Sponsored Programs Guidance "Cradle to Grave"



Misconduct of Science

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I. Introduction

All investigators have a duty to ensure that research performed or sponsored under their direction is of high quality and maintains the integrity of the scholarly process. This integrity is particularly important when working with funding provided by the federal government or other sponsors, as the funder expects an impartial and accurate deliverable that can be used to further investigation, development, and implementation of the project. Investigators must avoid misconduct in the research process to protect the reputations of themselves, the investigation team, and the institution, as well as the interests of the sponsor, its stockholders, and/or taxpayers.

"Research ethics," while concerned with misconduct issues, encompasses much broader concepts of responsible research. Research is a public trust and must be conducted in a socially-responsible manner. One instance of unethical practice has the potential to damage an entire project. While the original focus of research ethics dealt with human subjects, today the field has expanded to include all areas of research, and all researchers should be well-versed in ethical concepts regardless of their field of study.

II. Governing Bodies

Most governmental funding programs related to the sciences have provisions protecting against misconduct of research. Of particular interest to institutions of higher education are those of the National Science Foundation (45 CFR 689) and the Department of Health and Human Services (42 CFR 50 and 93). In addition, the University of Arkansas has adopted its own policy and procedures, most recently amended on February 10, 2010. The University policy closely mirrors the requirements detailed in the Code of Federal Regulations.

From the standpoint of research ethics, the main responsibility for guidance rests with the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC). These committees, normally required of institutions receiving federal funding sources, have the responsibility to review proposed projects in order to ensure they are conducted in accordance with accepted practices as related to human and animal research. In performing their reviews, the committees consider the guidelines of a number of organizations including

the USDA, NIH, Public Health Service, and International Committee of Medical Journal Editors (ICMJE).

III. Misconduct of Science

Research misconduct is *fabrication*, *falsification*, or *plagiarism* in proposing, performing, reviewing, or reporting research results.

a. Types of Misconduct

- 1. Fabrication: making up results and recording or reporting them as fact.
- 2. Falsification: manipulation of materials, equipment, or processes, or changing or omitting results to the extent they prevent the research from being accurately represented.
- 3. Plagiarism: the use of another's ideas, processes, results, or words without proper credit.

In some cases, misconduct of research can involve unreported conflicts of interest. Investigators should take care to follow conflict of interest guidelines to protect the integrity of their work. Research misconduct does <u>not</u> include honest errors or differences of opinion among investigators or reviewers.

In order to qualify as misconduct, aspects of the research must meet one or more of the following criteria:

- 1. Represent a significant departure from accepted practices.
- 2. Have been committed intentionally, knowingly, or recklessly.
- 3. Be proven by a preponderance of the evidence.

In general, the institution receiving funding is expected to monitor the work of its investigators and conduct inquiries and investigations if misconduct is suspected. The institution has an obligation to protect informants, witnesses, and the accused researcher during the course of the investigation and inform the sponsoring organization of the results.

b. Reasons for Misconduct

While reasons or justifications for misconduct vary among investigators found negligent in performing research, several common themes have been revealed during investigations.

- 1. Investigators are under intense pressure to publish in scholarly journals.
- 2. Investigators have a desire to be recognized and respected by their peers and institutional administrators.
- 3. Investigators have personal problems.
- 4. Some investigators are inherently dishonest.
- 5. Cultural differences among investigators create instances in which the importance of preventing misconduct is minimized.

c. Examples

In its presentation adapted from information provided by Virginia Tech University, Sinclair Community College of Ohio identifies several behaviors that signal misconduct among investigators.

- 1. Falsifying or "cooking" data.
- 2. Ignoring major aspects of human-subject requirements.
- 3. Not properly disclosing involvement with firms whose products are based on one's research.
- 4. Relationships with students, research subjects, or clients that may be interpreted as questionable.
- 5. Using another's ideas without obtaining permission or giving credit.
- 6. Unauthorized use of confidential information in connection with research.
- 7. Failing to present data that contradict one's own previous research.
- 8. Circumventing aspects of human-subject requirements.
- 9. Overlooking others' use of flawed data or questionable interpretations.
- 10. Changing the design, methodology, or results of a study in response to pressure from a funding source.
- 11. Inappropriately assigning authorship credit.
- 12. Withholding details of methodology or results.
- 13. Using inadequate or inappropriate research methods.
- 14. Dropping observations or data from projects without justification.
- 15. Inadequate record keeping.

d. Consequences

A finding of misconduct can have serious consequences for both the investigator and his/her institution. Depending on the extent of the infraction, misconduct can result in reprimand, loss of publishing privileges, reimbursement of funds to the project sponsor, or ineligibility to apply for future funding. In addition, proven misconduct will permanently tarnish the reputation of the investigator among his/her peers and damage the reputation of the institution. All investigators should realize that the impact of misconduct reaches far beyond the research or individual investigator. Other faculty, the project sponsor, and the public can all be negatively affected by an investigator's misconduct, and the consequences of undiscovered misconduct can have severe impacts on society.

