

In an ideal world, scientific discoveries would be independent of what scientists *wanted* to discover. A good researcher would begin with an idea, devise a method to test the idea, run the study as planned, and then decide based on the evidence whether the idea had been supported. Following this approach would lead us step-by-step toward a better understanding of nature.

Unfortunately, the life sciences are becoming increasingly estranged from this way of thinking. Early in their training, students learn that the quest for truth needs to be balanced against the more immediate pressure to

Permanent adopters

- Advances in Methodologies and Practices in Psychological Science
- AIMS Neuroscience
- Animal Behavior and Cognition
- Attention, Perception, and Psychophysics
- Behavioral Neuroscience
- Cognition and Emotion
- Cognitive Research: Principles and Implications
- Comprehensive Results in Social Psychology
- Cortex
- Drug and Alcohol Dependence
- European Journal of Neuroscience
- Experimental Psychology
- Health Psychology Bulletin
- Human Movement Science
- Infancy
- International Journal of Psychophysiology
- Journal of Business and Psychology
- Journal of Cognitive Enhancement
- Journal of European Psychology Students
- Journal of Experimental Political Science
- Journal of Media Psychology
- Journal of Personnel Psychology
- Judgment and Decision Making
- Management and Organization Review
- Memory
- Nature Human Behaviour
- NFS Journal
- Nicotine & Tobacco Research
- Perspectives on Psychological Science
- Royal Society Open Science
- Stress and Health
- The Leadership Quarterly
- Work, Aging and Retirement

Special issues

- American Journal of Political Science
- American Political Science Review
- American Politics Research
- Comparative Political Studies
- eLife
- Frontiers in Cognition
- Journal of Accounting Research
- Political Analysis
- Political Behavior
- Political Science Quarterly
- Political Science Research and Methods
- Public Opinion Quarterly
- Social Psychology
- State Politics and Policy Quarterly
- The Review of Financial Studies

For full list see https://cos.io/rr/

Registered Reports at *Royal Society Open Science*

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Registered Reports

1. Summary and benefits
2. Stage one
3. Stage two
4. Reviewer guidelines
5. More information

Summary and Benefits

A Registered Report (RR) is a form of journal article in which methods and proposed analyses are pre-registered and peer-reviewed prior to research being conducted (stage 1). High quality protocols are then provisionally accepted for publication before data collection commences. The format is open to attempts of replication as well as novel studies. Once the study is completed, the author will finish the article

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analytical chemistry | applied mathematics
artificial intelligence | astrobiology

http://rsos.royalsocietypublishing.org/content/registered-reports

Registered Reports at *Nature Human Behaviour*

Disciplines covered in the journal include:

Anthropology	Evolution
Artificial Intelligence	Genetics
Business Studies	Geography
Cognitive Science	Linguistics
Communication	Management
Criminology	Neurology
Cultural Studies	Neuroscience
Ecology	Political Science
Economics	Psychiatry
Education	Psychology
Epidemiology	Public Policy
Ethology	Sociology

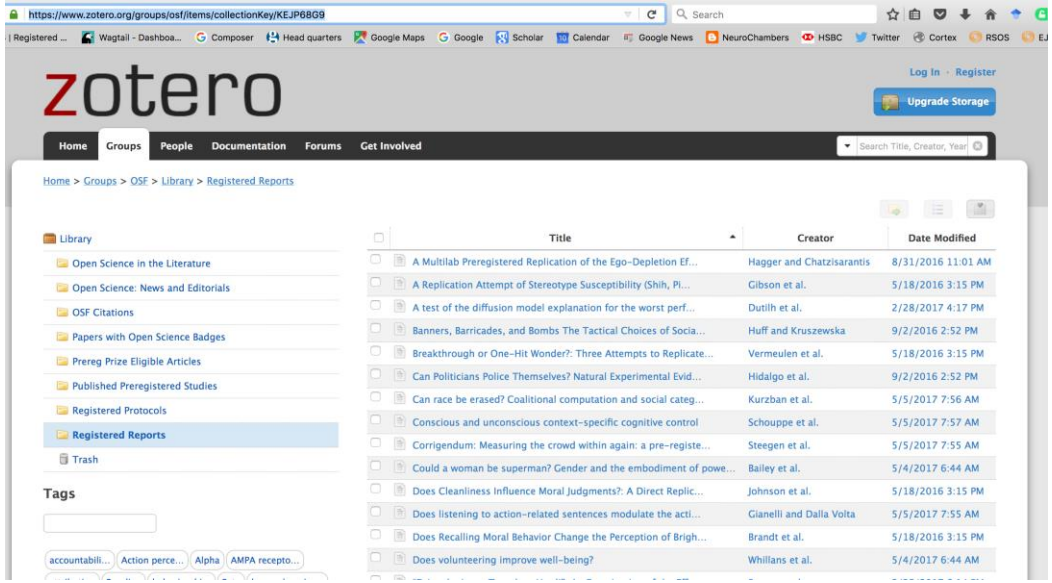
Current State

- **52** journals have adopted Registered Reports
  - **37** permanently
  - **15** as part of a special issue (e.g. JAR)

- Fields covered
  - **Life/medical sciences**: neuroscience, nutrition, psychology, psychiatry, biology, cancer research
  - **Social sciences**: political science, financial and accounting research (including JAR)
  - **Physical sciences**: chemistry, physics, computer science etc.

