



Guidelines for Conduct of Research and Scholarly Activities

(Revised August 2009)

University Office of the Vice President for Research
65 Bergen Street, Room 1414

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Newark, New Jersey 07101

FOREWORD

To the UMDNJ Academic Community,

These University Guidelines for Conduct of Research and Scholarly Activities were developed with extensive faculty involvement in a manner that reinforces the principles of academic scholarship and research. They were written in the interests of our students, faculty and other researchers, because of our concern for research ethics and the scientific method, and to fulfill our responsibility to the public for our research and scholarly activities.

This is a living document, and suggestions for change and improvement are always welcome. Address your comments to Dr. Kathleen Scotto, Vice President for Research.

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I INTRODUCTION AND BACKGROUND

Accepted research practices in the clinical, biomedical, behavioral and social sciences are based on the concept of science as the creation, dissemination and application of new reproducible knowledge, and on the essential quality of the research environment as a free and open one in which new and creative ideas may be tested. Good research practices are generally well known to and followed by the research community, and, until recently, were not usually committed to writing or formal codification. However, in the wake of highly publicized cases of alleged and actual research misconduct, changes are occurring in the research and scholarly activities environment and in the relationships among investigator, grantee institution and research sponsor.

A prominent example of these changes is the 1989 PHS regulation assigning grantee institutions the responsibility for preventing and dealing with research misconduct. The University's policy on [Research Misconduct](#) complies with this regulation. The primary purpose of these Guidelines is **prevention** of research and scholarly misconduct and of research disputes. The hope is that newer researchers, especially graduate students, postdoctoral fellows and junior faculty, will be given copies of the Guidelines and will use them in becoming acculturated to the principles of science, and in learning the policies and practices of their laboratories or research groups, which should develop their own individualized guidelines. The University Guidelines can also serve as a reminder to established researchers, and may help them in their role as mentors and in developing their own laboratory- or group-specific guidelines.

The University views this document as a protection for both itself and its responsible researchers in a climate of increased scrutiny of research and research practices, where the University has the responsibility to investigate any allegations of research misconduct involving investigators on grants for which the University is the grantee. Investigations of allegations of research misconduct focus particularly upon research data, and mandate a new co-responsibility shared by the researcher and the University to ensure the accuracy, completeness, availability and retention of research data.

These Guidelines are meant to increase awareness, thoughtfulness and care in the conduct of research and scholarly activities. The underlying principles and ideas are more important than any specific method of carrying them out, which may need to be tailored for different types of research, the research environment of each School and department, and the traditions and culture of each professional discipline. Each research unit should therefore develop its own specific guidelines and practices, within the constraints of the University Guidelines, to enhance the quality of research conducted by its members. The University

Guidelines and the specific research unit guidelines should then be provided to all new members of a laboratory or research group.

With the exception of University policies and other rules, the University's requirements concerning retention of and access to original research data, and federal regulations regarding research, these Guidelines are not intended as inflexible rules. Rather they are recommendations to promote the highest scientific and ethical standards, and to preserve and promote a fair and honest atmosphere for the conduct of research and scholarly activities, without inhibiting scientific freedom and creativity. However, serious derivations from commonly accepted practices for proposing, conducting or reporting research may result in corrective actions.

II RELATIONSHIP BETWEEN PRECEPTORS AND TRAINEES; SUPERVISION OF OTHER RESEARCH PERSONNEL

A senior or experienced researcher in each laboratory or research group should be specifically assigned the responsibility for the supervision of each trainee and non-independent junior researcher.

Junior faculty, postdoctoral appointees, graduate students and other trainees should be involved in research activities that provide meaningful training and educational experiences, and the opportunity to learn the concepts and technical skills of the field, not those that merely further the interests of the preceptor or the group.

A close working relationship between preceptor and trainee should be maintained at all times. The number of trainees for whom each preceptor is responsible should be limited to allow for scientific and personal interaction, appropriate oversight, and an appropriate research experience for each trainee. All preceptors, trainees, and other research personnel in a research group or laboratory should have regular and frequent meetings to share and discuss research directions, trends, goals, methods, results and interpretations.

