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DATA CONTROL & MANAGEMENT AND AUTHORSHIP GUIDELINES AT MICHIGAN STATE UNIVERSITY: THE NEED FOR BEST PRACTICES

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IN THIS ISSUE...

| IN 1113 1330E | |
|---|------|
| Introduction | P.1 |
| MSU's Guidelines: Data Control & Management | |
| Data Control & Management | P.2 |
| Questions & Responses | P.5 |
| Partial Listing of Other Policies | P.9 |
| Authorship | P.9 |
| MSU's Guidelines Authorship | P.10 |
| Responses to the Policy | P.12 |
| Case Studies and Responses | P.13 |
| Partial Listing of | |

Website:

Other Policies

www.msu.edu/user/gradschl/integrity.htm

P.19



Research Integrity

Introduction

Contributed by

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Research Integrity's (R.I.) audience has expanded since publishing the first and second issues on Authorship (Spring 1996) and Data Control and Management (Fall 1996). R.I.'s readership extends beyond the campus of Michigan State University to interested readers from around the country. As we approached the decision to reprint or revise the first two issues, the editorial advisors decided there were strategic advantages and overarching needs to establish a best practices issue by incorporating the two issues into one newsletter.

Two changes have occurred since the publication of the first two issues of *R.I.* On January 15, 1998, the University Research Council (URC) at Michigan State University passed the Authorship Guidelines, which were originally presented to the University community for debate and discussion in the Spring 1996 issue of *R.I.* Also approved by the URC on February 7, 2001, were the Data Control and Management Guidelines, which were developed to substantiate the recording of research data and its storage.

This issue provides the Authorship and Data Management Guidelines approved by the URC, and contains pertinent articles from the original 1996 issues of *R.I.* with editorial revising where appropriate. We invite the reader to focus on the principles and practices of authorship and management of data, rather on the appropriateness of the mechanisms as they read this issue of *Research Integrity*.



The Need for Best Practices at Michigan State University

Contributed by

David E. Wright, Ph.D.

University Intellectual Integrity Officer
Michigan State University

The Federal Commission on Research Integrity in 1995 stated that "institutional guidelines on data management and retention, authorship, and on supervision of students, fellows, and technicians are of paramount importance because they clarify for every member of the research environment the professional practices expected of them... Institutions are...strongly encouraged to develop practice guidelines..."

The Michigan State University Research Council has adopted guidelines in two of these critical areas—authorship and research data management. In my opinion these guidelines have already had a positive effect of informing researchers as to best practices and thereby of reducing instances of disputes among colleagues over authorship or data management. Further, when disagreements among collaborators do occur, the authorship guidelines provide an arbitration mechanism for resolving the dispute. We have recently begun to implement the arbitration provisions of the authorship guidelines and, while it is too early to make a definite assessment, I believe arbitration may prove very helpful relatively quickly before the harm or ruin in resolving disputes collaborative relationships.

MSU's Data Control And Management Guidelines

Following are a set of "Best Practices," approved on February 7, 2001, by the University Research Council (URC), developed to assure that research data are appropriately recorded, archived for a reasonable period of time, and available for review under the appropriate circumstances. Departments, Schools and Colleges may develop, adopt and promulgate their own data management guidelines if they prefer

to do so. In the absence of College or Departmental Guidelines, these URC Guidelines should apply.

1 Report on the Commission on Research Integrity, Integrity and Misconduct in Research, to the Secretary of Health and Human Services, The House Committee on Labor and Human Resources, November 1995.

Why These Guidelines Are Needed

The University is accountable for the proper maintenance and availability of primary research data created or collected by university personnel. Sponsors of university research, federal and state oversight agencies, or journals and other colleagues in the field may need or be legally entitled to review primary research data well after publication or dissemination of results.

Researchers involved in group investigations have rights to access to data gathered by all members of the group.

The University may be required to review internally the adequacy and integrity of data if findings of University research are called into question, or if violations of research regulations, e.g. those protecting human subjects of research, are alleged. Moreover, the University must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy and to assure compliance with laws and regulations governing the conduct of the research.

Accurate and appropriate research records are an essential component of any research project. Both the University and Principal Investigator (PI) have responsibilities and rights concerning access to, use of, and maintenance of original research data. Except precluded by the specific terms of sponsorship or other agreements, tangible research property, including scientific data and other records of research conducted under the auspices of Michigan State University,

belongs to Michigan State University. The PI is responsible for maintenance and retention of research data. Questions on the interpretation of this policy may be directed to the Vice President for Research and Graduate Studies or to the University Intellectual Integrity Officer.

2. Definitions and Applicability

Except where College or
Departmental policies on data control and management exist, these
"Best Practices" should be adopted
by all Michigan State University faculty, staff, students and other persons
at Michigan State University involved
in the design, conduct, or reporting
of research at or under the auspices
of Michigan State University. These
practices should apply to all
research projects on which those
individuals work, regardless of the
source of funding for each project.

Research data are defined as the recorded information, regardless of the form of the media on which it may be recorded, necessary to support or validate research findings. Included in the definition of research data are laboratory notebooks, field notes and journals, as well as x-ray film, photographs, negatives and slides, print outs, video and audio tape, computers and computer data storage devices, and synthetic compounds, organisms, cell lines, viruses, cell products, cloned coordinates, plants, animals and spectroscope data, however recorded or preserved.

The PI is the signatory person who has scholarly responsibility for the conduct of the proposed research.

Where research is funded by a contract with Michigan State University that includes specific provision(s) regarding ownership, retention of and access to technical data, the provision(s) of that agreement will supersede these guidelines.

