HOW TO REDUCE WASTE AND INCREASE TRANSPARENCY IN HEALTH RESEARCH

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RDC WEBINAR

DISCLOSURES

- No conflicts of interest
- Affiliations at uOttawa & University of Stirling
- Member of EQUATOR Canada
- Ambassador for Centre for Open Science

LEARNING OBJECTIVES

- Understand the problem of waste in health research
- Discuss how to enhance the transparency of health research
- Discuss how to move towards open science

A PROBLEM IN BIOMEDICINE:

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research

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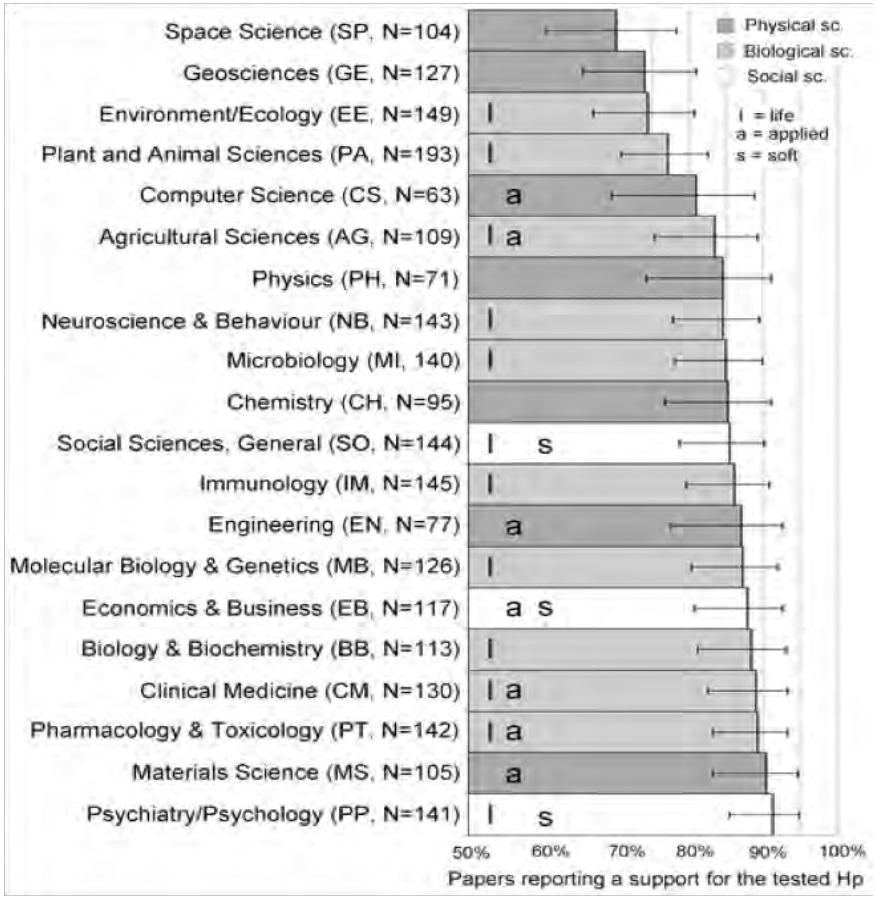
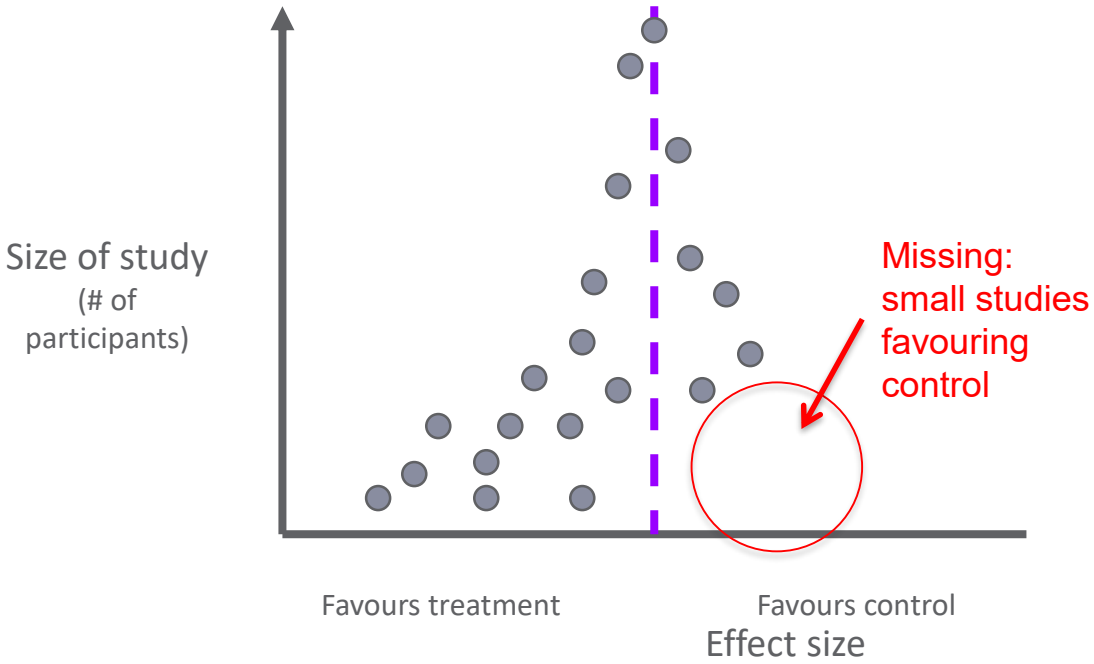


(Fanelli, 2010; PLoS One)

PUBLICATION BIAS

- Key reason negative and null results don't get published is because researchers don't write them up
  (Franco, Malhotra, Simonovits, 2014; Nature)



Prepared by Professor Amanda Burls and available from http://openaccess.city.ac.uk/id/eprint/13488Amanda.Burls.1@city.ac.uk

INCOMPLETE EVIDENCE

A PROBLEM IN BIOMEDICINE:

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research

GARDEN OF FORKING PATHS

Gelman and Loken, 2013

+ incentives and rewards

Outliers?

Controls?

Sex/Gender?

Hypothesis:
"Does X affect Y?"

GARDEN OF FORKING PATHS AND REPORTING ISSUES

- Selective outcome reporting

- Re-prioritization of outcomes (primary outcome becomes secondary and vice versa)

"There seem to be no formal guidelines in science as to when study results should or should not be published. The decision as to what to include in a publication and whether to publish is largely personal, although dictated by the fashion of the times to a certain extent."