Preceptors are obligated to provide guidance and direction in all aspects of research, including: the planning, design, performance, analysis and interpretation of experiments and other quantitative and qualitative research methods; the recording of results and preservation of resulting data; the preparation of oral and written reports; and the standards and ethics of research. Upon joining a research group or laboratory, trainees and all other research personnel must be informed of any risks involved in the research program, of safety regulations, and of all government and University regulations and policies on

topics that pertain to the research areas of the group or laboratory, such as biohazards, radiation safety, toxic waste, Institutional Review Boards and other requirements of clinical research, animal use, recombinant DNA, etc. In addition, trainees and other personnel must be instructed in and regularly reminded of appropriate standards of research conduct and research ethics. This should be accomplished by means of formal systematic instruction, as well as through the personal example of preceptors and senior researchers. The group's laboratory practices, record-keeping practices, and authorship/publication policies should also be described initially and discussed regularly with all trainees and other research personnel. New trainees should be made aware of these Guidelines and must be made aware of the University Policy on [Research Misconduct](#).

III SCIENTIFIC RECORDS AND RESEARCH DATA¹ (INCLUDING RESEARCH-RELATED BIOLOGICAL MATERIALS)

The goal of scientific record-keeping is to provide sufficient information so that the research can be repeated by another investigator who is appropriately experienced, and so that questions arising after publication can be answered. Investigators are obligated to record and preserve data in a form that allows future scrutiny and evaluation. The retention of accurately recorded, well organized and complete original research data and results (including unique reagents and research-related biological materials) also provides the most effective response to questions that may arise about the propriety of the conduct of the research. Inability to produce well-kept original research data may place the integrity of the research itself into question. Because of the complexity, diversity and changing technology of modern research, no single method of data recording can be advocated. Each researcher should consider how best to meet the goals of record-keeping with regard to his/her type of research.

Unless impractical for certain types of data or for certain disciplines, scientific notes are best kept in bound notebooks with numbered pages, and made in permanent ink on the day the studies are performed. Entries should contain the time and date, and should be signed. Depending on the type of data and research, entries may consist of printouts affixed to the notebook rather than handwritten notes. Computer technology has changed the concept of handwritten laboratory notebooks, but even with computer-generated and/or computer-stored data, it is important that descriptions of what was done and titles of computer runs be recorded. Hard-copy printouts of computer-stored data should be generated on a regular basis and bound into the notebook. If data are in a form that cannot be recorded in or affixed to a

¹ "Research Data" can include tangible and physical representations of experimental findings; in addition to sets of numbers, "data" can be unique reagents, tissue samples, cell lines, clones, other biological preparations, software, slides, videotapes, sound/voice recordings, photographs, etc.

notebook, notebooks can still record descriptions and chronologies of the experiments performed, descriptions of the instrumentation used, and the location and form of the data. Logbooks or inventories for radioactive substances, organic compounds, dangerous chemicals and biologicals are essential.

All data, unique reagents and research-related biological materials resulting from a research project should be available to all personnel working or collaborating on the project (except, of course, during periods of investigator "blinding"). Data should eventually be communicated to the external research community to facilitate use of the information gained. Individual research groups should establish policies for the internal and external sharing of research data and research materials, within the limits of fairness to all parties and within any constraints put forward by funding agencies. Research data and any unique research materials, such as recombinant DNA, DNA sequences, DNA or RNA constructions, antibodies, purified enzymes, receptors, model cell lines and organisms, etc., should be made available, if possible and appropriate, to other responsible researchers and collaborators. It is recommended that investigators contact the Office of Patents and Licensing prior to distributing reagents if there are concerns regarding intellectual property rights.