3. Ownership

The University's claim to ownership and stewardship of the scientific records for projects conducted at the University, under the auspices of the University, or with University resources is based on both regulation (OMB Circular A-110, Sec. 53; 42 CFR, Part 50, Subpart A) and sound management principles. Michigan State University's responsibilities in this regard include, but are not limited to:

- a) Complying with terms of sponsored project agreements;
- b) Ensuring the appropriate use of animals, human subjects, recombinant DNA, etiological agents and radioactive materials:
- c) Protecting the rights of faculty, students, postdoctoral scholars and staff, including, but not limited to, their rights to access data from research in which they participated;
- d) Securing intellectual property rights;
- e) Facilitating the investigation of charges, such as misconduct in research or financial conflict of interest;
- f) Responding to legal actions involving the University related to research carried out under its auspices.

Collection and Retention of Research Data

The PI is the custodian of the primary data, unless agreed on in writing otherwise, and is responsible for the collection, management and retention of research data.

The PI should adopt an orderly system of data organization and should communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, the PI should establish and maintain procedures for the protection of essential records in the event of a

natural disaster or other emergency.

Research data must be archived for not less than three years after the submission of the final project report or publication, whichever occurs last, with original data retained wherever possible. This should include prudent provision of off-site back-up of electronic and hard-copy data. In addition, any of the following circumstances may justify longer periods of retention:

- a) Data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
- b) If any charges regarding the research arise, such as allegations of misconduct in research or financial conflict of interest, data must be retained until such charges are fully resolved; and
- c) If a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

Beyond the period of retention specified here, the destruction of the research record is at the discretion of the PI and his or her department or laboratory. The PI should make a permanent record describing the destroyed data and the destruction date.

To enable the University to meet its responsibilities related to stewardship of research data (as described above under "Ownership"), the PI should make all data available for review. This obligation continues even after the PI leaves the University.

The PI should assure that research data or copies thereof are made available for review by co-investigators in group research projects.

Records will normally be retained in the unit where they are produced. Research records must be retained on the Michigan State University campus, or in facilities under the auspices of Michigan State University, unless specific permission to do otherwise is granted by the Vice President for Research and Graduate Studies.

Transfer of Data (in the event a researcher leaves Michigan State University)

When individuals involved in research projects at Michigan State University leave the University, they may take copies of research data for projects on which they have worked. The PI must, however, retain original data at Michigan State University.

If a PI leaves Michigan State University, and a project is to be moved to another institution, ownership of the data may be transferred with the approval of the Vice President for Research and Graduate Studies, and, with written agreement from the PI's new institution that guarantees: 1) its acceptance of custodial responsibilities for the data, and 2) Michigan State University access to the data should that become necessary.

Disputes Over Research Data Management, Control or Access

Disputes involving management, control and access to research data must be referred to the University Intellectual Integrity Office (UIIO) for advice. On request of the parties, the UIIO will arrange for arbitration of the dispute by a committee of faculty and students formed with the advice of the University Graduate Council.



What Constitutes Research Data?

Contributed by **Nigel Paneth, M.D., MPH**

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Reprinted from RI Fall 1996

Data are best viewed as all of the intermediary products of research. The final product of research, the scientific article, is covered by the laws of copyright. Another product of research, the discovery that may have financial value, is dealt with under patent law. The nebulous category "data" appears to have a much cloudier legal status, perhaps because until recently few people considered its ownership of any great importance. Intermediary products of research in the biological sciences can be organized into three categories: (1)Biological specimens (2)Information recorded about biological specimens (3) Unpublished written material based upon information describing biological specimens.

The first category includes biological organisms, tissues or cells of human, animal, [or plant] origin, or images of the same. The second category includes information extracted from medical records or interviews with study subjects; other survey data; information derived from research which is entered into computer storage; programs (unless already copyrighted) designed to retrieve such information; computer printouts of data; and printouts from other laboratory machinery, such as oscilloscopes or spectroscopes. Written materials include laboratory notebooks, records or minutes of research meetings; grant applications; research protocols; preliminary reviews and tabulations of the literature; and any and all manuscript drafts, including the final unpublished drafts of published papers.



If A Graduate Student
Believes His/Her Professional
Advancement Depends Upon
Publishing Data, And The Pl
Is Reluctant To Publish It,
May The Graduate Student
Go Ahead And Publish The
Data On Her Or His Own After
Graduation?

Contributed by Nigel Paneth, M.D., MPH

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Reprinted from RI Fall 1996

The first issue to address is why the faculty member is reluctant to allow publication. Is it because the work is not up to standard? If this is so, then the graduate student's case for independent publication is very weak. If the faculty member is operating out of professional jealousy or unwillingness to share credit, then the graduate student may well have a case, but the student has no more right to simply go out and publish at will than would the faculty member were the situation reversed. No party to disputed data can unilaterally publish from these data.

If the two parties cannot between them agree to an equitable solution, then some independent mediation is probably needed. When this arbitration has come from University administration, it has not always been successful. This is probably because the University administration is one particular stakeholder in research data, and has its own priorities. Arbitration should come from a committee representing the interests of all stakeholders in research.

It's time for every university to set up a data committee to deal with such differences of opinion. Such a committee ought to be composed of the following stakeholders in research data: research-active faculty, research staff, graduate students engaged in research, university administrators, community

members with an interest in research findings, Institutional Review Board members/ethicists, and perhaps others. Such a committee should have an absolute majority of individuals whose regular work involves research, because they are in the best position to assess competing claims to data.

The data committee should be able to provide a well-educated opinion as to the validity of the competing claims of the student and the professor. The University should recognize this committee as the ultimate arbitrator of competing claims among university members. It is likely that the authority of such a committee would be recognized by research journals, so that someone known to be willfully ignoring its decisions (e.g. by attempting to publish after leaving the University) would likely be denied publication.



When a co-Investigator leaves a lab, may they take the data they generated themselves with them?