-Kay Dickersin JAMA, 1990

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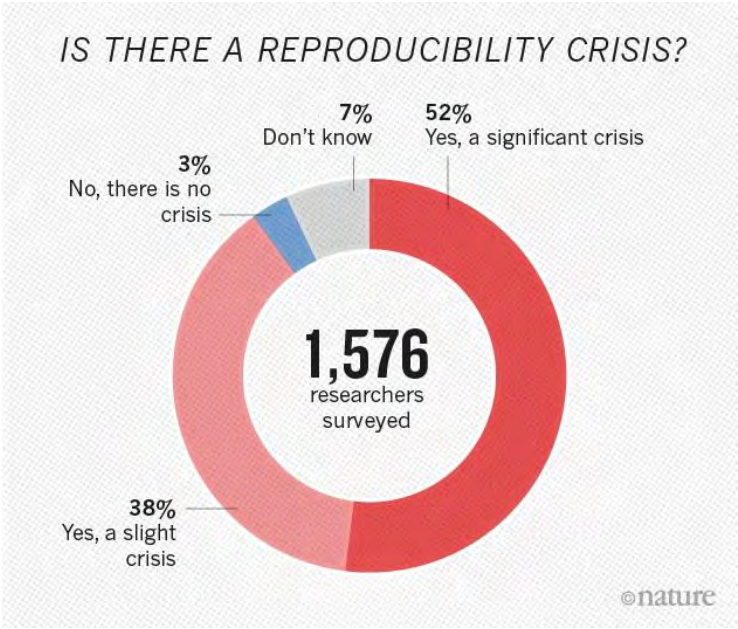

Baker, 2015; Nature

IRREPRODUCIBLE RESEARCH

- Why do patients partake in research?
- Why do governments fund research?
- Why do researchers study health topics?

Strategy for Patient-Oriented Research

SPOR

Putting Patients First

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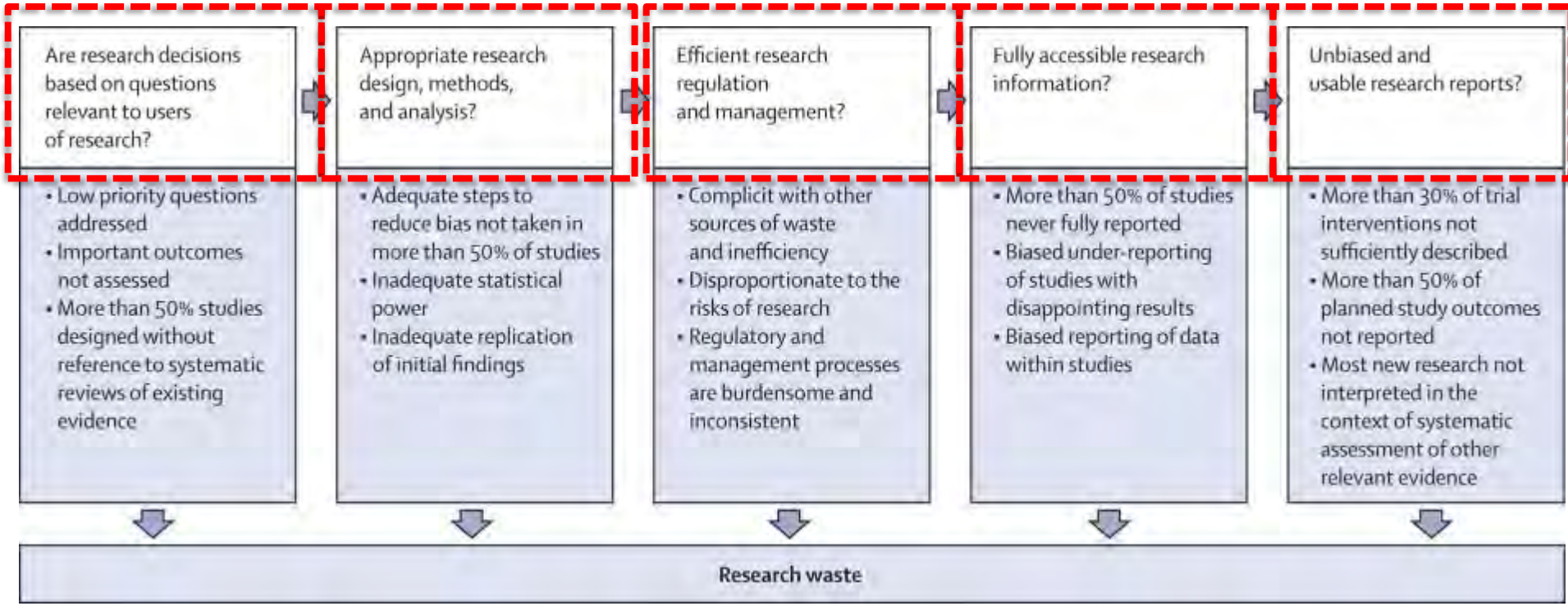
RESEARCH IS A CONTINUUM



