

AN INTRODUCTORY GUIDE TO RESEARCH ETHICS

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1.0 Preamble and Introduction

Generally, ethics is a branch of philosophy that deals with views of morality and attempts to provide a set of criteria for determining what is right and wrong within a particular context. Ethics should be upheld by all members of the scientific community. Science is cyclical in nature and ethics affects how this cycle works. Researchers develop scientific questions and investigate the outcomes, which then prompt a new generation of questions and hypotheses.

Research misconduct, a specific type of ethical violation defined as an intentional divergence from established research protocols, is the topic of discussion of this guide. An example of ethical misconduct includes the December 2010 retraction of a study by Dr. Andrew Wakefield, which linked autism and early childhood vaccination. Attempts to replicate through large-scale studies were unsuccessful. While evidence was lacking for this claim, preventable diseases reemerged in pediatric populations as parents continued to believe the original claim and chose not to have their children vaccinated.

An example of research misconduct specific to the UW-Madison campus occurred in 2006, when Dr. Elizabeth Goodwin of the Genetics Department resigned after several of her graduate students shared concerns that she had falsified data in a grant application and evidence was found that data had been mishandled.

This document is a guide, a starting point that will bring awareness that ethical conflicts do occur in all fields of science. While ethics may seem like a black and white topic, this guide is necessary because of the existence of gray areas, as documented by instances of research misconduct in many areas of science (publication, tenure, funding, plagiarism, data collection and analysis, conflicts of interest, authorship issues, human subjects considerations, the use of animals, and mentor/mentee responsibilities). This guide includes information on conflict of interest and of commitment (section 2.0), mentor/mentee roles and responsibilities (3.0), human participants and animal use in research (4.0), data falsification and fabrication (section 5.0), data ownership and intellectual property (6.0), authorship (7.0), plagiarism (8.0), explanations for research misconduct (9.0), and whistleblowing (10.0). The document also includes a list of resources (section 11.0) on the various aspects of scientific misconduct.

This guide is also intended to facilitate discussion. Being informed about the issues and being aware of potential situations in which ethical conflicts may

arise better prepares researchers to navigate and participate in scientific pursuits.

This guide was prepared by faculty, graduate, and postdoctoral students of the Department of Communicative Disorders and Waisman Center at the University of Wisconsin-Madison. Though this guide is within the framework of behavioral research, ethical principles should be understood and applied in all fields.

2.0 Conflict of Interest & Conflict of Commitment

Because they represent a potential threat to research integrity, conflicts of interest should be included in any discussion of the responsible conduct of research. A conflict of interest can be conceptualized as an outside affiliation, relationship, or activity that may inappropriately influence how an individual carries out the research process. Conflicts of interest can affect students, laboratory technicians, or principal investigators, as well as those who review research or allocate research funding.

Conflicts of interest can take a variety of forms, including financial, personal, professional, or theoretical. Financial conflicts of interest are perhaps the most obvious examples. They typically occur when there is a financial reward for an individual involved with a research project, depending on the outcome of the research. For instance, there is a financial conflict of interest when a pharmaceutical company funds safety testing of a new drug they would like to put on the market. Personal conflicts of interest occur when a personal view or relationship might interfere with the research process. For example, an investigator who believes that his child developed autism as a result of a vaccination might not be an impartial researcher of vaccine safety. Professional conflicts of interest emerge when an individual has two professional roles with conflicting goals such as when a psychiatrist who is also a researcher conducts a study that includes her own patients. Theoretical conflicts of interest occur when strong adherence to a particular theory interferes with impartial interpretation or review of research. This may occur in situations in which a reviewer has theoretical leanings that affect the rating she gives to a grant or article that challenges the theories held by the reviewer.

It is important to note that conflicts of interest do not *always* lead to research misconduct or unethical behavior. In some cases, conflicts of interest may be associated with highly productive research relationships. For example, research laboratories that study children with cochlear implants may partner with (and receive funding from) the companies that produce the devices in order to develop the most effective models. Because of the positive and productive nature of this relationship, it is undesirable to simply eliminate the conflict by ending the affiliation. Instead, researchers are expected to declare conflicts of interest when they disseminate research at conferences, in academic journals, or in the media. Declaring conflicts of interest allows consumers of research to reach their own conclusions about study findings and implications after receiving all relevant information.