Original research data, including "raw" (primary) data, must be retained for no less than five years after the termination of the grant under which the research was performed or after the publication of the research results, whichever is later, and **preferably indefinitely**. Where questions or allegations have been raised regarding the validity of the data or appropriate conduct of the research, all of the original research data must be preserved at least until such questions or allegations have been completely resolved. Absence of original data may create the presumption of misconduct or questionable research practices in the event of an allegation of misconduct. At present, there is no statute of limitations on research misconduct allegations. Therefore indefinite retention of data is in the researcher's best interests.

All original research data and materials belongs to the University but should ordinarily be maintained by the research unit of origin at the University, or by the School department, so that: (1) they can be made available to individuals involved in the research within the research group; (2) they are available for other investigators if the original work needs to be repeated or if questions arise (including questions about the propriety of the conduct of the research); and (3) the University can fulfill its institutional responsibilities and the requirements of any applicable laws and governmental regulations. Arrangements should be made to ensure that any investigator (faculty, non-faculty staff, student, postdoctoral fellow) who leaves the research group or laboratory will have access to the original data and materials from his/her research performed in that group or laboratory, and will be given copies of such data or samples of research-related

materials if requested and if feasible. If the principal investigator or laboratory head leaves the University, they will be given copies of research data and research-related materials if requested. Original research data and materials can be removed from the University **only** when the chair and dean determines that it is impractical for the investigator to make copies of the materials. If the principal investigator or laboratory head wants to retain the original research data or research materials, or when making copies or giving samples is impractical because of the nature or form of the data, he or she must make this request in writing to the department chair and dean, who must give prior approval. This written request must contain an itemized description of the original data or materials to be removed. The chair and dean must determine and approve of where and how the research data are to be maintained at the future location, and investigator must assure that the University will be given access to the data if there is a need to review it, or if questions or allegations of research misconduct should arise. Non-faculty staff and trainees who leave the laboratory, the research group or the institution must get written permission from the principal investigator or laboratory head in addition to the chair and dean to retain original data or research materials in lieu of copies. In some research projects, availability of research data, records or materials may be restricted by law, by the requirement for confidentiality or for investigator blinding, by governmental regulations and/or by contractual provisions with a sponsor.

Each research group or laboratory is encouraged to establish specific procedures regarding availability of and access to original research data and materials. These procedures should be consistent with these Guidelines, and must conform to University policies, including those on patents, copyrights, and the sale or transfer of materials. Disagreements among individual researchers or between research groups or laboratories concerning issues of access to and use of research data and materials which cannot be amicably resolved should be discussed with appropriate administrative officers, such as the department chair, the research dean, and/or the dean, or with the School's research ombudsperson.

IV AUTHORSHIP

Clear policies on authorship should be established by each laboratory and research group. Authorship should be limited to those who have made a substantial intellectual or technical contribution to the conception, planning, design and/or performance of the research, and/or to the analysis and interpretation of the data. If possible, all such individuals should participate in drafting or revising the manuscript. In certain disciplines and in certain journals, the scope of the contribution of each author may be indicated in a statement or acknowledgment in the manuscript. Certain individuals who participate in or make specialized contributions to a study may more appropriately be acknowledged in the manuscript as having

contributed materials, support, patients, advice, funds, etc., or as having collected the data, but should not be listed as authors. *General supervision of the research group is not sufficient for authorship. Purely "honorary" or mandatory authorships (as in the case of non-contributing department chairs, section heads or supervisors) violate these principles and are not acceptable.*

In research, scholarly or educational publications or presentations of any kind, ghost or guest authorship is also unacceptable. Authorship implies independent, substantial and fully disclosed participation in the research and in the preparation of the manuscript or presentation. However, representatives of a study sponsor or other outside entity who assist in drafting the manuscript or presentation should be listed as contributors or authors and must disclose their industry affiliation in the presentation or published document and to the journal.