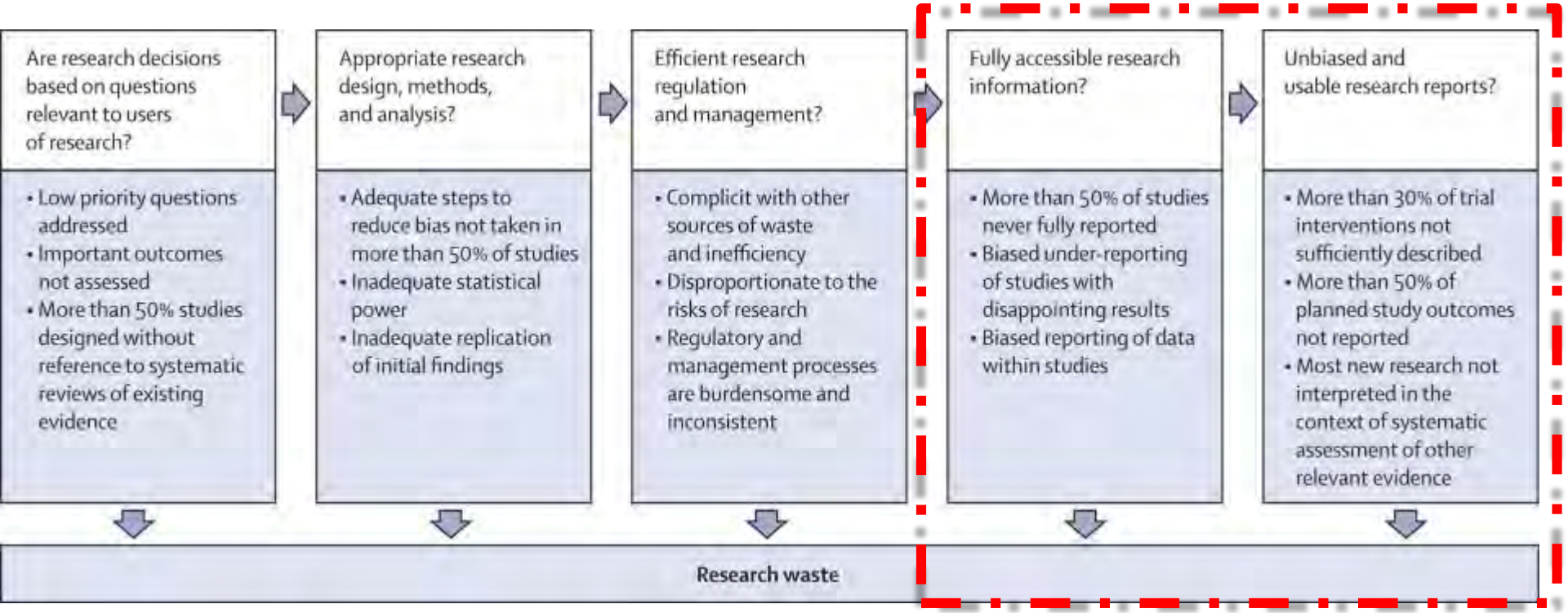
MacLeod et al., 2014; Lancet

WHAT IS THE SOLUTION TO THIS PROBLEM?

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research

Transparency

RESEARCH WASTE CONTRIBUTES TO IRREPRODUCIBILITY



MacLeod et al., 2014; Lancet

JOURNALOLOGY

SOLUTION: TRANSPARENT PREREGISTRATION

- A time-stamped, read-only version of your research plan created *before* you begin data collection.

It contains:

- Hypothesis
- Data collection procedures
- Manipulated and measured variables
- Statistical model

SOLUTION: TRANSPARENCY

1. What was planned?

   -Linking to protocols

2. What was done?

3. What is different between 1. and 2. and why?

4. What is the supporting evidence of 1., 2. and 3.?

WHAT PROBLEMS WOULD REGISTERED PROTOCOLS FIX?

- 1. Publication bias and selective outcome reporting
- 2. P-hacking: Unreported flexibility in data analysis
- 3. HARKing: Hypothesizing After Results are Known

When the research plan undergoes **peer review before results are known**, the preregistration becomes part of a Registered Report

PREREGISTRATION

- Preregistration makes the distinction between **confirmatory** (hypothesis testing) and **exploratory** (hypothesis generating) research more clear.

Presenting exploratory results as confirmatory increases the publishability of results **at the expense of credibility of results.**

WHY PREREGISTER?

- Make your research stand out
- Reduce waste
- Comply with policy (certain designs)

STUDY REGISTRATION: CLINICAL TRIALS

- **Clinical trials:**
- http://apps.who.int/trialsearch/

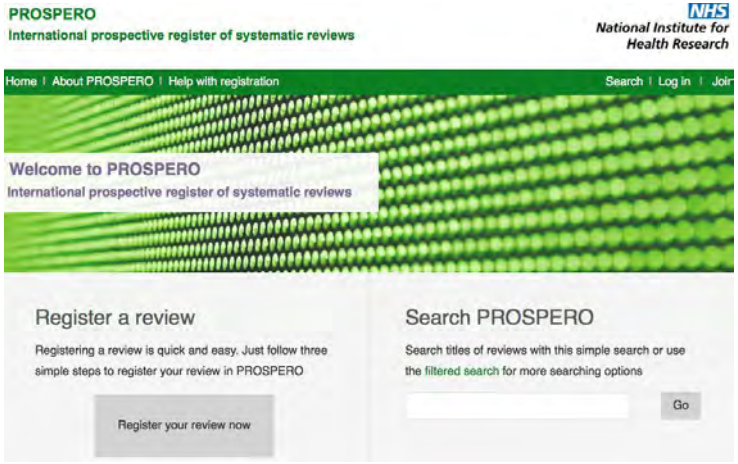
Article 11.3 TCPS2

- All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE).

POLICIES NEED TO BE ENFORCED

The COMPare Trials Project. Goldacre B, Drysdale H, Powell-Smith A, et al. www.COMPare-trials.org, 2016.

