

Guidelines for the Conduct of Research in the Intramural Research Program at NIH

<http://www.nih.gov/campus/irnews/guidelines.htm>

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Scientific Integrity

Intramural scientists at the NIH should be committed to the responsible use of the process known as the scientific method to seek new knowledge. All research staff in the Intramural Research Program should maintain exemplary standards of intellectual honesty in formulating, conducting and presenting research as befits the leadership role of the NIH.

Why is Scientific Integrity So Important?

The scientific community and the general public rightly expect adherence to exemplary standards of intellectual honesty in the formulation, conduct, and reporting of scientific research.

Without a high standard of *Scientific Integrity*, the scientific community and general public may become victims of *Scientific Misconduct*.

What is Scientific Misconduct?

- * **Fabrication** – making up data or results and recording or reporting them
- * **Falsification** – manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
- * **Plagiarism** – the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit

Scientific Misconduct

- * Scientific misconduct does not include honest error or difference of opinion
- * Scientific collaborators cannot plagiarize from each other
- * Truth in science is the goal of the discipline - to lie about what one has done is to put a knife in the heart of the profession!

A Real-life Example of Misconduct

* A clinician involved in several different clinical protocols admitted to falsifications and fabrications of clinical results.

* The finding of misconduct resulted in a 366-day

Federal prison term for him because his actions led to loss of government funds, obstruction of justice, and abuse of a position of trust.

Why does this matter?

Inaccurate information regarding patient status and date of death could result in an over- or under-estimate of treatment benefits, especially when length of survival and length of disease-free survival are end-points

Mentor-Trainee Relationship

The goals of a mentor-trainee relationship are to ensure that fellows receive the best possible training in how to conduct research and how to develop and achieve career goals.

Mentoring and being mentored are life-long essential components of professional life.

Data Management

Scientific data may be divided into 3 categories...

- * Experimental protocols**
- * Primary data - includes the following...**
 - Raw and processed data
 - Statistical calculations
 - Photographic images
 - Electronic files
 - Patient records
- * Procedures of reduction and analysis**

Any individual involved in the development and/or execution of an experiment and subsequent data processing is responsible for the accuracy of the scientific data.

These individuals may include, in addition to the person responsible for executing the experiment:

- * Principal investigator
- * Postdoctoral fellow
- * Student
- * Research assistant
- * Other support staff

Data collected at the NIH, as well as laboratory notebooks and research records, **belong to the NIH**, and should be retained for a period of time sufficient to allow for:

- * Further analysis of the results
- * Repetition by others of published material

Clinical data should be retained as directed by federal regulations

NIH requires that all data and laboratory notebooks be retained for 7 years

Peer review is the critical evaluation, conducted by one or more experts in the relevant field, of either a scientific document- such as a research article submitted for publication, a grant proposal, or a study protocol - or a research program.

Requisite elements for peer review include:

- * reviewers must be experts in the relevant subject areas
- * evaluation should be thorough and objective, and based solely on the material under review and published material
- * evaluation should be fair and unprejudiced; real or perceived conflict of interest should be avoided
- * reviews are usually conducted anonymously

Collaborative Science

Research collaborations facilitate progress and should be encouraged.

The ground rules for collaborations, including authorship issues, should be discussed openly among all participants from the beginning.

According to the *Guidelines for the Conduct of Research*, all research data should be made available to scientific collaborators.

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Core Issues for Scientific Collaborators

Overall Goals

Who Will Do What?

Authorship, Credit

Contingencies & Communicating

PUBLICATION PRACTICES & AUTHORSHIP

Publication of results fulfills our responsibility to communicate research findings to the scientific community.

Publication of clinical studies also fulfills our responsibility to have a scientific benefit in return for putting human subjects at risk.

Why is publication so important for scientists?