The primary (submitting) author should have reviewed all primary data on which the manuscript is based, and be able to identify the specific contributions of each co-author. He/she has overall responsibility for determining co-authorship, for ensuring the review and approval of the final manuscript by each co-author, for defending the study if necessary, and for making responses to post-publication questions and challenges. Each author should review, approve, take responsibility for, and be prepared to defend his or her specific contributions to the research and those aspects of the publication in his or her area of expertise, even if no longer associated with the research group or laboratory. If possible, all authors should be able to agree with, take responsibility for, and defend the conclusions and interpretations of the entire manuscript. In collaborative work, scientists of each research group are expected to accept responsibility for the work done in their group; in such collaborations, authors should nevertheless review all aspects of the research.

V PUBLICATION PRACTICES

Consistent with journal editorial policy, each publication should contain the information needed for the replication of the research by scientific peers, and for the assessment of the results and conclusions by knowledgeable readers.

Publications should make significant and complete contributions to the literature. Research results should be assembled into coherent logical units containing full development of a topic, or the entire breadth of a study. Division of research into incomplete fragments in order to produce a larger number of publications ("salami" publication) is not acceptable.

All material, including ideas, concepts, methods and text which is drawn from earlier work by the authors or by others should be properly cited. Related research from other laboratories should be fairly acknowledged.

A manuscript or paper reporting original research (new research findings) which overlaps substantially with another manuscript by the same author(s) already submitted, accepted for publication or published elsewhere, in print or in electronic media, is duplicative or redundant. This practice violates international copyright laws, wastes resources and may be misleading; it is therefore counterproductive and improper. In addition, repeated publication of original research without proper citation of the previous publication is a type of self-plagiarism. Except in specific circumstances (such as a complete report following publication of a preliminary report or presentation of an abstract or poster; secondary publication in another language in another country with approval of both editors and with reference to the first paper; or a review article, book chapter or presentation citing previously published data), investigators should avoid redundant submission and publication of their research.

The source of funding of the research should be identified in the publication. Situations which are or may be perceived as conflicts of interest, and financial involvements by one or more authors with the research, its sponsors or its results, should be clearly stated in publications.

Retractions or corrections of published research should be made promptly when necessary.

PUBLISHING THE RESULTS OF CLINICAL TRIALS:

The University and its researchers have an ethical obligation to try to make publicly available the results of research projects that prospectively assign human subjects to intervention and comparison groups in order to study the cause-and-effect relationship between a medical intervention (such as a drug, surgical procedure, device, behavioral treatment, process-of-care change, etc.) and a health outcome. Good faith efforts should be made to publish the results of such trials in a peer-reviewed journal in a timely fashion; contracts with sponsors should not prevent or obstruct such publication.

Publications of human subjects research should disclose fully all relevant financial and other substantive personal interests of any of the investigators.

VI FINANCIAL AND LEGAL MANAGEMENT

It is critical that all research projects meet the financial and legal standards the University has established. Numerous policies and processes are in place to ensure that all financial or legal agreements related to research entered into by investigators, departments or Schools of the University are sound.

For example, financial review will ensure that all University research agreements contain provisions for the maximum recovery of research costs.

Legal review is also necessary to manage and limit University risk in performing the research. Further, post-award legal matters related to intellectual property, patents, licensing, royalties, subcontracting and the like must be formally negotiated and documented by the Office of Patents and Licensing.

All proposals must undergo financial and legal review and approval processes prior to submission to a sponsor. Investigators must submit proper University authorization and completed sponsor application forms as required by each School's research office, at which time these documents will be carefully reviewed by the offices noted on the transmittal form.

Contact information for each School's research office, compliance offices and the Office of Patents and Licensing is provided on the last page of these Guidelines.

Selected University policies pertaining to the above requirements are on the University website:

[00-01-50-90:00](#)-Funding: Grants and Contract Proposals

[00-01-50-90:05](#)-Grants and Contracts: Administration

[00-01-20-21:00](#)-Intellectual Property: Copyrights and Royalties

[00-01-90-45:00](#)-Patents

VII CONFLICT OF INTEREST IN RESEARCH

Conflict of interest in research refers to situations in which financial or other personal considerations may compromise, **or have the appearance of compromising**, an investigator's professional judgment and objectivity, and/or ethics, in conducting or reporting research.