STUDY REGISTRATION: SYSTEMATIC REVIEWS



BioMed Central

Systematic Reviews

Check aims and scopes of specialty journals

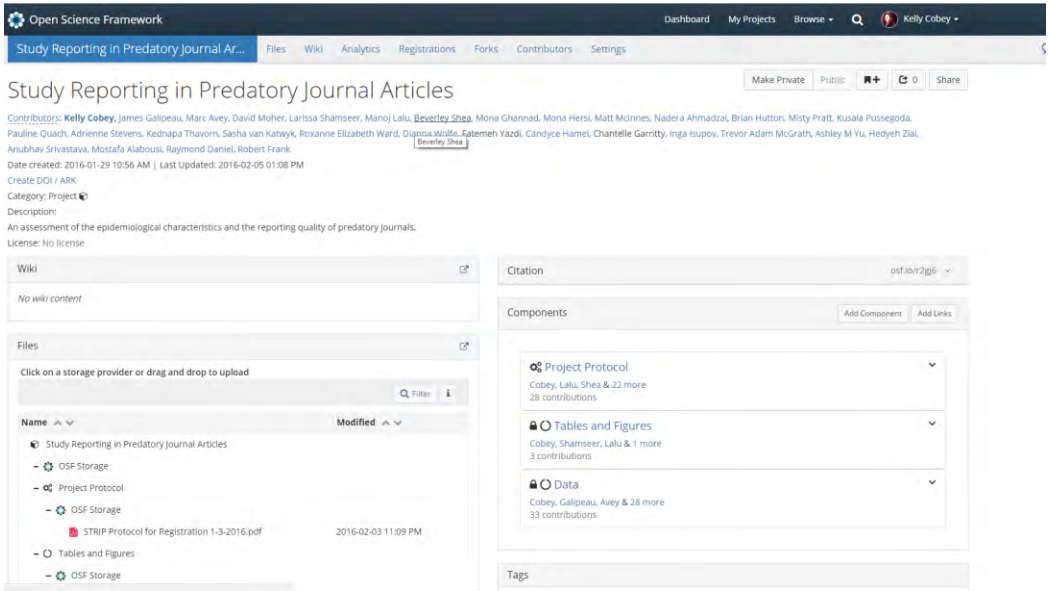
https://www.crd.york.ac.uk/PROSPERO/

*health related outcomes; currently only clinical research; no scoping reviews

STUDY REGISTRATION: OTHER DESIGNS

- Open Science Framework
- Free, immediate, protocol registration

https://osf.io/



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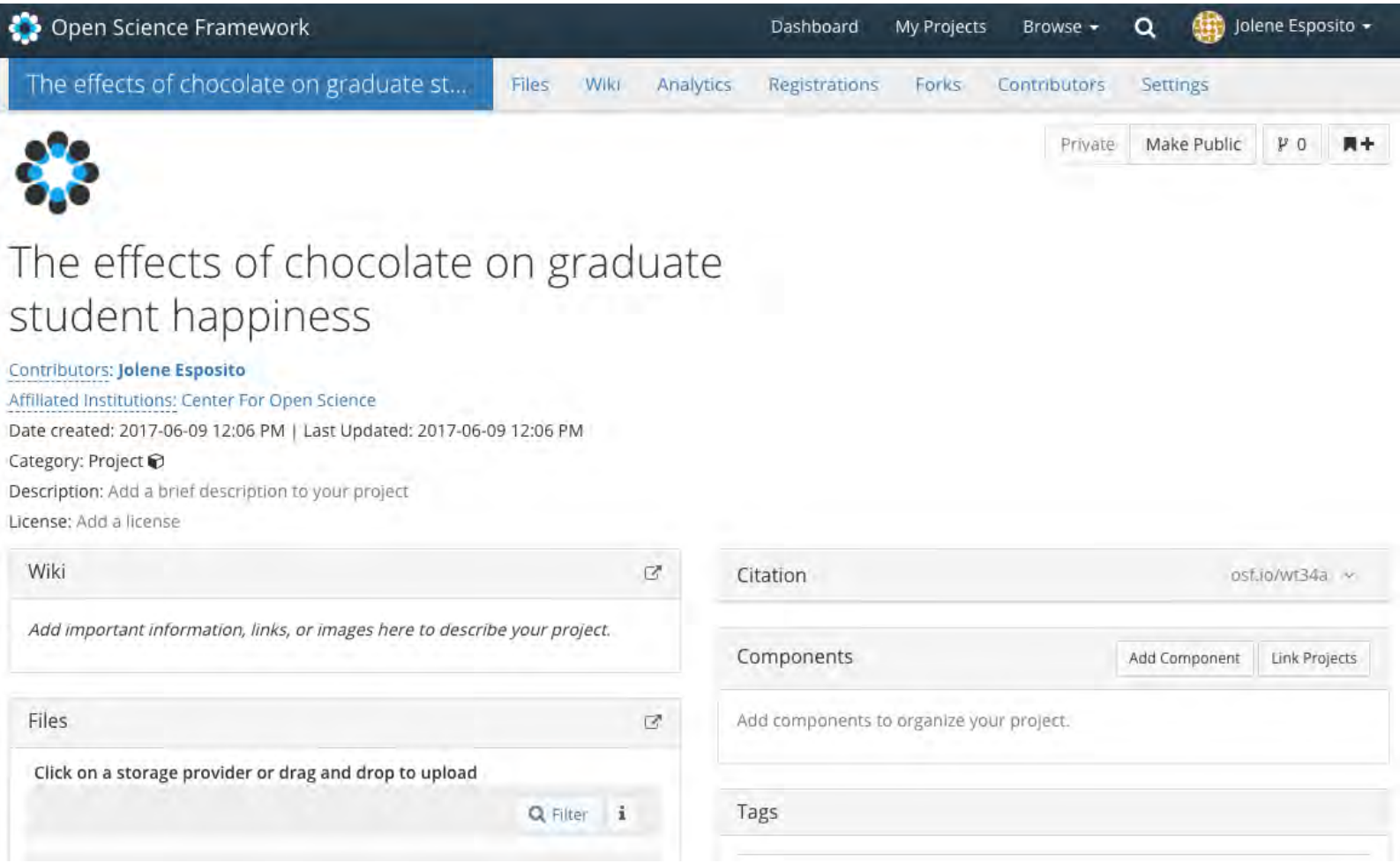

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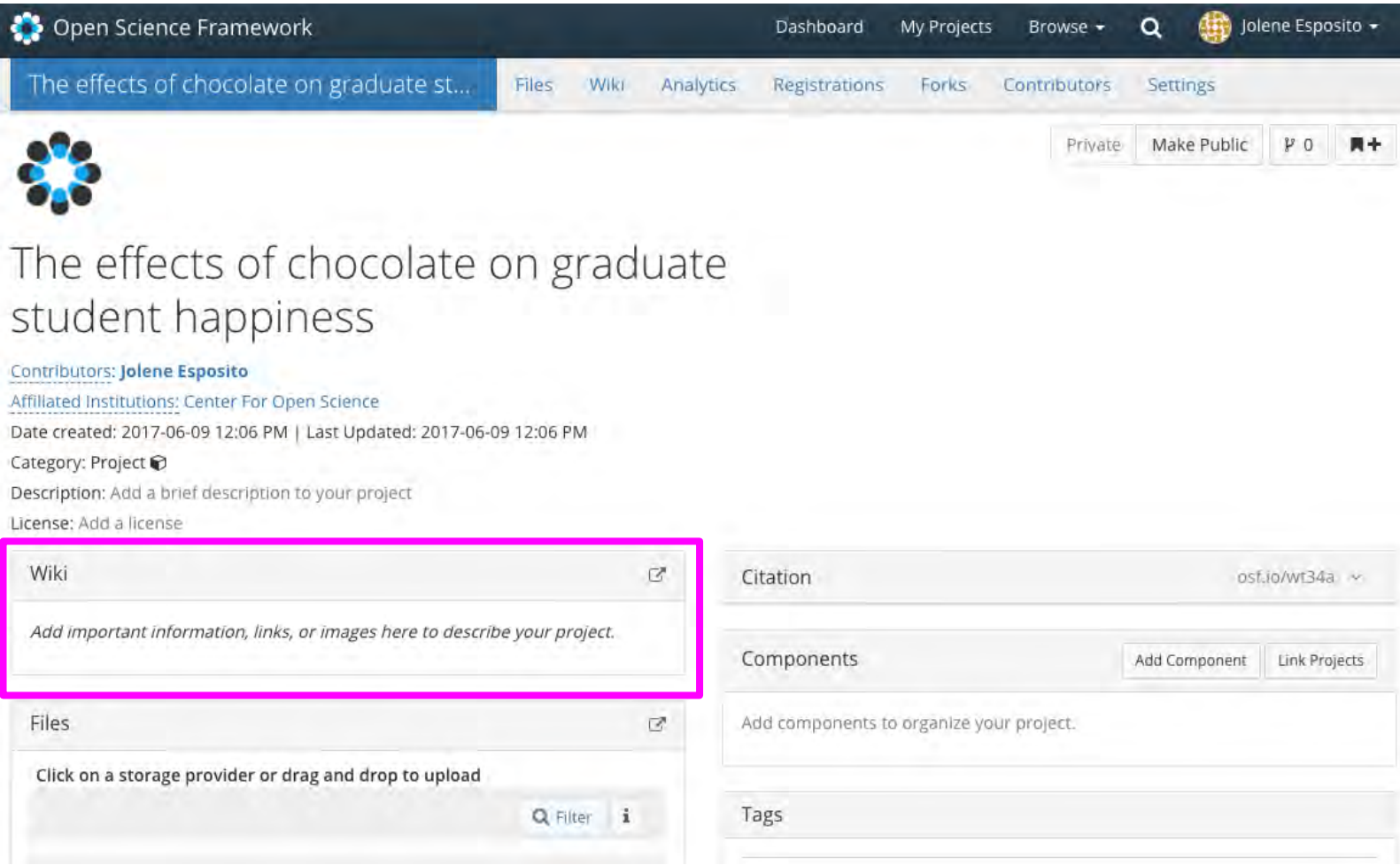