Many research institutions have regulations on how researchers allocate their time. A conflict of commitment occurs when the time or effort that a researcher expends on activities other than research, interferes with his research responsibilities. Conflict of commitment includes the use of resources owned by the research institution for unapproved purposes. Potential conflicts of commitment should be disclosed to the research institution.

3.0 Mentor/Mentee Roles and Responsibilities

Mentors serve many roles, including that of advisor, supporter, sponsor, and teacher. At all levels of accomplishment it is useful to have mentors. It is also a good idea to have more than a single mentor. Considerations when selecting a mentor should involve mutual respect, shared interests, shared research focus if possible, and the ability to provide constructive and timely feedback.

Good mentoring practices include careful listening, keeping in touch, encouraging multiple mentors and building networks. Mentors should seek to build a relationship through simple joint activities (attending campus lectures together, discussions over coffee), create some protected time to devote to mentoring activities, nurture self-sufficiency in mentees, share their own experiences with mentees, and provide constructive and honest feedback. Research has shown that there are many benefits of mentoring, particularly the mentoring of junior faculty – such as research productivity, teaching effectiveness, professional socialization, and job satisfaction. Why do people serve as mentors? Reasons include a desire to share their knowledge and experience and to extend their contribution to the field.

Mentees should seek out appropriate mentors and take the initiative to make things happen. Mentees should identify initial goals, seek feedback, and take an active role in their own learning. They should listen non-defensively and accept constructive ideas for change. Mentees should also keep the mentor informed of academic progress or difficulties. Effective characteristics of mentees include being goal-oriented, taking initiative, seeking challenges, and accepting personal responsibility.

Mentors need their own mentors. We can all expect to serve both roles (mentor/mentee) at various stages of our professional careers.

Potential mentoring pitfalls include limited time, lack of overlap in expertise, over-dependence, or lack of personality fit. Some of these issues can be worked out but others simply result in an ineffective mentor/mentee relationship. In those cases, it is best to acknowledge that the relationship is not working and to seek another mentor. In these cases, it is particularly helpful to have more than a single mentor.

How does ethics come into play in the mentoring process? Topics regarding the responsible conduct of research (RCR) should be discussed by mentor-mentee pairs, including authorship issues, conflicts of interest and so forth.

The mentor should serve as an ethical role model with respect to conducting research, interactions with students and colleagues, and compliance with regulatory guidelines (Institutional Review Board [IRB], animal research, budget oversight). Mentors should also recognize that there is a power differential in the relationship and make certain that advice is actually in the best interest of the mentee (e.g. not encouraging the person to stay an extra year because she/he is so good at running the lab), that confidential conversations are not used against the mentee in any way, and that mentees are encouraged to be self-sufficient (e.g. to stop publishing with the mentor after graduating or finishing the postdoc in order to establish their own program of research). Mentees need to be forthright with their mentors about their progress and their degree of competencies in various areas. Mentees should speak up if they believe their efforts are not being duly acknowledged within the research team in terms of assignment of projects or authorship. When mentees have multiple mentors they should facilitate communication rather than playing the mentors off against each other. Finally, mentees should respect confidential information that mentors may have shared about their own professional challenges in order to help the mentee with a similar difficult experience.

Sources:

Advisor, Teacher, Role Model, Friend, National Science Foundation
http://www.nap.edu/openbook.php?record_id=5789

Everyone Needs a Mentor (2004, 4th edition), by David Clutterbuck
<http://www.amazon.com/gp/search?i=books&linkCode=qs&keywords=1843980541>

C Bland, Univ. of Minnesota Medical School presentation
Medical College of Wisconsin website
Univ. of Texas at Austin, College of Natural Sciences website

4.0 Human Participants and Animal Use in Research

Research in which humans and animals are studied is assumed to have some benefit to society. In any study, there is a cost-benefit ratio attached to the use of either human or animal participants; the benefit to society is weighed against the cost of the specific role of humans and/or animals participate in the work.