The growing research collaborations between universities and industry are often mutually- beneficial, providing important resources for research projects, as well as conduits into public use for research

discoveries. At the same time, these collaborations create situations in which personal interests conflict with professional obligations; such conflicts can pose challenges to researchers' paramount responsibility to observe the highest levels of objectivity and freedom from bias.

It is of particular importance that financial interests or other types of personal gain do not compromise, **and are not perceived as compromising**, the safety of human research subjects and the integrity of clinical research. The mere perception of a conflict, especially in human subjects research, can be as harmful as an actual conflict, and can as readily undermine public trust.

Financial and other personal rewards from the conduct of research are not intrinsically unacceptable if the researcher's objectivity and integrity in designing, conducting, interpreting and publishing research are not compromised. The purpose of the University's policy on [Investigator Conflict of Interest \(00-01-20-89:00\)](#) is to identify and manage actual or perceived conflicts of interest. This policy requires that all financial and other personal interests that could be affected by the proposed research are fully disclosed **prior to commencing the research**. A University-wide Investigator Conflict-of-Interest Committee reviews disclosed interests which are deemed substantive as defined by the policy, decides whether there is a conflict of interest, and if there is, how it will be managed, reduced or eliminated.

VIII HUMAN SUBJECTS RESEARCH

Under federal regulations, research (as differentiated from clinical practice) is systematic investigation with the goal of contributing to generalizable knowledge, often involving the generation of data for publication. Human subjects research is research involving human individuals, human organs, human tissues, human body fluids, certain human cell lines, human materials for stem cell research, and use of records containing personally identifiable information or data derived from such records. Individual case reports in publications are considered human subjects research.

In addition to the standards and principles for designing, proposing, conducting and reporting the results of all types of research previously presented in this document, human subjects research entails unique ethical obligations to protect the safety and rights of the subjects. These obligations imply even greater responsibility of the investigator with regard to: appropriate study design (including randomization, statistical analysis, and case inclusion/exclusion criteria); accuracy, completeness, confidentiality, maintenance, and retention of research records and data; thorough training of new investigators and

continuing education of established investigators; and adequate supervision of all research personnel involved in a project.

All human subjects research at UMDNJ requires prior review and written approval or exemption by a University Institutional Review Board (IRB), and continuing adherence to IRB requirements and procedures during the conduct of the research. This requirement applies to human subjects research directed or performed by any UMDNJ faculty member, house officer, other employee, student, volunteer or other agent in connection with his or her University responsibilities, whether or not the research is carried out on University premises, regardless of sponsorship or if the research is unsponsored. It also applies to human subjects research conducted by anyone, regardless of institutional affiliation, using any property or facility of UMDNJ; and to research using UMDNJ's non-public information to identify or contact human research subjects or prospective subjects, regardless of affiliation of the investigator or location of the research.

All members of the research team, including students, clinical fellows and non-faculty employees, must be aware of and must adhere to the requirements of the University's Human Subjects Protection Policy and Program. These include prompt reporting of: any unanticipated problems or serious adverse events involving risks to subjects or others; complaints of subjects regarding their rights; changes in protocol, study design, consent form or investigators; protocol deviations or violations; external audits and audit results. All investigators and staff participating in human subjects research must undergo prior mandatory training in the principles, ethics and requirements of this type of research.

Under federal law, unless exempt under specific sections of the federal regulations, clinical investigations on new or lawfully marketed drugs, biologicals, medical devices and *in vitro* diagnostic biological products must be conducted under applicable Food and Drug Administration (FDA) regulations, including, but not limited to, Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or Product Licensing Application (PLA). Adherence is required to the ethical and scientific quality standards set forth in the federal regulations and in the FDA's "Good Clinical Practices Guidelines."

Because of the nature of human subjects research and the particular ethical relationship between investigator and study subjects, it is even more critical that original research records be retained by the research unit of origin or the department for at least five years after completion of the study or publication of the results, whichever is later, **and preferably indefinitely.**

Selected University policy pertaining to the above requirements are on the University website:

[00-01-20-90:00](#)-Human Subject Research: Protection of Human Subjects.