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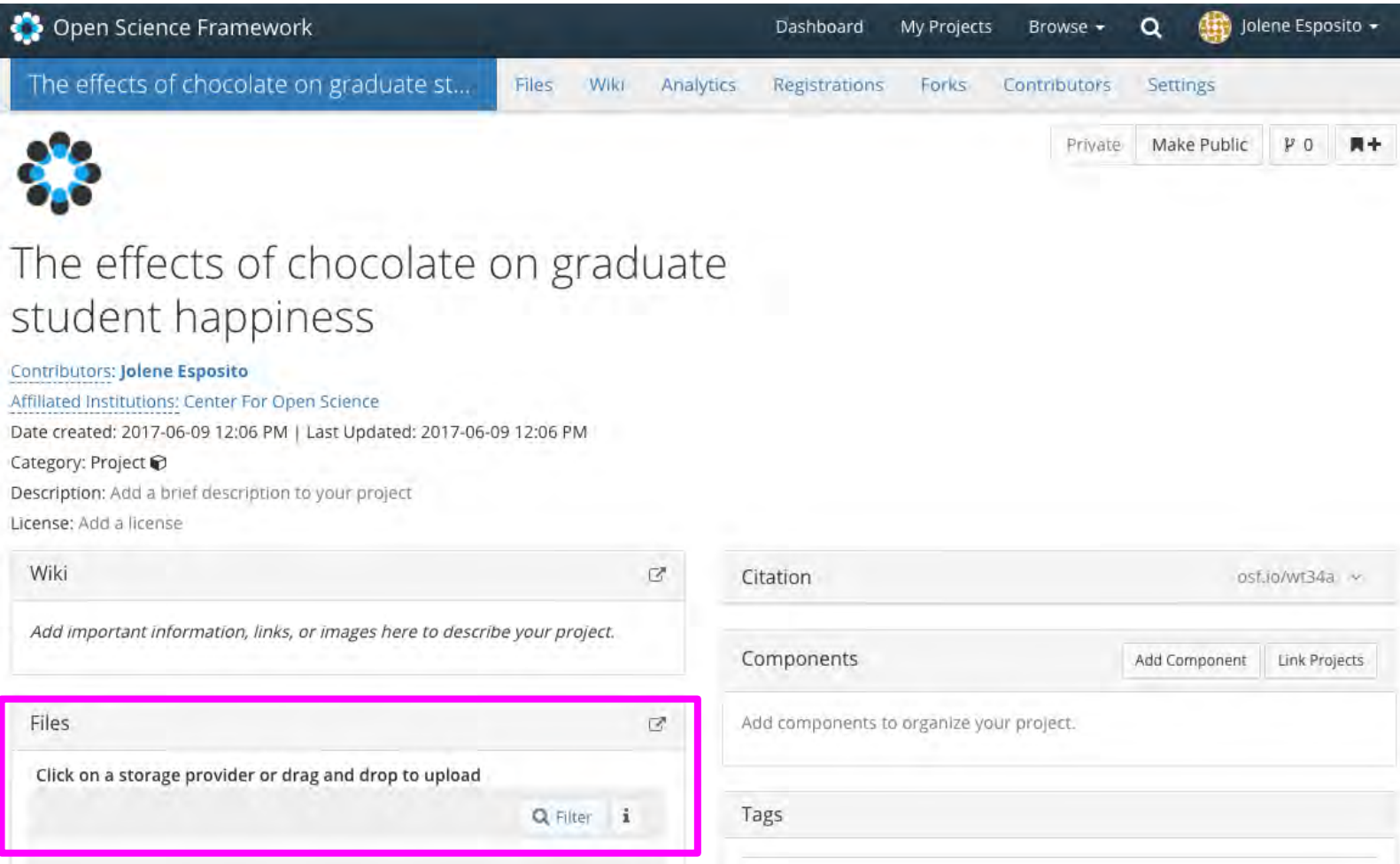

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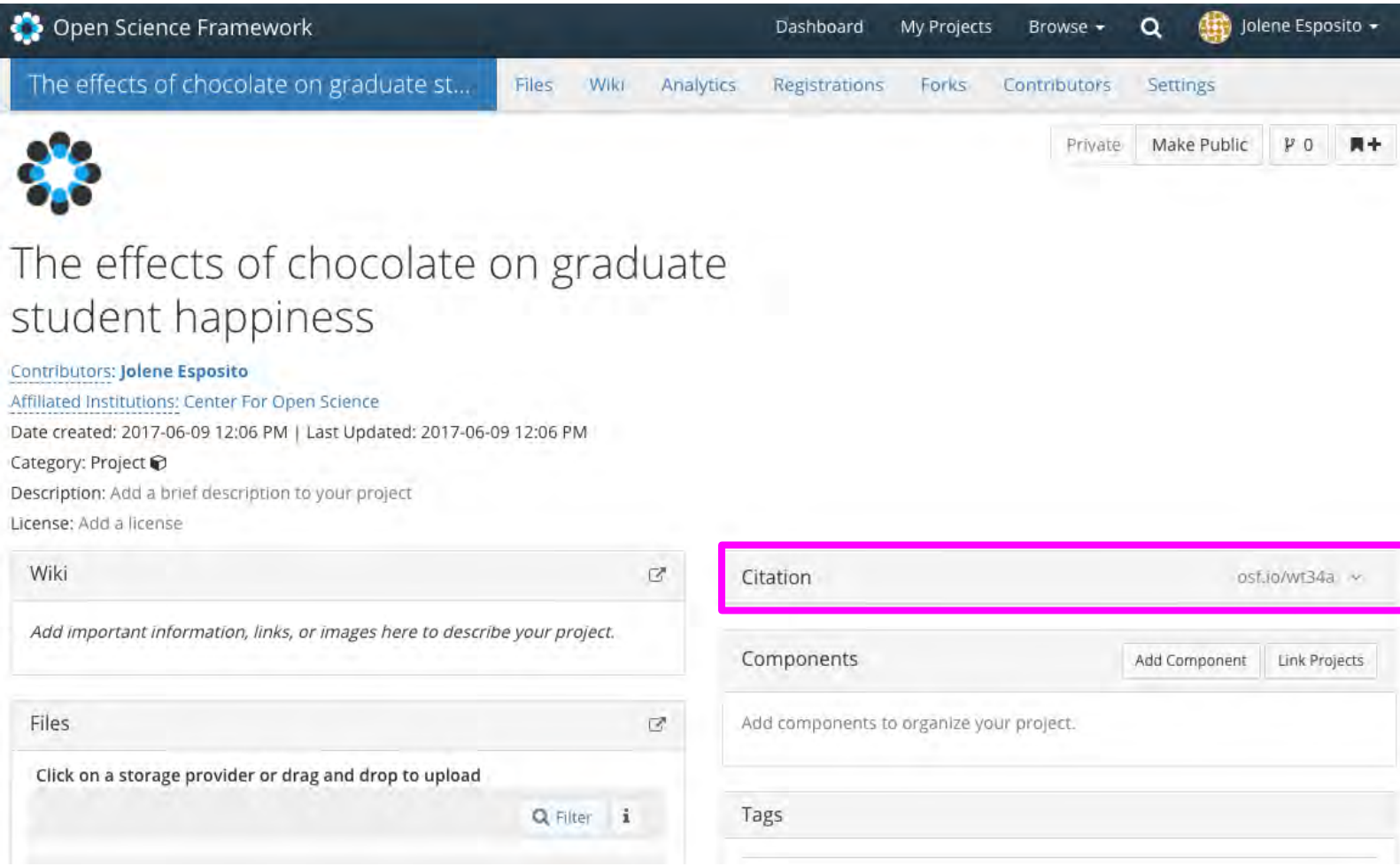