As everyone knows, the use of human participants for research purposes is governed by a strict set of procedures to ensure that no person is coerced into participation, that persons understand exactly what procedures they will experience as a research participant, that proper safety measures are in place when they are warranted, and that every human subject (or a parent or guardian, in the case of vulnerable participants such as children and persons with certain disabilities) signs a document indicating that they understand the experimental procedures, that they agree to serve willingly as a participant, and that they are free to terminate their participation at any time *without prejudice*, including prior to the completion of the experimental procedures.

All institutions have guidelines for the use of human subjects. You will, be required to read these to be certified to work in a lab that deals with human subjects in any form. The historical and conceptual basis for human subjects protection is found in the Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3/>).

Strict procedures for ethical treatment of animal subjects are also published by each institution in which animal experimentation is conducted. A good site for information on guidelines for animal experimentation is <http://www.apa.org/science/leadership/care/guidelines.aspx>

5.0 Data Falsification and Fabrication

Simply stated, *scientific falsification* is knowingly recording or reporting inaccurate or misleading facts associated with the research. Further, *data fabrication* can be considered a type of scientific falsification. Falsification and fabrication are classified as follows:

- Falsification
 - knowingly changing, omitting, or misrepresenting data
 - manipulating procedures within an experiment so that the data fit the desired hypotheses
- Fabrication
 - making up data

Data falsification and fabrication may have serious effects on the populations being studied. When untrue or inaccurate results are published, the public trusts their validity, and policies or treatments may be put into action that negatively affect the populations for whom the research was intended. This was the case for the fabricated data of Dr. Scott Reuben. Dr. Reuben was a researcher on pain management, whose research reports influenced the drugs doctors chose to prescribe to their patients. Besides the direct negative consequences of falsification on individuals, time and resources may be wasted if other researchers try to replicate the falsified data, conduct new research founded on the conclusion drawn from the falsified data, or interpret new data with the falsified data in mind.

Data falsification may be detected when others are unable to replicate the falsified findings; however, this is often insufficient to lead to suspicions that falsification has occurred. Falsification may be suspected when other researchers notice unusual behavior from the researcher conducting the falsification, or notice unusual characteristics of the falsified data. Scientific audits may be performed when suspicions of falsifications are reported. It may be difficult to accurately distinguish falsification from honest mistakes which were made during data collection and recording.

Each person involved in an experiment is trusted to accurately collect and report data, with the authors ultimately being accountable for the reported results

6.0 Data Ownership and Intellectual Property in Research

Research generates data, and some research also generates new products, techniques, or methods. In either case, ownership is an issue that requires ethical consideration. For example, the data collected during a grant-funded research project are not the sole property of the investigator, but could also be owned by the University, as is the case at UW-Madison. An invention or discovery by a faculty member or student may need to be disclosed to the university or the funding agency that supported the work contributing to such an innovation.

Data ownership (also referred to as data stewardship) encompasses the possession and responsible sharing of data. In general, science values the principle of openness as the sharing of data is considered to benefit society at large. A specific practice considered unethical is data hoarding, when an entity chooses to withhold access to the data because of concerns of providing too much information about a close breakthrough or possibly to avoid allegations of misconduct. Other issues of data ownership may arise due to the potentially large number of parties considered data owners on some level. Data ownership should be outlined at the beginning of a project especially between an academic institution and industry (public/ private sector), between an academic institution and researcher, when collaborating with colleagues, and between authors and journals. For information on data storage and transfer policies consult with the Archives and Records Management Services (ARMS) on campus.

The handling of intellectual property also requires careful consideration. For example, some Institutes of the National Institutes of Health might require that employees provide notification of inventions directly to the institute before decisions about patents and licensing are made. Here at UW-Madison, the Wisconsin Alumni Research Foundation (WARF) is a private non-profit organization that supports research at the university by patenting and licensing inventions from university research to generate income that can be returned to the university. It is important to be aware of patent and licensing regulations with specific regard to the funding agencies and institutions that may be involved.