IX ANIMAL RESEARCH

The development of knowledge necessary for the improvement of the health and well-being of humans and other animals requires *in vivo* research with a wide variety of animal species. Research using animals is governed by regulations from the Public Health Service, the U.S. Department of Agriculture under the Animal Welfare Act, and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). The Public Health Service definition of laboratory animal is any live, warm- or cold-blooded vertebrate animal, including wildlife, aquatic and farm animals, used or intended for use in research, testing or education.

The standards and principles for designing, proposing, conducting and reporting the results of animal research are identical to those previously presented in this document. In addition, the use of animals in research, testing and education entails unique scientific and ethical obligations for their proper care and humane treatment.

All use of vertebrate animals for research, testing or education, regardless of sponsor or if the research is unsponsored, requires prior approval by the Institutional Animal Care and Use Committee (IACUC), and continuing adherence to IACUC-approved procedures during the conduct of the research or other activity. All members of the research team, including students, postdoctoral fellows and non-faculty employees, must be aware of and must adhere to IACUC requirements and the IACUC-approved protocol. These requirements include prompt reporting of adverse effects or unexpected animal deaths, and approval of any significant deviations from the IACUC-approved protocol. In addition, the University is required to report any significant noncompliance or deviations from the IACUC-approved protocol not reviewed and approved by IACUC.

The care and use of animals in research, testing and education must adhere to the requirements and principles set forth in the following:

1. The Animal Welfare Act (Public Law 99-98), administered by the United States Department of Agriculture, of 1966 and amendments of 1972, 1976 and 1985. Research involving animals covered by the Animal Welfare Act, regardless of sponsor or if the research is unsponsored, must adhere to regulations in the Code of Federal Regulations Subchapter 9 (9CFR) Parts 1, 2 and 3.

2. The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (Public Health Service Policy on Humane Care and Use of Laboratory Animals, Public Law 99-158, Health Research Extension Act of 1985), administered by the Office of Laboratory Animal Welfare, NIH.

3. Guide for the Care and Use of Laboratory Animals, (ILAR, NCR), as required for accreditation by AAALAC International.

The attending veterinarian should be used as a resource to help the investigator provide humane care. He/she has specialized training and experience with laboratory animals, and is able to help with the selection and appropriate use of the animal model, care and maintenance, medical treatment, alleviation of pain and euthanasia.

All personnel with substantial laboratory animal contact must be enrolled in and adhere to an occupational health and safety program that includes initial and periodic medical histories and physical examinations, and immunizations.

All animals for research, testing and education must be ordered by the vivarium staff from IACUC-approved vendors with appropriate licensure, in accordance with University and School policies and procedures.

X UNIVERSITY OFFICES OF RESEARCH, COMPLIANCE, AND PATENTS & LICENSING

Research Offices

University Office of the Vice President for Research

973-972-5455

New Jersey Dental School

Office of Research, 973-972-1796

New Jersey Medical School

Office of Research, 973-972-7697

Robert Wood Johnson Medical School

Office of Research and Sponsored Programs, 732-235-4687

School of Health Related Professions

Office of Academic Affairs and Research, 973-972-6957

School of Nursing

Office of Research, 973-972-3876

School of Osteopathic Medicine

Office of Research and Sponsored Programs, 856-566-6066

School of Public Health

Office of Research, 732-235-9773

Compliance Offices

Office of Ethics and Compliance, 732-743-3344

Institutional Review Board, Newark Campus, 973-972-3608

Institutional Review Board, New Brunswick Campus, 732-235-9807/06

Institutional Review Board, Stratford Campus, 856-566-2712

Newark Campus IACUC, 973-972-4469

Piscataway/New Brunswick Campus IACUC, 732-235-4162

Stratford Campus IACUC, 856-566-6843

Patents & Licensing Office

Office of the Director of Patents & Licensing, 732-235-9353

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