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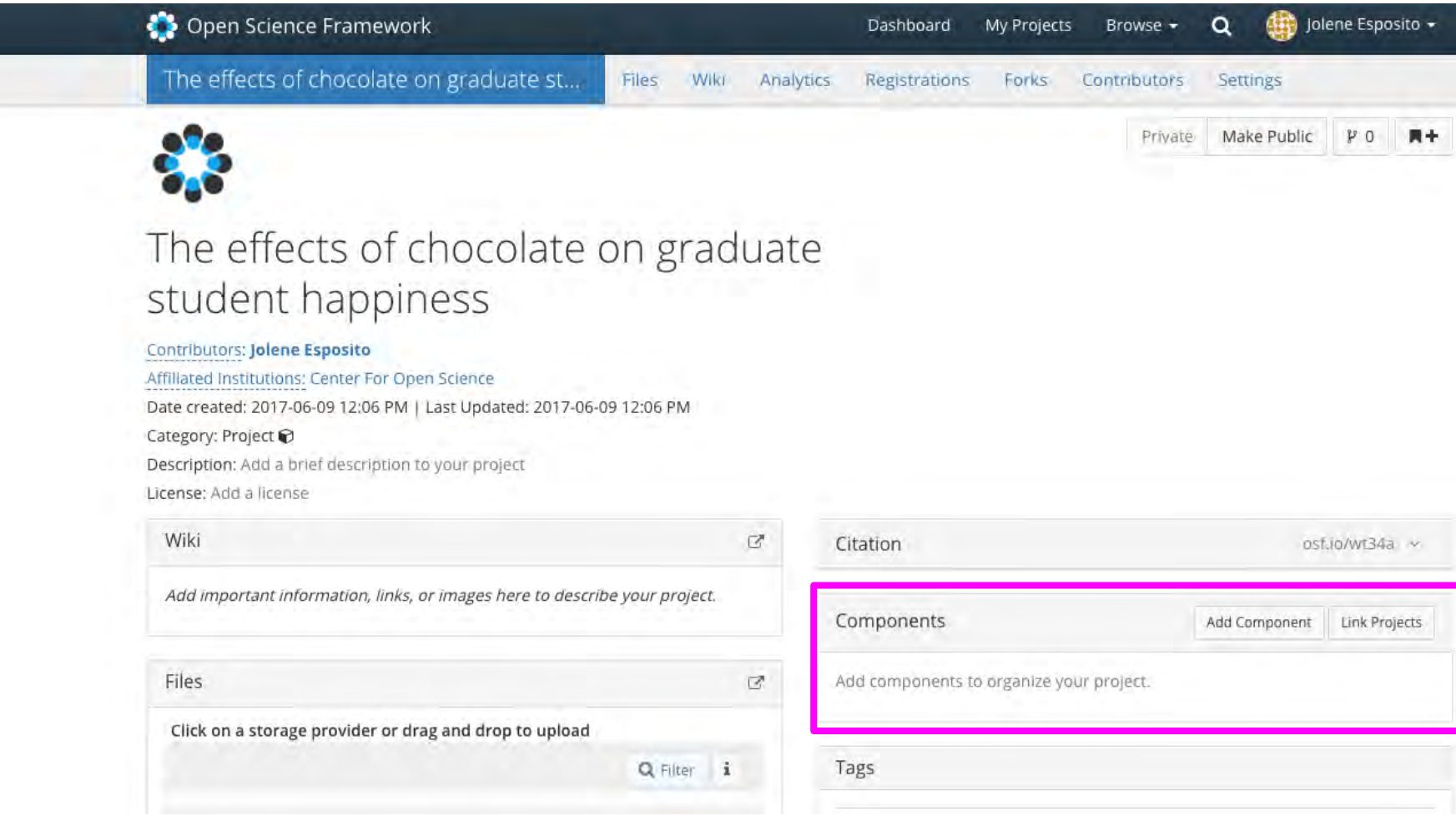