In addition to being mindful of university regulations and the policies of funding agencies, ownership raises other types of ethical questions in research. This has particularly come to light as advances have been made in genetic research and as patents have been applied to individual genes. While patents may provide protection to the advances made by some researchers, they might also limit the work done by others or the rate of progress that can be made to benefit society. Parties and individuals should

recognize the scientific responsibilities of data ownership and practice in responsible sharing.

<http://www.genome.gov/19016590>

http://ori.dhhs.gov/education/products/n_illinois_u/datamanagement/dotopic.html

<http://archives.library.wisc.edu/records/>

7.0 Authorship

An individual's publishing record plays a critical role in career advancement within academia. Under the pressures of productivity, authorship issues may arise. Some of the most prevalent authorship issues within research laboratory are: 1) who should be included as an author on a paper submitted for publication; 2) who should be the first, or "lead" author; and 3) what the appropriate order for the remaining authors should be.

- **Determining Authorship** - Guidelines for determining authorship qualifications range from broad guidelines which indicate that "all who make significant contribution and share responsibility should be authors," to more stringent guidelines which include statements like, "authorship credit should be based only on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data" (Claxton, p.41, 2005). Because the specific practices of research labs may differ, authorship decisions should be a joint decision among the individuals who are involved.

Other authorship issues include:

- **Coercion Authorship** – The practice of being pressured to give authorship to an individual because of his or her position.
- **Mutual Support/Admiration Authorship** – The practice of authors placing each other's names on papers even though they made little or no direct contributions to the paper.
- **Gift Authorship** – The practice of placing the name of a colleague on the paper, even though this person made few or no direct contributions to the paper as an author, out of respect for the colleague or in an attempt to make the paper appear more legitimate. (For more information, see Claxton, 2005).
- **Unapproved Authorship**: Listing someone as an author who has not agreed to be an author, or who has not been consulted about authorship.

These issues highlight the need to consider establishing a set of authorship guidelines, which is a straightforward and responsible way to limit authorship disputes. Some institutions, funding sources and research journals have begun to establish their own guidelines for authorship, but this is not a widespread practice at this time. Authorship standards vary widely across disciplines, institutions, and research labs. For this reason, authorship

guidelines will most likely need to be established and implemented by principal investigators at the level of their individual labs.

A second point we will underscore is the benefit of frank and honest discussion about authorship both before a project begins, and as a project progresses. Continued discussion is vital because of the likelihood that roles and responsibilities will shift during the research process. For example, the person who initially took the lead on a particular project may not be the most appropriate choice for first author by the time a project is completed. We believe that these ongoing conversations, combined with written authorship guidelines, are the best ways to prevent authorship disputes and to facilitate discussion as soon as potential conflicts arise.

The National Institutes of Health Office of Research Integrity has developed valuable online resources for responsible authorship. One such resource is the *Responsible Authorship Quick Guide*, which contains information about common authorship mistakes, dilemmas, and additional resources. The website also includes short quizzes about hypothetical authorship dilemmas (e.g., assigning credit for authorship, collaborative authorship, and conflict of interest).

See http://ori.hhs.gov/education/products/niu_authorship/index.htm

8.0 Plagiarism

Plagiarism is defined as “the unauthorized use or close imitation of the language and thoughts of another author and the representation of them as one's own original work”

(<http://dictionary.reference.com/browse/plagiarism>). It is also possible for an author to plagiarize his or her own work.

Like the other issues discussed in this guide, plagiarism becomes more complicated when closely examined. Guidelines state that any text taken verbatim from another source should be enclosed in quotes. However, guidelines do not address how much rephrasing an author must do if he or she takes text from another source and chooses not to quote the author. Researchers should choose to be overly-cautious when trying to identify possible plagiarism. Issues regarding intellectual property may overlap with issues of plagiarism.