Contributed by

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University Intellectual Integrity Officer

Michigan State University

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The answer to this question balances the co-investigator's interest in continuing the research at her or his new institution, the principal investigator's right and responsibility (respectively) to control and to safeguard data, and the institution's responsibility to retain and safeguard data.

Universities with data management policies have differed in their approaches to the balancing of the interests of the departing co-investigator, the PI and the institution. But in all cases with which I am familiar the institution itself is responsible for producing the original data during investigations of alleged research misconduct or when funding agency audits occur for some other reason.

Typically, the PI is designated the "custodian" of the data by the institution. Under most

policies, co-investigators on leaving the institution may generally take with them only copies of the data. Misunderstandings and possible disputes are best avoided when the institution as a whole, or the pertinent entity within the institution (e.g. the department or the laboratory), has a clear policy or guideline on this question, to which all the investigators assent before initiating the research. (For further discussion, see the COGR policy recommendations on data management and the UCSF data management policy later in this issue of Research Integrity).



What are critical issues concerning management of and access to photographic negatives and digital images as data sets?

Contributed by

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Reprinted from RI Fall 1996

A variety of experimental methods in the natural, agricultural and medical sciences and engineering produce data that are recorded on photographic negatives, e.g. from light, laser confocal and electron microscopes, on autoradiograms or as digital images. It is often expensive and time-consuming (and sometimes impossible) to produce multiple copies of a single photographic negative or autoradiogram. In fact, even if feasible, the expense and time required for duplication may be very impractical, since one may not identify the images that are most useful for a future manuscript or presentation until after the entire set of experiments has been completed. There are a number of issues to consider and a variety of solutions for providing management of and access to such unique data as well as for digitized images.

With the increasing reliance on and quality of digitization of photographic images, collecting images on disk and/or digitizing existing images from photographic negatives or positives is easily accomplished. Diskettes may be shared by researchers and/or each person involved in a project may have their own. Digitized data may also be transferred with ease around the campus or around the world via the Internet. Capturing initially or copying images digitally provides a mechanism for all members of a research team to have access to the data set. The primary data set, including all original (nonprocessed) images, may be kept by the principle investigator.

Editorial staffs of some journals who publish large numbers of photographic images and disciplinary societies whose main research data consist of images are currently debating such issues as whether original, non-processed images should be required for archival purposes and/or included as an insert with processed images in published papers. An additional topic is the extent of detail of the processing methods and programs used by the authors that should be required in a Methods and Materials section of a manuscript.

Members of a research team should discuss and come to an agreement on who may use images and how, where and when the use of research data in the form of images will be handled. The extent to which image processing will be permitted, recorded in data notebooks and described in papers, theses and dissertations should be discussed with the goal of a mutually-agreed upon set of expectations and responsibilities by all members of the research group. Such discussions will constitute a valuable learning experience for students in their professional development and for understanding one facet of research integrity.



If a collaborative research project generates intellectual property (that is a potentially patentable invention) who owns it and who should obtain the patent?

Contributed by
Norman M. Pollack, Ph.D.
Director, Office of Intellectual Property
Michigan State University

According to MSU Patent policy:

Any discovery or invention which a) results from research carried on by, or under the direction of, any employee of the University which is supported by University funds or by funds controlled or administered by the University, or b) results from an employee's duties with the University, or c) has been developed in whole or in part through the utilization of University resources or facilities not available to the general public shall belong to the University ("University Inventions").

Most academic institutions have similar policies, and of course companies also insist on owning any inventions made by their own employees. Since the question of patent ownership comes up all the time, MSU and other organizations have arrived at certain standard ways of resolving it in cases where an invention is made in the course of a collaborative project. Ownership is typically determined on the basis of inventorship.

Inventorship is defined under patent law. When a U.S. patent application is filed, it is important to name as inventors all of the individuals who made a significant creative contribution to the invention, and equally important not to name as inventors any individuals who did not make such a contribution. It is the job of the patent attorney to determine who should be named as an inventor, based on the legal definition of inventorship.

According to the conventions used by MSU and most other institutions, any invention made solely by an MSU employee belongs entirely to MSU; any invention made solely by an employee of the other organization belongs to that organization; and any invention made jointly by employees of both MSU

and the other organization belongs jointly to both.

If an invention is jointly owned by MSU and another academic institution, we negotiate an inter-institutional agreement that spells out which institution will take the lead in prosecuting patent applications and licensing the invention, and how the institutions ill share the legal costs and (hopefully) any resulting license income.

If an invention is jointly owned by MSU and a company, the company generally takes the lead in patenting the invention at its expense in return for an exclusive license under any resulting patents.



If research may have produced a patentable invention, should investigators delay publication of their data?

Contributed by
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Director, Office of Intellectual Property
Michigan State University

Publication or public disclosure of an invention anywhere in the world creates an immediate bar to patent action in most countries. The only significant exception is the United States, where there is a one-year grace period for filing a patent application. Losing patent rights outside the U.S. may result in a loss of two-thirds or more of the commercial potential of an invention. Accordingly, the timing of publication versus the filing of a first patent application may have very significant consequences.

Since publication is so important to MSU researchers, the Office of Intellectual Property (OIP) does not advocate delaying your publication plans in order to submit invention disclosures. Instead, we suggest a strategic approach, in which you routinely submit an invention disclosure well in advance of the date on which you plan to give a talk or submit a manuscript for publication.

If you discuss your findings with OIP before

you are ready to publish, we can advise you about patent aspects of your work and help you decide whether to submit in invention disclosure. If you do decide to submit an invention disclosure, it may be helpful to send us a draft of your manuscript in electronic form, so that a patent attorney can use your words in preparing a patent application before your work is published or publicly disclosed.

