

Rules and Guidelines for Responsible Conduct of Research

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I. Orientation and Guidance for Faculty

General expectations for the academic conduct of faculty members and many specific requirements governing the conduct of research are set forth in the following documents:

- Policies and Guidelines Governing Appointments, Promotions, & Professional Activities of Faculty Members of The Johns Hopkins University School of Medicine (Gold Book).
<http://www.hopkinsmedicine.org/som/faculty/policies/goldbook/>
- Professional Development Guide for the Faculty of The Johns Hopkins University School of Medicine (Silver Book).
<http://www.hopkinsmedicine.org/som/faculty/policies/silverbook/SilverBook2006.pdf>
- The Sponsored Projects Handbook.
<http://www.hopkinsmedicine.org/Research/ora/handbook/index.html>
- Guidelines of the Johns Hopkins Medicine Institutional Review Boards and the Office of Human Subjects Research.* <http://irb.jhmi.edu/Guidelines/>
- Animal Care and Use Regulations and Policies.*
<http://www.jhu.edu/animalcare/committee1.html>
- Conflict of Interest and Commitment Training Module.*
http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/coi_training_module.html
- Rules and Guidelines for Responsible Conduct of Research.
http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/responsible_conduct.html
- Procedures for Dealing with Issues of Research Misconduct.
http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/research_misconduct.html
- Procedures for Dealing with Issues of Professional Misconduct.
http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/professional_misconduct.html
- Grievance Procedure for Faculty, Fellows, and the Student Body.
<http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/grievance.html>

All faculty members should have copies of these documents and should be familiar with their contents. In addition, the Office of Faculty Development supports the professional development of our faculty, more information may be found at:

http://www.hopkinsmedicine.org/fac_development/

As teachers and researchers, faculty should be informed about ethical issues in research. Because these issues have rarely been part of their formal training, both current and new faculty should devote some effort and time to those issues. In order to better inculcate in their trainees a clear understanding of the principles of academic integrity. Faculty also serve as role models and the manner in which they conduct their own research must be above reproach. Discussion of research ethics should be a regular part of department and division meetings.

A. Rule

1. The Office of the Registrar of the School of Medicine will distribute to each new faculty member an electronic or hard copy of the documents listed above and the booklet *Honor in Science* published by Sigma Xi. Faculty will be required to sign an acknowledgement of receipt of the above documents at the time they respond to their initial letter of appointment from the Dean.

* Online certification required.

II. Supervision of Students, Postdoctoral Fellows, and Other Research Personnel

The Johns Hopkins University School of Medicine is committed to fostering an environment that promotes academic and professional success for all research personnel. It is essential, therefore, to encourage an atmosphere of mutual respect, collegiality, fairness and trust. Preceptors bear significant responsibility in creating and maintaining this atmosphere during interactions with employees and trainees. Moreover, the complexity of contemporary scientific methods, the need for careful experimental design and the precautions one must take in data interpretation all require that the preceptor assume an active role in guidance and supervision. In this setting, the School of Medicine has established the following Rules and Guidelines related to supervision of students, postdoctoral fellows and other research personnel.

A. Rules

1. As a part of their orientation, the Office of the Registrar of the School of Medicine must provide each new medical or graduate student with an electronic or hard copy of [Rules and Guidelines for Responsible Conduct of Research](#) and also the [Procedures for Dealing with Issues of Research Misconduct](#) and the [Procedures for Dealing with Issues of Professional Misconduct](#) and the booklet *Honor in Science* published by Sigma Xi. At the time of registration these documents must also be given to all postdoctoral fellows, whose written acknowledgement of receipt will be kept on file in the Registrar's Office.
2. All medical and graduate students must sign a 'code of honor' at the time of orientation. Postdoctoral fellows and other research personnel will sign a 'code of honor' at the time of their registration. The signed documents will be maintained in the Office of the Registrar (students and fellows) or in appropriate departmental offices (other research personnel).
3. Within a research unit, responsibility for supervision of each student, fellow, or other (non-faculty) member must be assigned to a specific faculty member. For individual research

projects, supervision should be carried out by the responsible investigator; overall supervision of each student or fellow must be assigned to a faculty advisor or program director.