- * Publications share findings that benefit society and promote human health
- * Publications establish scientific principles
- * Credit for a discovery belongs to the first to publish
- * Reputations and research funding are based on the number and impact of publications
- * Prestigious positions are gained through reputation and publications

Other than presentations at scientific meetings, publication in a scientific journal should normally be the mechanism for the first public disclosure of new findings.

Why?

[An exception may be appropriate when serious public health or safety issues are involved.]

Timely publication of new and significant results
is important for the progress of science

BUT

- * each publication should make a substantial contribution to its field
- * each paper should contain all the information necessary for other scientists to repeat the work because the principal method of scientific verification is the ability of others to replicate the results

Authorship is:

- * the primary mechanism for determining the allocation of credit for scientific advances and thus the primary basis for assessing a scientist's contributions to developing new knowledge.

As such, it potentially conveys great benefit, as well as responsibility.

Authorship involves:

- * the listing of the names of participants in all communications to scientific colleagues (oral or written) concerning experimental results and their interpretation, based on significant contributions to the conceptualization, design, execution, and/or interpretation of the research study and a willingness to assume responsibility for the study.
- * making decisions about who will be the first author, the senior author, and the corresponding author

How else is credit established besides authorship ?

Acknowledgments - for individuals who have provided encouragement and advice about the study, editorial assistance, technical support, or space, financial support, reagents, or specimens.

The use of anyone else's discoveries, words, ideas, data, or analyses must be cited in a way that others can find the ***reference*** and see the contribution.

When should authorship issues be discussed?

- * Each research group should freely discuss and resolve questions of authorship before and during the course of a study.
- * Each author should review fully material that is to be presented in a public forum or submitted (originally or in revision) for publication.
- * Each author should indicate willingness to support the general conclusions of the study before its presentation or submission.

Annals of Internal Medicine Authorship Criteria

Authors should meet **all** of these criteria:

- * Conceived and planned the work, or interpreted the evidence it presents, or both
- * Wrote the paper, or reviewed successive versions and took part in the revision process
- * Approved the final version

What is missing from this list?

Annals of Internal Medicine Authorship Criteria

The following, by themselves, are not criteria for authorship:

- * holding position of administrative leadership
- * contributing patients or reagents
- * collecting and assembling data

Irresponsible Authorship

Honorary authorship

- an author who does not meet the criteria

Ghost authorship

- failure to include as an author someone who made substantial contributions to the article

Refusal to accept responsibility for an article despite ready acceptance of credit

Duplicate and redundant publications

from Rennie et al, JAMA 280:222, 1998

Rennie et al's Hypothesis

Research articles in large-circulation prestigious medical journals would be more likely to have **honorary authors**.

Review articles in smaller-circulation journals that publish symposia proceedings would be more likely to have **ghost authors**.

from Rennie et al, JAMA 280:222, 1998

Authorship Analysis

	Research articles	Reviews
Honorary	79 (16%)	61 (26%)
Ghost	65 (13%)	23 (10%)

The corresponding authors of 492 research articles and 240 reviews in: Amer J Cardiology, Amer J Medicine, Amer J ObGyn, Annals Internal Medicine, JAMA, and NEJM were surveyed.

from Rennie et al, JAMA 280:222, 1998

Dr. Colleen May is a participating neurologist in a clinical trial to assess the efficacy and toxicity of a new anticonvulsant medication.

For the duration of the 2-year study, each neurologist is to meet with each of his/her patients for an average of 30 minutes per month.

In Dr. May's case, this amounts to an average of 20 hours per month.

During each visit, the physicians administer a variety of specialized tests, requiring judgments dependent on their experience and training in neurology.

At the completion of the study, the results are to be unblinded and analyzed by the project leaders.

It is anticipated that at least two publications will be prepared for the New England Journal of Medicine.

Dr. May has just learned that she will be listed in the Acknowledgements, but not as a coauthor of the manuscript.

Dr. May argues that she has provided nearly 500 hours of her expert time, far more than needed to complete a publishable study in her experimental lab.

Does Dr. May have a case for authorship?