Keep in mind that the filing of a patent application takes time and effort. The more notice OIP has of a planned publication, the better job we will be able to do in getting your invention protected in a timely fashion.



What Constitutes Research Data?

Contributed by
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Reprinted from RI Fall 1996

A central idea related to the question of what constitutes research data is that of intent. Research is something that is deliberately thought out, including research questions or hypotheses, with methods designed to gather the data. I would also include the expectation that the reason for gathering data is the extension of knowledge in some area, not idle curiosity.

In anthropology, as in all disciplines involved in studying human behavior, proposed research must first be cleared by the University Committee on Research Involving Human Subjects (UCRIHS). In more informal terms I would say that anytime an individual spends time either observing or interviewing people, knowing that this is the basis for material to be used in their research project, then that individual is gathering research data.



Partial Listing Of Other Policies on Data Control and Management

- Northwestern University,
 "Guidelines for Investigators in Scientific Research" 1991.
- National Institute of Health, Bethesda, MD "Guidelines for the Conduct of Research at the National Institute of Health" 1990.
- Harvard University School of Medicine, "Guidelines for Investigators in Scientific Research" February 16, 1988.
- The Johns Hopkins University, Baltimore, MD "Rules and Guidelines for Responsible Conduct of Research" 1990.
- University of Michigan Medical School, Ann Arbor, "Guidelines for the Responsible Conduct of Research" March 1989.
- University of California, San Francisco, "Research Integrity: Policies and Procedures" October 1995.



Authorship: Defining The Issue

Contributed by

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Authorship is the currency of the academic economy. Our worth as scholars is most often measured by our publications. Therefore, the issues surrounding authorship have always been particularly important as well as sensitive for scholars in all stages of their careers.

On this campus, more disputes and allegations of misconduct have involved plagiarism (50% in the 1999-2000 academic year) than any other single alleged lapse in research ethics.

While the concept of plagiarism seems simple and straight forward, in fact there is no universally accepted definition of plagiarism

and consequently, what constitutes plagiarism is an important matter for ethical discus-In 1999, The Office of Science and Technology Policy included in its definition of plagiarism "...the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts."² Importantly, plagiarism is only the most visible of many potentially contentious areas involving authorship. More than 40% of the research disputes and allegations (not involving specific allegations of plagiarism) submitted to the Intellectual Integrity Office last year involved authorship.

These general authorship issues include:

- Criteria of authorship. On what criteria should one be considered an author?
- 2. Order of authorship. Who is the first, second, third, etc., author?
- 3. Honorary authorship. Honorary authorship means naming an individual as an author who has not by virtue of his/her contribution to the research earned that right. Honorary authorship may take many forms. There is agreement that it is wrong to add the name of a person who had little or nothing to do with the study to increase the probability that the manuscript will be accepted. But some argue that including as an author a laboratory director who provides only funding, equipment and overall supervision of a lab is also a form of improper honorary authorship.
- 4. Refusal to publish. Is the refusal to publish ever unethical?
- 5. Restrictions on authorship. Do restrictions on authorship, for example, in certain industrial research contracts involving graduate students who need the data for their dissertations, present ethical problems?

A wide range of professional associations, government agencies (e.g., Public Health Service Office of Research Integrity) and journals have in recent years undertaken wideranging discussions of authorship. Some of these organizations, most often professional associations, have promulgated their own authorship policies. But are they the best source of standards on authorship? Should universities adopt their own policies?

This issue of Research Integrity brings to focus important aspects regarding authorship. First, the MSU guidelines, passed by the URC are outlined for review. Second, questions concerning the establishment of the current authorship guidelines, and some ethical issues surrounding the current authorship practices are examined. The following articles, originally printed in the Spring 1996 issue of Research Integrity, raise the question whether MSU should adopt a policy on authorship. Professor Edward Huth, chairperson for the International Committee of Medical Journal Editors, whose proposed set of authorship standards the MSU guidelines are closely modeled, argued that the University should adopt its own policy on authorship.

By contrast, Professor Jerry Dodgson, Chairperson of the Microbiology Department, argued that the guidelines were too restrictive and expressed concern as to how these guidelines or practices were to be enforced. Also included are case studies on problematical authorship practices and commentary on those case studies by graduate students and faculty.



2 From "Research Misconduct: A New Definition and New Procedures for Federal research Agencies." Office of Science and Technology, Executive Office of the President. October 14, 1999 Available on-line at: http://www.optp.gov/html/9910_20_2.html

Michigan State University Guidelines On Authorship

Adopted by the University Research
Council
January 15, 1998

(To apply to all academic units which have not adopted their own written policies)

- Authorship A person claiming authorship of a scholarly publication must have met the following criteria:
- a. substantial participation in conception and design of the study, or in analysis and interpretation of data;
- substantial participation in the drafting of the manuscript or in the substantive editing of the manuscript;
- c. final approval of the version of the manuscript to be published;
- d. ability to explain and defend the study in public or scholarly settings. (Note: these criteria follow closely those recommended by several professional associations. See especially the International Committee of Medical Journal Editors, Annals of Internal Medicine 1988; 108: 258-65.)
- 2. Acknowledgment Contributions that do not justify authorship should be acknowledged separately in the notes to the manuscript. These may include general supervision of a research group, assistance in obtaining funding, or technical support.
- 3. "Honorary Authorship" A claim of authorship by, or assignment of authorship to, persons who may have been associated in some way with a study but do not meet the four criteria in item 1 may constitute an unethical research practice.
- 4. Graduate Student Authorship "Faculty should be especially aware of their responsibility to safeguard the rights of graduate students to publish the results of their research." (MSU Research Handbook, 1985, p. 16, section 4.3.1.)