- **59** fully completed RRs (~2-3 times that provisionally accepted & awaiting data)

https://www.zotero.org/groups/osf/items/collectionKey/KEJP68G9



Frequently asked questions

1. "Are Registered Reports suitable for my field?"

- Applicable to any field engaged in hypothesis-driven research where one or more of the following problems apply:
  - **Publication bias**
  - **Significance chasing (e.g. *p*-hacking)**
  - ***Post hoc* hypothesizing (hindsight bias)**
  - **Low statistical power**
  - **Lack of direct replication**
- Not applicable for
  - **Purely exploratory science**
  - **Methods development**

  } No hypothesis testing

2. "Could researchers cheat by 'pre-registering' a study that they have already conducted?"

- Time-stamped raw data files must be submitted at Stage 2 with basic lab log and certification from all authors that data was collected after provisional acceptance
- Submitting a completed study at Stage 1 would therefore be fraud
- Strategy would backfire anyway when reviewers ask for amendments at Stage 1

Registered Reports aren't designed to prevent fraud but to incentivize good practice

3. “Will this limit exploration or stigmatize exploratory research?”

- No. **The are no restrictions on the reporting of unregistered exploratory analyses**.
- Confirmatory and exploratory analyses are simply reported separately in the final paper

What stigmatizes exploratory research is *post hoc hypothesizing* to fit a deductive framework

Exploratory research is simply not valued in its native form

Registered Reports for Clinical Trials: Launch pending at *BMC Medicine*

Standard Registered Reports

1. Researchers acquire funding

2. Researchers obtain ethics approval and any regulatory approvals

3. Submit RR to journal for Stage 1 peer review

4. Following revision, journal Stage 1 in principle acceptance (IPA) for high quality submissions

5. Researchers obtain (as necessary) any ethics and regulatory approval of *revised* protocol

6. Researchers conduct the research and, when completed, submit a Stage 2 manuscript to journal

7. Following positive Stage 2 review, full paper is published.

Registered Reports for Clinical Trials

1. Researchers acquire funding

2. Submit RR to journal for Stage 1 peer review

3. Following revision, journal offers conditional acceptance (CA) for high quality submissions

4. Authors submit CA-approved protocol for ethics and regulatory approval

5. CA-approved protocol revised as necessary. The revised protocol, ethical approval and regulatory reviews passed to journal.

6. Journal offers full Stage 1 in principle acceptance (IPA)

7. Researchers register the IPA protocol on clinicaltrials.gov

8. Researchers conduct the trial and, when completed, submit a Stage 2 manuscript to journal

9. Following positive Stage 2 review, full paper is published, ideally with any regulatory reviews, e.g. from the FDA.

Going even further…

Can we integrate ethical review, grant funding and Registered Reports?

- Possible solution: **Registered Reports funding model**
- Authors submit their research proposal *before* they have funding.
- Following review by the both the funder and the journal, the strongest proposals would be offered financial support by the funder AND in-principle acceptance for publication by the journal.

RR partnerships in development

- **Journals/publishers**
  - *Nicotine and Tobacco Research*
  - *PLOS Biology*
  - *Royal Society Open Science*
  - *BMC, including BMC Medicine*
- **Funders**
  - CHDI
  - Cancer Research UK

First RR funder/journal partnership underway between *Nicotine and Tobacco Research* (Marcus Munafo) and Cancer Research UK

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Article Contents

References

Improving the Efficiency of Grant and Journal Peer Review: Registered Reports Funding FREE

Marcus R. Munafò, PhD

Nicotine Tob Res (2017) 19 (7): 773. **DOI:** https://doi.org/10.1093/ntr/ntx081
Published: 06 April 2017

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Peer review—the process whereby scientific research is evaluated by independent experts within the field—remains a cornerstone of scientific research, and acts as a critical gatekeeper in relation to both grant funding

https://doi.org/10.1093/ntr/ntx081

Information Hub at the Center for Open Science

Registered Reports

Peer review before results are known to align scientific values and practices

- Registered Reports
- Participating Journals
- Details and Workflow
- Resources for Editors
- Funders
- FAQ
- News

Transparency, open sharing, and reproducibility are core values of science, but not always part of daily practice. Registered Reports are a publication format that emphasize the importance of the research question and the quality of methodology by conducting the peer review prior to data collection and analysis. Accepted papers then are virtually guaranteed publication in the journal if the authors follow through with the registered methodology.

"Registered Reports eliminates the bias against negative results in publishing because the results are not known at the time of review" said Daniel Simons, Professor at University of Illinois, Urbana-Champaign and co-Editor of Registered Replication Reports at Perspectives on Psychological Science. Chris Chambers, Professor at Cardiff University, section editor at Cortex and Royal Society Open Science, and chair of the Registered Reports Committee supported by the Center for Open Science (COS) adds, "Because the study is accepted in advance, the incentives for authors change from producing the most beautiful story to producing the most accurate one."

Two articles provide an introduction to the Registered Reports concept: one is an introduction to a special issue of 15 Registered Reports in

https://cos.io/rr/

- Detailed FAQs
- Table comparing journal features

For more info, email me (chambersc1@cardiff.ac.uk) or David Mellor at the COS (david@cos.io)