4. The School of Medicine has articulated the roles of both teachers and learners. Preceptors must be familiar with the document; [*Teacher/Learner Policy*](#); students, and fellows will be informed of this policy at the time of their registration at the School of Medicine.
5. Preceptors must familiarize all trainees and other research personnel with appropriate governmental and institutional requirements, such as those required for the conduct of studies involving healthy volunteers or patients, animals, radioactive or other hazardous substances, and recombinant DNA. Preceptors must ensure compliance with all appropriate institutional and government requirements.
6. Preceptors of postdoctoral fellows must also acquaint themselves with relevant institutional policies set by the Office for Postdoctoral Affairs, including expectations regarding annual reviews of progress, length of appointment and notification of termination.

B. Recommendations

1. The ratio of trainees to faculty members should be commensurate with ability to adequately supervise and ensure that close interaction is possible for scientific interchange as well as for supervision at all stages of research.
2. The degree of supervision by preceptors should take into account the experience and skill of the trainees. A preceptor should help the trainee develop not only sound research practices and technical expertise, but also good research ethics.
3. Preceptors should have realistic expectations regarding the performance of trainees and other research personnel and should inform them of these expectations.
4. The preceptor should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting, and storing data. The editing of manuscripts alone does not constitute adequate supervision by the preceptor
5. Collegial discussion among preceptors and trainees contributes positively to the scientific efforts of the members of the group and to informal peer review. For this reason, preceptors should schedule periodic meetings with their students, fellows and other members of the research team.
6. As training of students and fellows moves to its conclusion, training programs and preceptors should ensure that trainees are aware of institutional resources, such as the Professional Development Office, that provide guidance in future career pathways.
7. Preceptors should be alert to behavioral changes in trainees or other research personnel that may indicate inordinate personal or academic stresses or substance abuse. Stresses are

particularly likely to occur at times of transition or as deadlines approach. Since the care with which research activities are conducted may be adversely affected by stress, a trainee or employee may need closer supervision at such times. When such questions arise, a preceptor may seek advice from an associate dean with responsibility for graduate students, medical students or postdoctoral fellows, or the office of human resources.

III. Data Gathering, Storage, Retention*

The University-wide *Policy on Access and Retention of Research Data and Materials* may be found at http://jhuresearch.jhu.edu/Data_Management_Policy.pdf

The purpose of both the University-wide policy and the School of Medicine guidelines are to protect both the researcher and the institution with measures designed to address compliance requirements and to diffuse some of the burden associated with data management. The department, research administration, divisional and university administration, and the researcher are all partners in the management and protection of data produced at the University.

The retention of accurately recorded results is of utmost importance for the progress of scientific research. Researchers spend a good deal of their time collecting data; original laboratory data must be retrievable not only to answer scientific questions, but also to respond to questions that may arise about the propriety of research conduct. Data are used to confirm or reject hypotheses, to identify new areas of investigation, to frame the development of new techniques, and more. Errors may be mistakenly characterized as misconduct when the primary experimental results are unavailable. Moreover, a common denominator in most cases of alleged research fraud has been the absence of a complete set of verifiable data.

Data management issues are becoming increasingly complex and must be addressed before any data are collected. Four areas of consideration should be addressed:

1. Ownership
2. Collection
3. Storage/Protection of research subject confidentiality/Data Sharing

The integrity of data and the usefulness of the research it supports depend on careful attention to detail throughout the research lifecycle, from initial planning through final publication. The rules and recommendations in this section are designed to ensure that all research data are recorded appropriately and that access to them will be available when necessary. The inability to produce original data tends to place the integrity of research in question.

A. Data Ownership

Research produces data and conclusions. As a product, common sense might suggest that the person who conducts the research should own the product – the data. Conditions imposed by funders, research institutions, and data sources may dictate otherwise.

Ownership does not imply custody. Custody must remain with the investigator but the University owns all data generated by research projects conducted at or under the auspices of The Johns Hopkins University regardless of funding source, unless stipulated otherwise by funding agreement. Regardless of custody, ownership implies unlimited access.