- 5. Senior Author and Order of Authorship - The senior author is generally defined as the person who leads a study and makes a major contribution to the work. All the authors at the outset of a project should establish senior authorship, preferably in a written memorandum of understanding. memorandum of understanding should reference the authors' agreement to abide by their departments' policy on authorship or this University default policy on authorship. At the outset of the study the senior author should discuss the outline of work and a tentative order of authorship with the study participants. As projects proceed, agreements regarding authorship may need to be changed. It is the responsibility of the senior author to assure that the contributions of study participants are properly recognized.
- 6. Disputes Over Authorship Disagreements over authorship, e.g. who has a right to be an author or the order of authorship, should be resolved by the Senior Author in collegial consultation with the other authors. When this process cannot reach resolution, the Senior Author should arrange with his or her chairperson for arbitration by a knowledgeable and disinterested third party acceptable to all the authors. If the authors cannot agree on a mutually acceptable arbitrator, then the Vice President for Research and Graduate Studies shall appoint an arbitrator. During the arbitration process all the authors are expected to refrain from unilateral actions that may damage the authorship interests and rights of the other authors.
- 7. Accountability Every author listed on a publication is presumed to have approved the final version of the manuscript. Each author is

- responsible for the integrity of the research being reported.
- 8. Plagiarism The word plagiarism is derived from the Latin plagiarius, an abductor, and plagiare, to steal. The expropriation of another author's text, and the presentation of it as one's own, constitutes plagiarism. Plagiarism, in turn, constitutes misconduct in scholarship under University policies and procedures. Plagiarism in scholarly projects should be reported to one's chairperson, dean or the University Intellectual Integrity Officer. (American Historical Association, Statements on Standards, 1993, p. 13)
- Distribution -This policy should be widely distributed, especially to each new faculty, graduate student and research staff member in academic units.

All issues of Research Integrity can be accessed on the web at: www.msu.edu/user/gradschl/integrity.htm



Professions Defining their Standards: Authorship

Contributed by

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Reprinted from RI Spring 1996

Are the disciplines that call themselves professions obliged to deliver anything to society when they choose to thus distinguish themselves?The professions claim this right in part through pursuing and educating the young in knowledge of a higher level than is common to all of us. But for centuries they have also distinguished themselves through voluntarily setting standards for behavior among their colleagues and relations with the public. Can they legitimately call themselves professionals when economic, or political, or social pressures lead some members to ignore those standards and begin to cut some ethical corners? That depends in part on a profession's response.

In today's hot competition for status, for power, for income, standards for authorship have increasingly been ignored. Witness the problems of gratuitous authorship, of ignored work of subordinates, of other kinds of misrepresentation to journal editors and readers. Can the professions define their standards explicitly and apply them when necessary or must other parties who depend on their services do that for them? What are the choic-Journal editors at a distance usually have no clues to violations of standards for authorship; they cannot be expected to effectively discipline an entire profession from their own narrow windows. Should government define standards with legal weapons and turn professionals into passive targets for external regulation?

The only reasonable answer is for professions to act as professions. They should define their own standards. They should recognize violations. They should take actions to defend those standards. They should educate their trainees in those standards with the hope that the coming generations in their fields will have those standards in their bones and continue to merit the badge "professional."

The standards proposed in this MSU draft are closely similar in principle to those published by such professional groups as the American Chemical Society, the American Psychological Association and the International Committee of Medical Journal Editors. I believe that the MSU faculty would bring merited distinction to itself by adopting such standards. They would thus affirm that they are truly members of professions.



Authorship Policy: Is The Cure Worse Than The Disease?

Contributed by
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Reprinted from RI Spring 1996

I would certainly agree with Dr. Edward Huth that it is the responsibility of professionals to set, promulgate and enforce standards of authorship. The American Society of Microbiology (ASM), for example, defines an author as "one who made a substantial contribution to the overall design and execution of the experiments." However, I find the MSU Default Policy on Authorship, based primarily on guidelines of the International Committee of Medical Journal Editors, unrealistically restrictive to cover the diversity of authorship issues that arise in the "real world."

The trend throughout academia is towards larger and more interdisciplinary teams of scholars, a trend which inherently leads to many "close calls" on authorship. The danger is that an overly prescriptive policy will be used to deny authorship to those who have indeed made "substantial contributions."

As a hypothetical example, is an engineer who provides imaginative and crucial input to the design of a particle detector qualified to be an author on the paper describing the detection of a new form of matter, even if she or he is not well enough versed in theoretical physics to "defend the study in public or scholarly settings?" If a crucial foreign col-

league's facility in English precludes their "substantial participation in the drafting of the manuscript," are they no longer a worthy author? In both cases the ASM policy would (reasonably, in my view) award authorship, while the Default MSU Policy would not, at least if interpreted to the letter of the law.

Beyond my concern about the detailed wording of the MSU Authorship Policy is the unanswered question of enforcement. Journal editors and funding agencies have, for obvious reasons, encouraged academic and research institutions to handle such problems internally, but no one, to my knowledge, has presented a good idea of exactly how this is to be done.

In a previous authorship dispute of some notoriety at MSU, the relevant administrator told me that the University could NOT intervene, because this would interfere with the freedom of expression rights of a graduate student. Has the University changed its position and, if so, what mechanism will be taken to resolve such disputes? Will this lead to mandatory University-level review of all submitted manuscripts? When it comes to authorship disputes, I would submit that things "ain't broke," and I fear that a central administrative "cure" may be worse than the "disease."



Framing The Issues: Case Studies

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The following case studies illustrate potential ethical problems associated with authorship. While hypothetical, each case study touches upon actual and potential problems faced by members of this University. These case studies raise issues that should be discussed from both a graduate student's perspective and a faculty member's perspective and each study is followed by commentary from each. The issues brought forth in the responses are by no means exhaustive and are meant to encourage dialogue.

