

# Interim Research Products

HEALTH RESEARCH ALLIANCE

MEMBERS' MEETING

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# Where we are

- Potential to advance science
  - No standard definitions or rules
  - Implications for review are unclear
- We are asking the community for advice

# What are interim research products?

(working definitions)

## *Complete, public research products that are not final*

This is a very broad definition. We do not intend to focus on research products specifically addressed in other policies, such as data, clinical trials, physical collections, etc.

## Intended examples and current focus

**Preprints** are complete and public drafts of a scientific documents. Speeds dissemination, establishes priority, generates feedback, may reduce publication bias.

**Preregistering** protocols is publicly declaring key elements of a research project in advance, such as hypotheses, measures, confirmatory research protocols and analysis plans. May reduce biases like p-hacking.

# Why now?

A dynamic situation with the potential to advance science

- Growing recognition that interim research products could speed the dissemination of science and enhance rigor
  - Many disciplines have been using preprints for years (economics, physics)
  - Groups like [ASAPbio](#) suggest expand preprints could increase the impact of NIH research
  - Groups like the [Center for Open Science](#) suggest preregistration could enhance rigor of NIH supported research
- Change happening at different rates for different disciplines
- No clear definitions
- NIH rules are narrow

# NIH's interest: Stable rules that advance science

## Recognize common practices and encourage beneficial innovation

- Allow disciplines to adopt interim research products at their own pace (and recognize that many already do)
- Do not prevent innovation that increases rigor and dissemination

## Prevent bad practices from taking root

Clearly state standards NIH cannot accept as community norms are being established

- Interim products that are not preserved, risk NIH reviewer identity, etc, are not usable
- Example: a file on a lab webpage is not an acceptable preprint.

## Next Step:

# An RFI on interim research products

1. Feedback on what is considered to be interim research products, and how they are used.
2. Insight on how particular types of interim research products might impact the advancement of science.
3. Feedback on potential citation standards.
4. Insight on the need and potential impact of citing interim products on peer review for NIH applications.
5. Advice on how NIH reviewers might evaluate citations of interim research products in applications.

# Implementation details under consideration:

## Possible standards for citing interim research products

- Registered or indexed (findable)
- persistent identifier, that links to a repository that will maintain the privacy of the end user
- Uses the CC-BY license. Readable by both human and machine
- Includes a record of modifications, and a link to the final version
- Declares any competing interests
- Policy statement clarifying scope: “does not apply to research products specifically addressed in other policies, such as data (URL), clinical trials (URL), physical collections (URL), etc.”

# Implementation details under consideration: Possible standards specifically for preprints

- a clear statement in the document that the information is preliminary (understandable to non-experts)
- concordance with standard practices for scholarly publication, including:
  - following norms for authorship in that discipline;
  - including or linking to supplemental data;
  - providing appropriate funding acknowledgments;
  - conforming to applicable regulations and ethical standards , including those regarding human participants, animal welfare, and dual use technology.



# Discussion and feedback

# Selected reading

## For more information about preprints

- Desjardins-Proulx P, White EP, Adamson JJ, Ram K, Poisot T, Gravel D (2013) The Case for Open Preprints in Biology. PLoS Biol 11(5): e1001563. doi:10.1371/journal.pbio.1001563. Berg JM,
- Bhalla N, Bourne PE, Chalfie M, Drubin DG, Fraser JS, Greider CW, Hendricks M, Jones C, Kiley R, King S, Kirschner MW, Krumholz HM, Lehmann R, Leptin M, Pulverer B, Rosenzweig B, Spiro JE, Stebbins M, Strasser C, Swaminathan S, Turner P, Vale RD, VijayRaghavan K, Wolberger C. SCIENTIFIC COMMUNITY. Preprints for the life sciences. Science. 2016 May 20;352(6288):899-901. doi: 10.1126/science.aaf9133.

## For more information about preregistration

- Bailoo JD, Reichlin TS, Würbel H. Refinement of experimental design and conduct in laboratory animal research. ILAR J. 2014;55(3):383-91. doi: 10.1093/ilar/ilu037
- Dal-Ré R, Ioannidis JP, Bracken MB, Buffler PA, Chan AW, Franco EL, La Vecchia C, Weiderpass E. Making prospective registration of observational research a reality. Sci Transl Med. 2014 Feb 19;6(224):224cm1. doi:10.1126/scitranslmed.3007513
- National Academies of Sciences, Engineering, and Medicine. *Reproducibility Issues in Research with Animals and Animal Models: Workshop in Brief*. Washington, DC: The National Academies Press, 2015. doi:10.17226/21835.
- [https://osf.io/peut2/?\\_ga=1.256408971.1617774245.1468588454](https://osf.io/peut2/?_ga=1.256408971.1617774245.1468588454)
- <https://wiki.galaxyproject.org/FrontPage>