An oft-overlooked facet of plagiarism is self-plagiarism. In the case of redundant or duplicate publication, authors submit articles, substantial portions of articles, or manuscripts detailing previously published data sets and analyses to more than one journal, perhaps with an altered list of authors. Young researchers should be aware that once a manuscript has been submitted to a journal, it is inappropriate to submit any portion of that manuscript to any other journal, unless the manuscript has been formally rejected. If an article has been published, no portion of it may be republished in another article without proper citation. Working outside of this submission stipulation violates copyright laws, and may result in inexact meta-analyses, exaggerated perceived significance of a finding, and wasted efforts by publishers, reviewers and readers.

While intentional self-plagiarism occurs, authors may also plagiarize themselves unintentionally. In some fields, describing an apparatus using the exact same wording that he or she used in a used in a previous article is considered plagiarism.

To avoid plagiarism, researchers should:

- Use proper citations to identify other authors and contributors to a work.
- Enclose direct quotations in quotation marks, along with appropriate citation of author and year (page number if required).

- Only cite material that has been closely read. This will ensure that the conclusions drawn and referenced are correct and as the original authors intended them.
- Cite the initial publication of an idea, fact, theory, or conclusion; rather than citing a more recent document which contains a reference to the original authors.

Software that identifies redundant publications and comparable language is becoming more widely used. However, plagiarism continues to be a vehicle for scientific misconduct.

Websites with tips on how to avoid plagiarism:

<http://owl.english.purdue.edu/owl/resource/589/01/>

http://www.plagiarism.org/plag_facts.html

9.0 Explanations for Research Misconduct

Research misconduct occurs despite the serious implications it can have for individuals' careers and the scientific community at large. The following list describes some reasons scientists may commit research misconduct:

- Pressure to secure research funding, publish research articles, and achieve professional advancement in the face of limited time and other professional responsibilities such as teaching, mentoring, and university service.
- Desire to promote one's own intellectual achievement or theoretical viewpoint.
- Conflicts of interest and/or commitment (see section 4.0) including sources of direct or indirect financial gain from publication, patent ownership, or corporate sponsorship.

Let us consider the following high-profile case of research misconduct first mentioned in the Preamble. Andrew Wakefield was accused of research misconduct in connection with a paper published in 1998 in *The Lancet* linking the measles, mumps, and rubella (MMR) vaccine to autism. The publication was later retracted in response to findings that Wakefield failed to disclose a financial conflict of interest associated with his relationship with a Legal Aid Board that was investigating possible legal action in relation to the claim that the MMR vaccination was harmful to children (Horton, 2004). Despite the financial incentive, one might also imagine that Wakefield had a strong belief in the link between the MMR vaccine and autism and thus, was willing to undertake questionable practices to make his point. The effects of Wakefield's actions were far reaching as MMR vaccination rates dropped and there was an increase in the cases of measles in Britain following publication of the Wakefield study (Deer, 2006).

Motivations and thought processes behind research misconduct may never be understood in a specific case such as this. However, it is good professional practice for researchers to be reflective of the external and internal pressures on the planning, execution, and documentation of their projects.

Deer, B. (2006, April 2). Schoolboy, 13, dies as measles makes a comeback. *The Sunday Times*. Retrieved March 22, 2011, from <http://www.timesonline.co.uk/tol/news/uk/article701151.ece>

Horton, R. (2004). A statement by the editors of The Lancet. *The Lancet*, 363 (9411), 820-821.

10.0 Whistleblowing: Procedures, Responsibilities, Potential Consequences

The term “whistleblower” is typically used to designate a person who reports suspected misconduct of a colleague or another person to a superior or superiors. A whistleblower typically provides superiors with more than just suspicions of misconduct; some form of evidence is usually part of the disclosure (in the absence of evidence, expressed suspicions of misconduct are often regarded as less official, expressions of hostility toward a colleague).

There are at least three major issues with whistleblowing in the arena of scientific misconduct. One is the general issue of potential consequences of being a whistleblower, regardless of the outcome of the case. A second issue concerns whistleblowing responsibility—when should the whistle be blown, and what is required for “responsible” whistleblowing? The third issue concerns the mechanics of whistleblowing—how is it done? There are no formal codes for answering these questions, but some general suggestions are offered below.

What are the risks of whistleblowing, and what are the (potential) whistleblower’s responsibilities?