Case Study #1

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Professor X is part of a collaborative group of scientists and graduate students who have accepted a research contract from Company Y to develop a drug. Company Y financed the study and retained money for data analysis. Professor X carefully reviewed the contract with the director of the Office of Intellectual Property to assure that faculty and students' rights to publish weren't unduly restricted. The collaborators, university and company agreed that the company would have the right to do its own data analysis first, and had the right to review publications in advance to protect intellectual property and to delay publication up to six months to provide time to file patent applications.

However, during the course of this study, the company made a marketing decision not to produce a high dose version of the drug despite the fact the preliminary data showed it to be efficacious. Company Y suppressed the study by refusing to analyze the data or pay for the data analysis. Company Y did not want to market the high dose drug and, therefore, did not want any studies appearing in print to show the efficacy of the drug.

This refusal to analyze the data has the effect of potentially depriving the faculty to publish and potentially deprives graduate students the information upon which their thesis depends.



• Does the refusal to publish results of properly conducted studies constitute research misconduct?

Response

Contributed by **Howard Brody, M.D., Ph.D.**

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This case can be addressed on two different levels, at least. The most obvious concerns lie with the individual investigators. Since the investigators have the study data, can they analyze it themselves, without the financial support of Company Y, and publish anyway? Should the university assist them in this process? Does the obstruction to publish by Company Y constitute a breach of contract, for which the university attorney should seek redress on the investigators' behalf?

But there is another level, which I would like to explore, which involves the relationship between the corporate world and the academic world, as more and more research sponsorship comes from corporate sources. This case, I believe, illustrates some of the problematic features of the university/corporate relationship. Another case anecdote may also illustrate some of the pitfalls.

A prominent academic family physician published a widely hailed study several years ago. He studied the impact of cartoon advertising of cigarette products and demonstrated a marked impact upon younger adolescents, despite tobacco industry denials that this advertising was aimed at a youth market. After his study was published (in a highly regarded journal), the tobacco company sued him to obtain the names and addresses of the research subjects. Their claim was that the study was poorly conducted and misleading, and that by re-analyzing the raw data they could show different results, which were more favorable, to them. The investigator viewed this effort both as a violation of the confidentiality investigators promise subjects, and also as simple harassment designed to discourage future investigations of this sort among academic physicians.

Accordingly, the investigator refused to

release the confidential information to the tobacco company, but offered instead to submit all his raw data for review by a truly independent third party.

The tobacco company next sued the investigator's university for release of the identifying data under the Freedom of Information Act. Initially the university sided with the investigator; but as time went on the university counsel withdrew support of the faculty member, urged him to release the data, and ended up siding with the tobacco company against the faculty member when he continued to refuse to comply. Many inferred some relationship between this stance and the heavy financial contributions the tobacco industry had made and was continuing to make to this Southern University. In the end the physician had to resign his University appointment and enter private practice, severely limiting if not ending his career as an investigator.

This rather egregious anecdote illustrates the dangers for the university in trying to protect research integrity during a time of shrinking financial resources. Some decisions to protect the integrity of the investigator will be both politically and financially unpopular with the university administration, to the extent that they offend powerful corporate interests. I would hope the university would be prepared to defend research integrity and to come to the defense of the investigators in such cases. Sadly, in many such cases today, faculty are being advised to get their own legal counsel immediately, and not to trust that the university administration and legal counsel will necessarily support their interests as investigators and scientists.

The question at the conclusion of the case study somewhat mis-states the ethical values raised by the case. The rights of the investigators to publish are, I would suggest, secondary to the public interest and the interests of patients in having valid scientific evidence made available through appropriate scientific channels. In this case, the important fact that a higher dose of a certain drug works better than a lower dose for selected patients might never see daylight if the company is successful in blocking analysis the data and publication. Physician-investigators and medical journals are under fire today for lapses in research integrity for failing to publish negative study results, thus creating a body of literature, which "tilts" incorrectly toward the value of therapeutic interventions. The lack of integrity in refusing to publish positive results, as in this case, seems even more serious.



Graduate Student

Panel Response ³ Reprinted from RI Spring 1996

Several issues were raised regarding this case study concerning the vulnerability of graduate students and the responsibility for educating graduate students.

A six-month delay constitutes too much time and is unfair to graduate students, because this kind of contract gives too much power to the company. It is difficult for graduate students to sit back and wait for six months when their degree may be on the line. In addition, every paper a graduate student is able to publish is very important to the job search process, and waiting six months or more for the data analysis from Company Y can be potentially detrimental to their careers.

The education of graduate students should be a priority over the concern of granting industrial institutions too much power over the research being conducted by graduate students, post-docs and professors. It should be the responsibility of the principal investigator (PI) to advise graduate students of the terms of Company Y's contract BEFORE the research is conducted and to continue discussions if circumstances change.

The need for a required research ethics seminar, which would be discipline specific, is paramount in the eyes of graduate students.

This case study should be an example for the university not to engage in these kinds of practices. It is too detrimental for graduate students, post-docs, professors and the public at large.

1

Case Study #2

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Professor M has a large laboratory with two post-docs, six graduate students and a variety of technical and undergraduate staff. The research is funded by two federal grants, one foundation grant and a contract. The graduate students and post-docs are all working on different aspects of the same larger laboratory project on the environmental factors that affect cellular processes that lead to disease. One or a combination of the funding sources funds all.

Two graduate students, A and B, are nearing completion of their research and are writing manuscripts for publication that will also form the basis for chapters in their dissertations. They are also assisting Professor M in the preparation of a grant proposal renewal. The renewal is based, in part, on the data generated by the two graduate students, as well as one of the post-docs on the project. The post-doc's salary will be funded by the renewal, but both graduate students are expected to have completed their work and not require additional support.