IV. Research Ethics

Conducting ethical research requires that investigators be familiar with a number of concepts, many of which are subjective in nature. Many instances of ethics violations do not necessarily rise to the level of misconduct; however, it is incumbent upon all investigators to ensure that ethics issues receive equal attention in the planning and conducting of research. While violation of ethics may not involve misconduct, it is safe to state that misconduct virtually always involves ethics issues.

Many organizations have established codes of ethics to provide guidance for ethical principles among those in their fields. A code of ethics statement often covers issues related to honesty, objectivity, integrity, carefulness, openness, respect for intellectual property, confidentiality, responsible publication, responsible mentoring, and respect for colleagues. Other considerations of a code of ethics include social responsibility, non-discrimination, competence, legality, animal care, and protection of human subjects (National Institute of Environmental Health Sciences).

a. Authorship

In the most basic sense, "authorship" involves consideration of whose names will appear on the byline of a published study. The ICMJE states that those considered as authors of a research project must play a significant role in all of the following:

- 1. Design, data collection, and analysis;
- 2. Drafting and editing of document; and
- 3. Approval of final published version.

In addition, authors must accept full responsibility for the content of the published work. Those whose roles are limited to obtaining funding, providing general supervision, or collecting data do not rise to the level of authors. These individuals should be noted in the acknowledgements section of the paper. Another consideration related to authorship is the order in which authors are listed in the byline. This decision should be mutually agreed upon by all authors; however, in general, the principal investigator is listed first.

b. Plagiarism

Plagiarism is defined as "the passing off of somebody else's ideas, thoughts, pictures, theories, words, or stories as your own" (University of Minnesota). In addition to being unethical, plagiarism is also illegal and punishable in a court of law. Plagiarism can be either intentional or unintentional, but all investigators should be diligent in avoiding any semblance of plagiarism in their work. A number of writing techniques can be utilized to avoid plagiaristic practices:

- 1. Cite sources of all ideas that are not original or common knowledge;
- 2. Use quotation marks to identify exact quotes;
- 3. State that an upcoming passage is someone else's idea, and provide appropriate credit; and/or
- 4. Provide citations at the end of paraphrased passages.

While often overlooked, another form of plagiarism is "redundant publication." Defined by the ICMJE as "publication of a paper that overlaps substantially with one already published," redundant publication is a violation of copyright laws, ethical conduct, and cost-effective use of resources.

c. Peer Review

Most professional organizations and journals employ a peer review process as a final step of a research project. Under peer review, prior to publication of research findings, editors submit the completed manuscript to experts in the subject matter. Reviewers are responsible for providing constructive criticism of the study related to issues such as importance, usefulness, and relevance to the field of study. In addition, reviewers consider the study's use of sound methods and ethics and ensure that the reported results are accurate and complete. Those involved in peer review have as equal a responsibility to adhere to ethical principles as researchers. Reviewers must ensure confidentiality and protection of intellectual property and avoid conflicts of interest in the review process. In general, it is not proper for peer reviewers to be colleagues of those whose work they are reviewing.

d. Data Management

Research projects are data-driven, and the integrity of any project is only as good as the data upon which it is based. Investigators are responsible for insuring that data used in a study is obtained without undue harm (ethical) and is not manipulated or altered in any way (truthful). They also must consider data ownership and storage responsibilities, as well as releasing and sharing access to the data. As stewards of research data, investigators must be concerned with a number of issues, including oversight of the data collection method, protecting research subjects, protection of integrity and privacy, delegation of work with data, and responsible use and portrayal of data results (University of Minnesota). Data ownership and access can be complicated issues for many investigators. While investigators may have plans for future use of collected data, after a study is made public, it is customary for the data to be made available to others in the field. The concept of intellectual property, however, often comes into play. Questions of inventions, discoveries, improvements, copyrights, and licenses must be considered by both the owner of the data and those seeking access. Some funders require a data sharing plan to be provided with a research proposal in order to avoid future conflicts.