There is no doubt that whistleblowing is risky, especially when the whistleblower is a student (doctoral or postdoctoral) directing his or her complaint against a supervisor, or a junior faculty member directing her or his complaint against a senior faculty member, or a non-faculty person (such as a research scientist) directing a complaint against a faculty member. The sequel to the Goodwin case at UW-Madison (Couzin, 2006) makes this abundantly clear. Individuals must weigh the risks and benefits to themselves, the university, and to society before deciding to blow the whistle. It is important to keep in mind that either whistleblowing or the decision *not* to say something when you have strong reason to believe scientific misconduct has occurred or is occurring, may have both short and long-term consequences. For example, if scientific misconduct is discovered several years after it has taken place, and during the course of an investigation or revelations from other parties it becomes clear that you had knowledge of the misconduct—even if you were not engaged in the misconduct—other scientists may form judgments based on your decision to keep your suspicions private.

When should the whistle be blown, and what is required for responsible whistleblowing?

When a scientist has what he or she believes to be credible evidence of scientific misconduct, whistleblowing may be a reasonable option. Credible evidence is not easy to define precisely, but may include eyewitness evidence of misconduct (as in the famous 1981 Darsee case at Harvard Medical School (Broad & Wade, 1982, p. 13-15), documented evidence of claims made by an investigator that are at odds with first-hand knowledge of colleagues or students working in the same laboratory (as in the Goodwin case, see Couzin, 2006), or hard-copy demonstrations of plagiarism. Rumor, innuendo, and personal animus must be removed from any formal complaint against a colleague or other scientist against whom charges are made. The whistleblower's own records of the events leading up to the complaint are critical, and may include diaries, logs, written summaries of meetings with other interested parties (such as fellow students or colleagues), and so forth.

How is whistleblowing done?

Many universities have written procedures for reporting suspected scientific misconduct (see, for example, the UW-Madison's procedures at <http://www.grad.wisc.edu/research/policyrp/smisconduct.html>). The procedures are likely to vary across institutions (compare the UW-Madison information published on the web to (for example) procedures and policies at the University of Iowa (<https://research.uiowa.edu/dsp/assurance6>), the University of Arizona (<http://uhap.web.arizona.edu/chap2.html>, Section 2.12.09), and Harvard University (http://hms.harvard.edu/public/coi/research_issues/index.html). Whistleblowers should always consult the currently-published procedures of their local institutions, and follow them as precisely as possible.

11.0 References and Resources

References

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Resources

On the Web

- UW-Madison's policy on research misconduct
<http://www.wisc.edu/search/?q=research+misconduct>

This website provides information about UW-Madison's policy on research misconduct from a legal perspective.

- UW-Madison Graduate School's Research Policy
<http://www.grad.wisc.edu/research/policyrp/rpac/index.html>

This website provides information regarding the UW-Madison's Graduate School research policy and includes links to resources discussing a variety of topics including: ethical principles, conflicts of interest, human subjects research, and research misconduct.

- Council on Governmental Regulation (COGR): http://www.cogr.edu/Pubs_intellectual.cfm

This website provides information on data management and intellectual property. This website includes links to the views of various governmental agencies (including NIH) as well as case studies for practice with negotiating these issues.

- The U.S. Department of Health and Human Services' Office of Research Integrity: <http://ori.hhs.gov/>

This website provides information on the Department of Health and Human Services' policies on integrity in biomedical and behavioral research.

- The U.S. Department of Health and Human Services' Office of Research Integrity guide to responsible authorship: http://ori.hhs.gov/education/products/niu_authorship/index/htm

This website provides a quick guide to authorship policies.

- Committee on Publication Ethics (COPE): <http://publicationethics.org/>

This website provides an online forum for publishers and editors of academic journals to share and discuss aspects of publication ethics and includes case studies concerning these issues.

Books

Broad, W., & Wade, N. (1983). *Betrayers of the Truth: Fraud and Deceit in the Halls of Science*. London: Century Publishing.

Committee on Science, E., and Public Policy (COSEPUP) (2009). *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition* (3 ed.). Washington, D.C.: The National Academies Press.

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