During a weekly lab meeting, Professor M decides that in order to increase the grant proposal's competitiveness, he needs to make some changes in the content of the two graduate students' manuscripts. The manuscripts will be submitted as part of the proposal in order to justify further funding. Professor M requests that the data from a specific set of experiments be moved from the manuscript of Student A to one manuscript of Student B.

Considerable discussion follows. Student A believes that the experiments in question are basic to the support of his arguments in his manuscript and that they are necessary for his dissertation to be considered a significant contribution. He also reminds Professor M that he is a graduate student first and that faculty members have a responsibility to provide the best advice possible to students. Student B has no objections to the experiments being moved into her manuscript, because she believes that they are so basic that they support a number of additional lines of research currently being done in the

³ In 1996, the following remarks were compiled by the editor from responses and concerns to these case studies expressed by graduate students, including Frank Daffin, Department of Physics (cyclotron), and others who wish to remain anonymous.

laboratory. Student B, however, does not want to include these experiments in the writing of her own dissertation, which she believes should be only her work as a single-authored publication. Student B also has more authors on her manuscript than Student A and is concerned that she, even as first author, won't be viewed as seriously as Student A when it comes to job interviews.

Both Professor M and Students A and B have legitimate concerns in this case.



- What constitutes authorship? When or how should this be discussed with graduate students?
- What are the issues and values that affect graduate students progress towards a degree and what that degree means, and how are those balanced with a faculty member's need to develop the most competitive grant proposal possible?
- What are the different perspectives on the relative importance of a dissertation as compared to publications?
- What are the issues and conflicts that can arise from working in scientific teams?
- How do faculty balance the conflicts inherent in the roles of mentor on the one hand and grantee with pressures to produce and time limits on the other?
- How do students balance the roles of student on the one hand and employee being paid to produce data on the other?
- How do faculty help students understand and reconcile these roles?

We continue to invite contributions, suggestions and comments from faculty, graduate students, and administrators. Please contact the editor, Julie Reyes at: reyesjul@pilot.msu.edu.

Response

Contributed by Ronald Patterson, Ph.D.

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The case study is very complex. The questions posed at the end are thoughtprovoking, and will generate discussion among readers of the case. I have found that case studies are best discussed verbally, especially when they are so complex and include multiple issues. My only comment relates to the next to last question. We do NOT view students as employees being paid to produce data, but as trainees receiving an assistantship to help defray the cost of their graduate education. I believe that if we (i.e., academe) begin to consider students as employees, then we are in a great deal of difficulty and invite disastrous consequences. Students (employees) may then wish to unionize to gain benefits accorded to other employees (for example; a 40 hour work week, better pay [as a technician], better health benefits, a rigid job description with details regarding teaching, etc.)



Response

Contributed by Les Manderscheid, Ph.D.

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In the "ideal world" all questions of authorship are resolved when the actors begin the study. Thus, the Professor, post-docs and graduate students would agree on the research procedures and who would include what in each manuscript along with the authorship. But if such a world existed, we would have no surprises in research and probably no funding because the results

would be known in advance. In the real world of uncertainty, we need to discuss authorship at an early stage and agree on the likely authorship issues for each anticipated manuscript. However, surprises will occur as the research progresses and the participants need to be flexible and creative in responding. It is clear that agreement exists with respect to the dissertations, and that agreement is consistent with the integrity of the degree.

The authorship of the manuscripts and especially the moving of findings by Student A into the manuscript of Student B is less clear. As a mentor, Professor M needs to explain as fully as possible why the proposal will increase the likelihood of funding. As future researchers the students need to understand what a good proposal contains. With respect to authorship, will Student B's manuscript be jointly authored? If Student A is making a major contribution to the manuscript, it probably should be. If the contribution is minor, can a footnote acknowledge the contribution? What is common practice in the discipline?

Students are entitled to appropriate recognition for their contributions, as are all others. Professor M has a special duty in mentoring the students to explain why the proposal makes sense and how the individual interests of each student are being protected. As students, the two need to learn from the experience in order to be good researchers and mentors in the future. In the process everyone needs to recognize that the quality of all degrees produced in this lab will be reduced by a public scandal but enhanced by the success of the lab in obtaining funding that produces a cure for the disease and a Nobel Prize.



Graduate Student Panel Response

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Some students believe that a thesis (or dissertation) gets you out of school and a paper (or manuscript) gets you a job. This

case study reveals important issues of honorary authorship and what must be done to ensure ethical standards and practices in this situation.

Frank Daffin suggests that before any work is initiated, the whole issue of authorship must be discussed; he acknowledges that "things do change" so that the need for honest, continuous discussion about the issues of authorship must be initiated, especially among the collaborators. Three suggestions for how these discussions should take place are as follows:

- All discussion concerning authorship, for example, who decides whose names go first, must take place before the work is done:
- Because things change, for example, people drop out, people change the focus of what they are doing, it is imperative that regularly scheduled meetings with the laboratory staff and collaborators take place during the course of the study; and,
- 3) Since the PI makes these decisions, the criteria must be made explicit for all members of the study. Consequently, the graduate students agree that honorary authorship is "clearly wrong."



Case Study #3

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Andrew has been bogged down with other commitments for many months, and now finds himself struggling to finish his thesis. He finds himself among a large number of index cards and notes typed out in various files; he is coming to realize that he has not been at all careful to take proper notes about where various ideas and lines of thought came from, or even whether some of the sentences or paragraphs are direct quotes from various sources.