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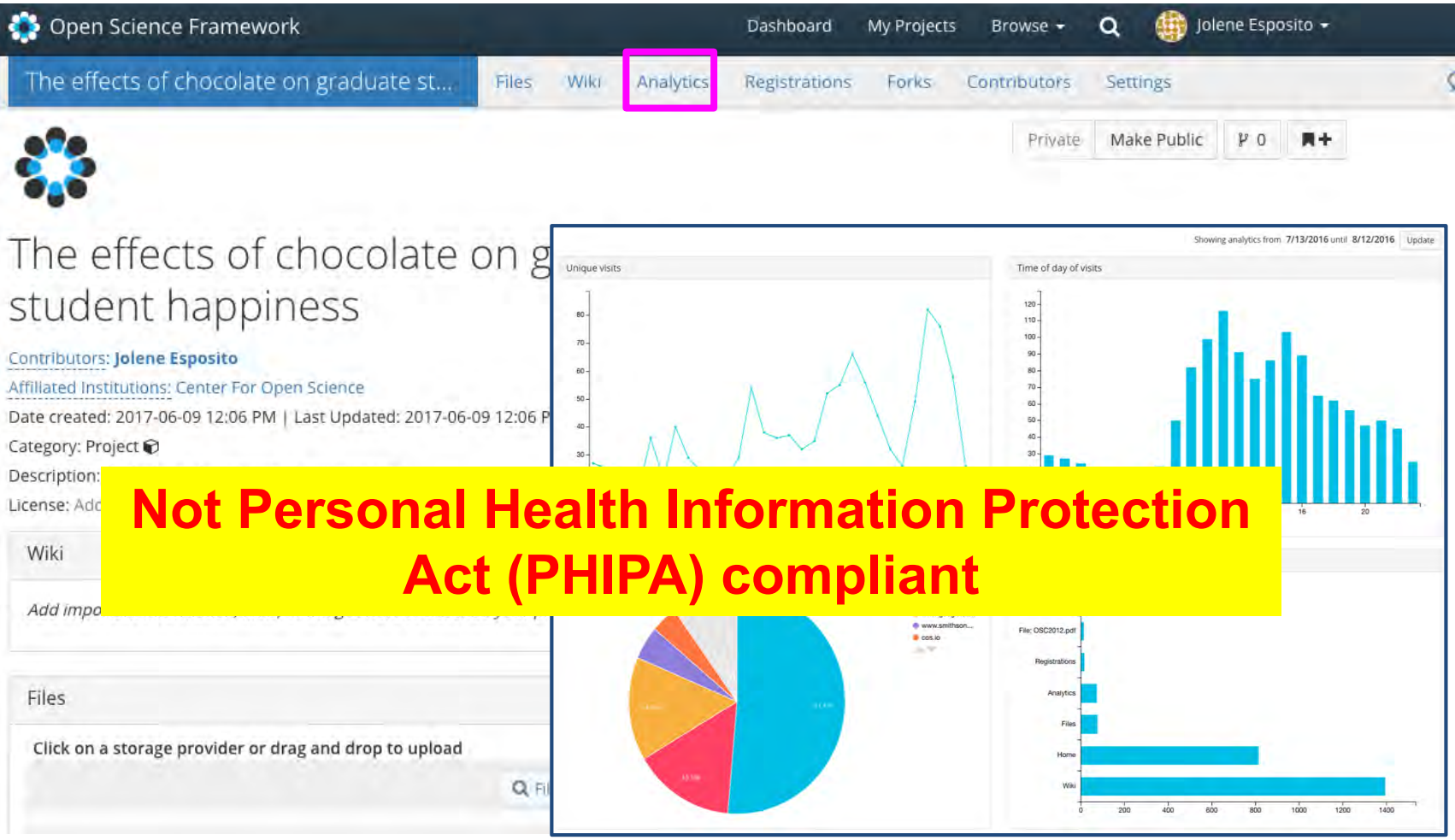

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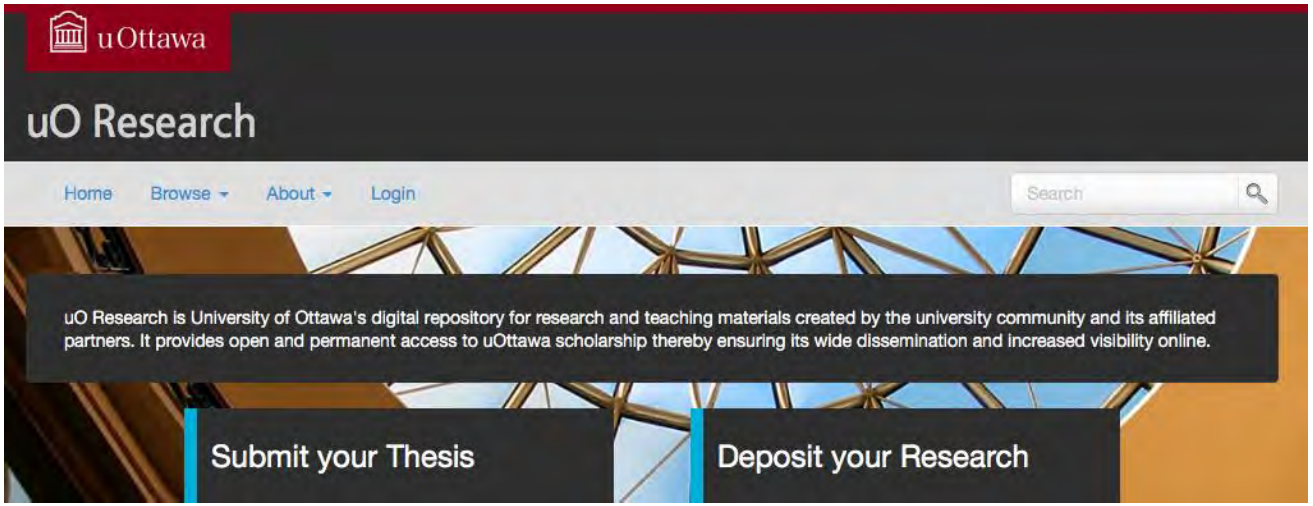
STUDY REGISTRATION: OTHER DESIGNS

- Institutional repositories

http://ruor.uottawa.ca/



WILL I BE SCOOPED?

1. Date-stamped preregistrations make your claim verifiable.
2. By the time you've preregistered, you are ahead of any possible scooper.
3. Embargo your preregistration.

MOVEMENT TOWARDS OPEN SCIENCE

Open science: University of Toronto researchers to publish lab notes in real time *(photo by Arij Al Chawaf)*

neuro

Institut et hôpital neurologiques de Montréal
Montreal Neurological Institute and Hospital

"The objective is to expand the impact of brain research and accelerate the discovery of ground-breaking therapies to treat patients suffering from a wide range of devastating neurological diseases."