Funders. Funders provide support for research for various reasons. The government is interested in improving the general health and welfare of society. Private companies are motivated by profits along with benefits to society. Philanthropic organizations are interested in advancing particular causes.

These different interests result in different ownership claims. Typically:

- The government gives research institutions the right to use data collected with public funds as an incentive to put research to use for the public good.
- Private companies seek to retain the right to the commercial use of the data.
- Philanthropic organizations retain or confer ownership rights depending on their interests.

Because the claims of funders can and do vary considerably, researchers must be aware of all obligations to them before data collection begins.

With government funding, it is important to distinguish between grants and contracts. Under grants, researchers must carry out the research as planned and submit reports, but control of the data remains with the institution that received the funds (see below). Conversely, contracts require the researcher to deliver a product or service, which is then usually owned and controlled by the government. If your research is supported by government funds, make certain you know whether you are working under a grant or a contract. The difference is significant and could determine who has the right to publish and to use your results.

Data Sources. It is becoming more common for research subjects and other entities that are the source of data to seek some control over the data derived from them. Countries with unique resources, such as tropical rain forests, individuals with rare medical conditions, and entities with unique databases, have at one time or another claimed ownership of research results based on their data. Research subjects and entities that have or can be the source of important data may no longer be willing to provide or to be the source of data without some ownership stake in the results.

Well before any data are collected, ownership issues and the accompanying responsibilities must be carefully addressed. Before undertaking any work, make certain you can answer the following questions:

- Who owns the data I am collecting?

- What rights do I have to publish the data?
- Does collecting these data impose any obligations on me?

Without firm answers to each of these questions, in writing when financial interests are involved, you are not ready to begin your research. In most cases ownership provisions must be approved by the institution that receives and is responsible for the administration of research funds. Researchers should not enter into agreements that affect the control and use of data without first obtaining institutional approval. The results could be disastrous and expensive if ownership is later disputed.

B. Data Collection

There is no one best way to collect data. Different types of research require different collection techniques. Four important considerations, however, apply to all data collection and will help ensure the overall integrity of both the process and the information collected.

Appropriate Methods. Reliable data are dependent on reliable methods. Although the need for appropriate methods may seem obvious, methods can be compromised by bias, choosing one method or set of experimental condition so that a particular conclusion can be drawn. Responsible research is research conducted using appropriate, reliable methods and adequate controls.

Attention to Detail. Quality research requires attention to detail. Experiments must be set up properly and the results accurately recorded, interpreted, and published. Inattention to detail can result in mistakes that will later have to be corrected and reported. Correcting the record takes time and resources better spent on the research itself.

Authorized. Many types of data collection must be authorized before they can proceed. Typically permission is required to use:

- Human and animal subjects in research;
- Hazardous materials and biological agents;
- Information contained in some libraries, databases, and archives;
- Information posted on some web sites;
- Published photographs and other published information; and
- Other copyrighted or patented processes or materials.

Researchers have a responsibility to know when permission is needed to collect or use specific data in their research. If you are unsure whether permission is needed, check before proceeding with data collection. Contact the office of the [Institutional Review Boards](#) if in doubt.

Recording. The final step in data collection is the physical process of recording the data in some type of notebook (hard copy), computer file (electronic copy), or other permanent “record” of the work done. The physical formats for recording data vary considerably, from measurements or observations to photographs or interview tapes. Whatever format is used for recording data, it is important to keep in mind the purpose of any record is to document what was actually done and the results that were achieved. Care should be taken in cross referencing data for projects that depend on diverse formats.

In recording data, follow two simple rules to avoid problems later should questions arise about your work:

- Hard-copy evidence should be entered into a numbered, bound notebook so that there is no question later about the date the experiment was run, the order in which data were collected, or the results achieved. If for some reason, the data and results cannot be entered into a numbered bound notebook, a periodic data summary, either in electronic or paper format, should be kept in a dated record.
- Data recorded using a computer should be validated in some way, e.g. permanent bulk back up on tape, to assure it was actually recorded on a particular date and not changed at some later date.