He knows he has been in the habit of writing things down while reading, sometimes writing out a whole paragraph from a text, sometimes writing a paraphrase of the ideas, sometimes with this leading off into his own

thoughts. He is clear that there are many cases where he has not indicated the source, and at least some cases where something written down is in fact a direct quote, even though it is not attributed as such. And he begins to worry that a lot of his notes are in fact of this sort.

He discusses his worry with a close friend: "I can't possibly go back and find the exact source where each of these ideas and possible quotations came from; that's an impossible job. I suppose I could try to 'rework' passages that I suspect may be direct quotes. But what counts as reworking them sufficiently? And since I'm not sure which they are, I'll have to do this with so many of them — even ones I think are likely my own words to begin with!" Andrew states to his friend, "That would just take too long." Andrew realizes that this will not address the issues about attributing the sources of the ideas, and is tempted to just do a bit of rewording, and hopes that will suffice.



- What should Andrew do?
- What issues, both practical and moral, are at stake? And which are most important?
- Would it change things if what Andrew seemed to remember was that occasionally he had specifically lifted pas sages with the intent to plagiarize, but now he doesn't want to, and isn't sure which passages these are?

Response

Contributed by
Lawrence Busch, Ph.D.
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I find it astonishing that someone could arrive at the point where they were finishing their thesis and find themselves in this kind of disarray. My immediate thought on reading this case was that Andrew should not be in

graduate school at all as he appears to lack the minimum skills needed for graduate study.

But there is at least one other possibility: It may well be that Andrew did not receive the kind of mentoring that is appropriate for graduate study. Did his advisors point out to him, either in classes or in informal discussions, the importance of attention to sources? On the other hand, the very fact that Andrew is now so concerned about it suggests that they must have provided that advice.

However, in neither case can Andrew be excused from the practical and ethical requirement that both novel ideas and direct quotes be properly cited in his work. On a practical level, surely some of the notes he has are common knowledge and do not require citation unless quoted verbatim (although given what Andrew has done, one might question whether he has the competence to determine what is common knowledge and what is not). Moreover, in our society where authorship is highly valued, using ideas and quotes without citation is unethical behavior. (This is not true in all societies, but I assume that Andrew is an American.) Therefore, Andrew has a moral obligation to cite his sources, especially when he makes a direct quote. Were I his advisor, I would send him back to the drawing board to check his sources, regardless of the effect that it might have on his graduation date. Lack of time is an unsatisfactory excuse for failing to live up to one's moral obligations.

My position would remain the same if he intended to plagiarize but then decided not to do it. However, this would be a more serious violation of ethical norms since there would have been a deliberate, premeditated attempt to engage in unethical behavior.



Graduate Student Panel Response

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"We have little sympathy for Andrew, and feel that he must be held responsible for his actions." Andrew must recheck his sources and referenced papers even if this is difficult, takes time and is a pain. However, faculty have a responsibility in teaching the skill of disciplinary traditions in writing style to graduate students so that they can learn this in a timely manner. According to Frank Daffin, "post-docs are a blessing in labs because they help graduate students learn to write." Also, many graduate students learn from senior graduate students assuming they are plugged into the network. Although graduate students should have some basic level of ethical standards and practice doing citations, faculty should be involved in providing guidance for plagiarism issues. An ethics seminar on plagiarism, responding to the specific needs of each discipline should be required by each department involving all faculty in developing criteria for the seminar. This seminar should address: what plagiarism is; how to define it; what are the "gray" areas; how far is too far in citation practices; and, where do you draw the line.

In this case, intent is not important because Andrew made an egregious error in judgment and has to go back and fix it until it is right. There are differing opinions concerning what gets changed and how much should be reworded with plagiarism cases, which brings up the question of who helps you learn the boundaries as a graduate student? This should be made explicit in a handbook, seminar and/or informal departmental discussions.



Allegations Of Misconduct In Research And Creative Activities

Since 1996, the University Intellectual Integrity Office (UIIO) has received 40 allegations of misconduct, with 15 of those involving plagiarism. During the 1999-2000 academic year, the UIIO handled ten allegations of misconduct in research and creative activities, five of which involved plagiarism. The UIIO assisted in settling four access to, and control of, data disputes and four authorship disputes in the 1999-2000 academic year with over half of these involving graduates students.

Partial Listing Of Professional Authorship Policies

- American Chemical Society. Ethical Guidelines to Publication of Chemical Research. In: Dodd, J.S. Ed. The ACS Style Guide. Washington, DC: American Chemical Society; 1986: 217-22.
- American College Personnel Association. Statement of Ethical and Professional Standards. Journal of College Student Personnel. 1981; 22: 184-9.
- American Historical Association. Revised Statement on Plagiarism and Related Misuses of the Work of Other Authors. Washington, DC: American Historical Association, 1993.
- The Endocrine Society Publications Committee. Ethical Guidelines for Publication of Research. Journal of Clinical Endocrinology and Metabolism, 1988; 66: 1-2
- American Psychological Association. Authorship. In: Publication Manual of the American Psychological Association. 3rd ed. Washington, DC: American Psychological Association; 1983: 20-21.
- Council of Biology Editors Style
 Manual Committee. Ethical Conduct
 in Authorship and Publication. In: CBE
 Style Manual: A Guide for Authors,
 Editors, and Publishers in the
 Biological Sciences. 5th ed.
 Bethesda, MD: Council of Biology
 Editors; 1983: 1-6.
- International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Annals of Internal Medicine, 1988; 108: 258-65.



Other Authorship Policies Located on the Web

http://www.councilscienceeditors.org/services_ATF.shtml

http://www.councilscienceeditors.org/services_FriedmanArticle.shtml

http://www.nejm.org/hfa/authorandacknowledge.asp

http://www.sfn.org/guidelines/

http://www.icmje.org/

http://www.hms.harvard.edu/integrity/authorship.html

http://www.theaha.org/pubs/standard.htm

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