The Ottawa Hospital | L'Hôpital d'Ottawa

JOURNAL PRACTICES AND POLICIES CHANGING …

PLOS BIOLOGY

Browse Publish About

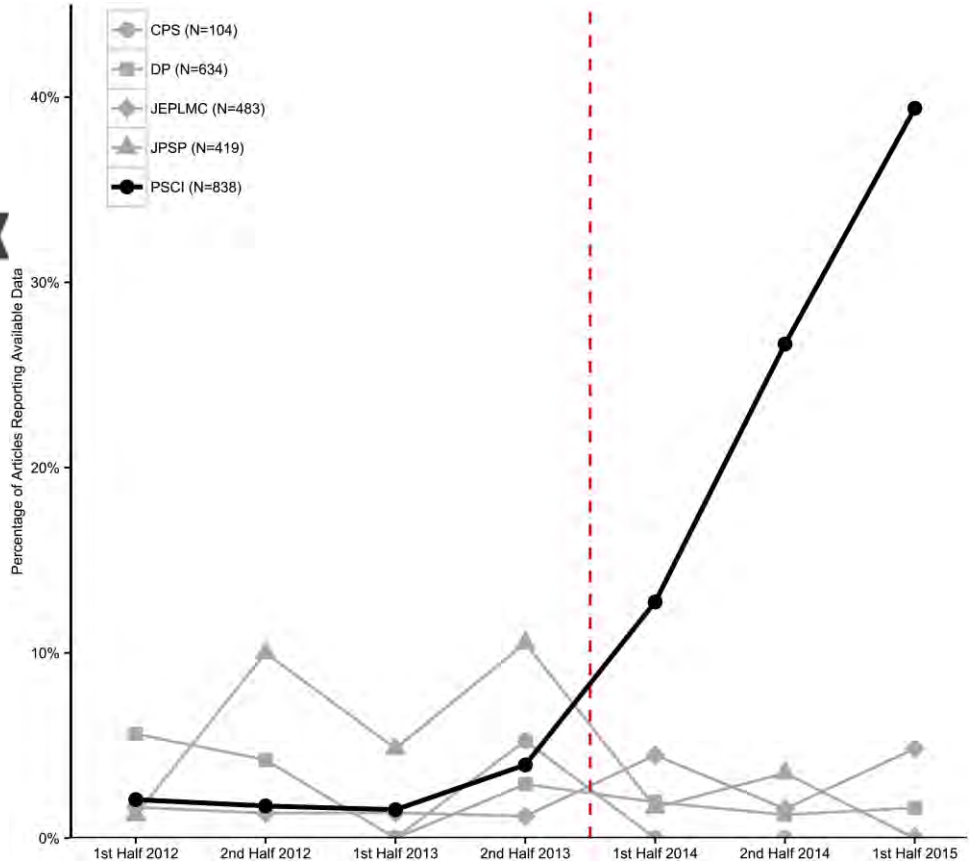
OPEN ACCESS PEER-REVIEWED

META-RESEARCH ARTICLE

Badges to Acknowledge Open Practices: A Simple, Low-Cost, Effective Method for Increasing Transparency

Mallory C. Kidwell, Ljiljana B. Lazarević, Erica Baranski, Tom E. Hardwicke, Sarah Piechowski, Lina-Sophia Falkenberg, Curtis Kennett, Agnieszka Slowik, Carina Sonnleitner, Chelsey Hess-Holden, Timothy M. Errington, Susann Fiedler, Brian A. Nosek

Published: May 12, 2016 • http://dx.doi.org/10.1371/journal.pbio.1002456



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TRANSPARENCY AND OPENNESS PROMOTION GUIDELINES

Summary of the eight standards and three levels of the TOP guidelines

Levels 1 to 3 are increasingly stringent for each standard. Level 0 offers a comparison that does not meet the standard.

	LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3
Citation standards	Journal encourages citation of data, code, and materials—or says nothing.	Journal describes citation of data in guidelines to authors with clear rules and examples.	Article provides appropriate citation for data and materials used, consistent with journal's author guidelines.	Article is not published until appropriate citation for data and materials is provided that follows journal's author guidelines.
Data transparency	Journal encourages data sharing—or says nothing.	Article states whether data are available and, if so, where to access them.	Data must be posted to a trusted repository. Exceptions must be identified at article submission.	Data must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Analytic methods (code) transparency	Journal encourages code sharing—or says nothing.	Article states whether code is available and, if so, where to access them.	Code must be posted to a trusted repository. Exceptions must be identified at article submission.	Code must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Research materials transparency	Journal encourages materials sharing—or says nothing	Article states whether materials are available and, if so, where to access them.	Materials must be posted to a trusted repository. Exceptions must be identified at article submission.	Materials must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.
Design and analysis transparency	Journal encourages design and analysis transparency or says nothing.	Journal articulates design transparency standards.	Journal requires adherence to design transparency standards for review and publication.	Journal requires and enforces adherence to design transparency standards for review and publication.
Preregistration of studies	Journal says nothing.	Journal encourages preregistration of studies and provides link in article to preregistration if it exists.	Journal encourages preregistration of studies and provides link in article and certification of meeting preregistration badge requirements.	Journal requires preregistration of studies and provides link and badge in article to meeting requirements.
Preregistration of analysis plans	Journal says nothing.	Journal encourages preanalysis plans and provides link in article to registered analysis plan if it exists.	Journal encourages preanalysis plans and provides link in article and certification of meeting registered analysis plan badge requirements.	Journal requires preregistration of studies with analysis plans and provides link and badge in article to meeting requirements.
Replication	Journal discourages submission of replication studies—or says nothing.	Journal encourages submission of replication studies.	Journal encourages submission of replication studies and conducts blind review of results.	Journal uses Registered Reports as a submission option for replication studies with peer review before observing the study outcomes.

Nosek BA, et al. Scientific standards. Promoting an open research culture. *Science* 2015; 348: 1422–25

JOURNAL DECLARATIONS

"The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

BMJ

BMJ 2013;347:f4796 doi: 10.1136/bmj.f4796 (Published 7 August 2013)

EDITORIALS

Declaration of transparency for each research article

An antidote to inadequate reporting of research

Douglas G Altman *director*[1], David Moher *senior scientist*[2]

[1]Centre for Statistics in Medicine, University of Oxford, Botnar Research Centre, Oxford, UK; [2]Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital - General Campus, Ottawa, ON K1H 8L6, Canada

JOURNAL AUTHORSHIP STATEMENTS

CRediT

Contributor Role	Role Definition
Conceptualization	Ideas; formulation or evolution of overarching research goals and aims.
Methodology	Development or design of methodology; creation of models.
Software	Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.
Validation	Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.
Formal Analysis	Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data.
Investigation	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.
Resources	Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.
Data Curation	Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later reuse.
Writing – Original Draft Preparation	Creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).

WHY FOLLOW THESE TRANSPARENCY PRACTICES?

- **Allow your work to be audited and prevents duplication**
- **Ensures work is useable**
- **Provides open access account of the study**
  - Not all publications are open access; duty to public; duty to patients
- **Increasing requirement to share data and materials**
  - E.g., ICMJE, Tri-Agency, institutional guidelines, journal policies
  - Data preservation not new, but this facilitates open data re-use
  - Budget time (and money) to complete a comprehensive data and materials management plan

THE SYSTEM OF INCENTIVES AND REWARDS PROMOTES WASTE

- Academics face a pressure to publish
  - Publish or perish
- Institutions and funders often value quantity over quality
  - E.g., # of publications
- Metrics used to assess researchers may not promote the best possible science
  - E.g., DORA initiative calls for institutions to move away from impact factor as a means of assessing researchers

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