The Office of Research Integrity provides a comprehensive guide to data management <http://ori.hhs.gov/education/products/clinicaltools/data.pdf>

C. Data Storage/Protection of Research Subject Confidentiality/Data Sharing

Data Storage. Responsible handling of data begins with proper storage and protection from accidental damage, loss, or theft:

- Lab notebooks should be stored in a safe place.
- Computer files should be backed up and the backup data stored in a secure place physically removed from the original data.
- Samples should be appropriately saved so they will not degrade over time.

Data that are subject to privacy restrictions must be stored in a safe place accessible only to authorized personnel. Additional information is available at the sites of the [Johns Hopkins HIPAA office](#) and the [Institutional Review Boards](#). Whatever the method used to protect private or confidential information, the researcher who collects or uses the information has the primary responsibility for its protection.

Data Sharing. Once a researcher has published the results of an experiment, it is generally expected that all information about that experiment, including the primary data, should be freely available for other researchers to use. Some journals require that the data published in articles be

available to other researchers upon request or stored in public databases. In the specific case of federally funded research, research data must be available in response to Freedom of Information Act (FOIA) requests unless there are compelling reasons for confidentiality.

Period of Retention. Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common definition of a reasonable period of time. NIH generally requires that data be retained for three years following the submission of the final report. Some government programs require retention for up to seven years.

A. Rules

1. Custody of all original data must be retained by the unit in which they are generated. When hospital records, which cannot be kept in the research unit, are used in research projects, summaries must be maintained by the investigator. An investigator who moves to another institution must submit to the department director a written request to remove original data from the University. If the department director does not approve the removal of data, an appeal may be made to the Dean.
2. Researchers at the School of Medicine are required to retain records associated with a human subjects research project in accordance with federal and institutional policies. The stored data must be kept in a secure, protected manner in accordance with institutional policy.

Federal and Institutional Requirements. Links to applicable federal and institutional requirements may be found at the sites of the [Johns Hopkins HIPAA office](#) and the [Institutional Review Boards](#).

Corporate Sponsors. For research sponsored by corporations or private foundations, the investigator should maintain the records for either the length of time required by the private sponsor or the time required by federal regulation or institutional policy, whichever is longer.

* This document was based in large part on the Office of Research Integrity's *Introduction to the Responsible Conduct of Research*, written by Nicholas Steneck. Full text of this document may be found at <http://www.ori.hhs.gov/education/products/RCRintro/index.html>

IV. Authorship Guidelines*

A. Authorship

1. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
2. Authorship credit for original, research-based works (in any medium) may be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) sufficient participation in the work to take public responsibility for appropriate portions of the content; and 4) final approval of the version to be published. Authors should

meet conditions 1, 2, 3, and 4. Other contributions such as provision of a key reagent, or collection of data may also be considered as long as conditions 2, 3 and 4 are met.

3. Authorship credit for reviews or commentaries not based in original research should be based on conditions 2, 3 and 4.
4. Acquisition of funding, collection of data (for example, from a fee-for-service core facility), or general supervision of the research group (e.g. by former or current mentors not directly involved in the conception or execution of the publication), alone, does not justify authorship.
5. Financial and material support should be disclosed.
6. “Ghost-writing,” a practice whereby a commercial entity or its contractor writes an article or manuscript and a scientist is listed as an author, is not permissible. Making minor revisions to an article or manuscript that is ghost-written does not justify authorship.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship.

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

B. Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section, with written permission where consistent with journal guidelines.

Because readers may infer their endorsement of the data and conclusions, all persons must give permission to be acknowledged.

* This document was based in large part on requirements written by the International Committee of Medical Journal Editors. Complete text of the ICMJE requirements may be found at <http://www.icmje.org/>

V. Publication Practices

Among the missions of the School of Medicine is the discovery and dissemination of new knowledge for the benefit of mankind. It is essential that publications in all of their many forms be based upon rigorous validation of the findings, and unbiased presentation of those findings based upon the data obtained and the existing knowledge in the field. Premature publication of data without adequate tests of reproducibility or assessment of significance is not in keeping with accepted standards. In such circumstances, if any of the work is questioned, it is difficult to determine whether the research was done accurately, the methods were described properly, the statistical analyses were adequate, or whether appropriate conclusions were drawn. Submission of multiple similar research publications differing only slightly in content is strongly

discouraged. Investigators should review each proposed publication with these principles in mind.

A. Recommendations

1. Substantive publications, rather than those that are fragmented, repetitive and redundant, should be encouraged.
2. All publications should adhere to the authorship guidelines, as stated above, and appropriately acknowledge all significant contributions.
3. Published papers should credit sponsors of the work and any acknowledgement requirements in grant and contract documents should be adhered to scrupulously, since they are contractual obligations. Moreover, it is important that reviewers and readers be informed of the sponsorship of research projects in order that they may be alert to possible bias in the research arising from a sponsor's financial interest in the results.
4. All NIH supported, peer-reviewed publications must adhere to the mandatory NIH Public Access Policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>).

VI. Research Unit Guidelines

Given the diversity of research units in terms of scientific problems and methods, particular units should develop rules or guidelines to foster outstanding research. Such guidelines should be provided to all new investigators prior to their starting work in the unit. However, all research units should establish guidelines to include the following:

1. The principal investigator should create an environment conducive to unbiased analysis of all data without intentional or unintentional pressure to support a particular hypothesis.
2. Units should establish formal mechanisms for frequent and open communication between all members of the unit. One example would be scheduling frequent laboratory meetings at which all members of the unit openly discuss and critique research findings.
3. All members of the unit should be instructed on accepted methods for recording, storing and protecting research data, both in terms of laboratory notebooks and electronic data. It is the principal investigator's responsibility to ensure that accepted practice for documentation, data storage, and data protection are followed.
4. In collaborative efforts, the respective roles and authorships of all participants should be clearly delineated at initiation of the project.

A. Rules

1. All members of a research unit are to be fully informed with respect to what is expected of them at the time they join the unit. Clear and achievable goals and expectations should be

defined.

2. It is the principal investigator's responsibility to ensure that the unit adheres to all University and Department guidelines, including complying with governmental regulatory agencies, maintaining a fiscally responsible operation, and creating a safe work environment.
3. The principle investigator and all laboratory personnel must disclose any conflicts of interest at a regularly scheduled laboratory meeting. A conflict of interest occurs when a researcher or Johns Hopkins has a financial or other interest that might affect the researcher's judgment when conducting a research study. In some situations, the results of a study might lead to a financial gain for the investigator(s) and/or Johns Hopkins. [The Office of Policy Coordination](#) manages conflicts of interest and can provide more information.

VII. Reporting Research and Professional Misconduct

The trust and good faith traditionally associated with The Johns Hopkins University School of Medicine will flourish only if every member of this community bears responsibility for upholding the highest standards of integrity. Should research or professional misconduct occur, early identification and intervention are in the best interest of everyone. Steps to be taken by anyone who suspects that another's research or professional conduct has been improper are detailed in *Procedures for Dealing with Issues of Research Misconduct*: http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/research_misconduct.html

and *Procedures for Dealing with Issues of Professional Misconduct*: http://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/professional_misconduct.html.

Many concerns about suspected misconduct may be put to rest without formal proceedings. The Director of the Division of Research Integrity is available to discuss suspicions in confidence; notification of the Director of the Division of Research Integrity does not necessarily result in the immediate commencement of the inquiry process.

The Institution recognizes the risks to persons who report apparent research or professional misconduct and has made every effort to protect them as well as those who might be accused in error. The Institution will take appropriate action against those intentionally bringing forward allegations with malicious intent. The Institution will adhere to federal rules and guidelines regarding the protection of whistleblowers, as applicable.*

A. Rule

It is a professional obligation of faculty, students, or fellows to inform superiors if they have reservations about the integrity of the work of another member of this academic community and to follow appropriate procedures (see above).

*The institution is required to establish policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those who, in good faith, make allegations." 42 C.F.R. Part 50.103(d)(13).