The University of Minnesota recommends that researchers consider the following questions when developing a data sharing plan or determining whether or not their data will be available for public use:

- 1. Who is in charge of data?
- 2. How will data be collected?
- 3. Will there be identifying information in the data and, if so, how will it be rectified?
- 4. How will data be stored to ensure privacy and protection?
- 5. Who will ensure that no data is excluded in analysis?
- 6. How long will data be stored?

e. Animal Research

Animals often play important roles in research; however, the use of animals for the benefit of society is a controversial issue. While many researchers defend animal research as a requirement for developing solutions to important problems, some organizations focused on animal welfare strongly object. In order to alleviate these organizations' concerns, research institutions have established Institutional Animal Care and Use Committees (IACUC) to insure that animals are treated humanely and ethically. The USDA, Public Health Service, and NIH also provide guidelines related to animal research.

Animal research is governed by the Animal Welfare Act of 1966. Under the Act, revised in 1990, research institutions are required to treat animals humanely and provide appropriate care, transport them in humane conditions, and protect against animal theft and sale of stolen animals.

f. Human Research

The concept of research on humans is governed by respect for individuals and respect for life. Research on human subjects in World War II concentration camps was the catalyst for the development of the field of research ethics. Today, it arguably remains the most important ethical consideration related to research.

In respecting the individual, the investigator must first be concerned with the concept of informed consent. Under informed consent, research subjects must be voluntary participants who are educated in the details of study in which they are participating. They cannot be coerced in any way and must agree to be studied. Secondly, investigators must insure privacy and confidentiality of research subjects. Issues including genetic and biomedical research are particularly sensitive, and the 2003 Health Information Portability and Accountability Act (HIPPA) has placed additional restrictions on treatment of data.

The benefit and beneficence of research is also an important consideration when dealing with human subjects (University of Minnesota). Essentially, this concept requires that the investigator analyze the cost-benefit ratio in terms of human treatment and solutions to a problem. Research subjects must never be exposed to unnecessary risk, and the level of risk must be proportional to anticipated benefits. Investigators must also be concerned with justice, ensuring that no segment of the population is overburdened or exploited in the name of research. Minority groups, women, those with mental impairments, children, prisoners, and other disadvantaged populations are all susceptible to exploitation. In order to insure that human research is conducted ethically, the University of Minnesota recommends adherence to the following guidelines:

- 1. Subject must voluntarily consent to the study and be free to discontinue involvement at any time.
- 2. The research must have value to society and the benefit must be proportionate to the burden placed on the subjects.
- 3. All subjects must be protected and kept safe.
- 4. All steps must be taken to prevent harm, injury, or death.

- 5. Research must be conducted by responsible, qualified personnel.
- 6. No populations should be excluded or overly-burdened unless there is a justifiable reason for doing so.

g. Other ethical concerns

The National Institute of Environmental Health Sciences has published an extensive list of additional unethical practices it refers to as "other deviations from acceptable research practices." Several of these practices are not only unethical but also rise to the level of misconduct previously discussed.

- 1. Publishing the same paper in two journals without informing the editors.
- 2. Submitting the same paper to different journals without informing the editors.
- 3. Not informing collaborators of intent to file a patent.
- 4. Including a colleague as an author in return for a favor.
- 5. Discussing confidential data under peer review with a colleague.
- 6. Eliminating outliers from data sets without explanation.
- 7. Using inappropriate statistical techniques in analysis of data.
- 8. Bypassing the peer review process.
- 9. Failing to conduct a thorough review of literature to identify other contributors to the subject matter knowledge base.
- 10. Being untruthful on a grant application.
- 11. Enlisting two graduate students to perform the same research project.
- 12. Overworking or exploiting graduate students.
- 13. Failing to keep research records.
- 14. Failing to maintain research data for appropriate period of time.
- 15. Making derogatory comments or personal attacks during peer review.
- 16. Using racist language.
- 17. Deviating from approved research protocol.
- 18. Not reporting an adverse event in a human research experiment.
- 19. Wasting of research animals.
- 20. Exposing subjects to biological risks.
- 21. Rejecting a manuscript in the peer review process without reading it.

- 22. Sabotaging someone's work.
- 23. Stealing supplies, books, or data.
- 24. Rigging experiments.
- 25. Making unauthorized copies of data or materials.
- 26. Owning over \$10,000 in stock in a company that sponsors your research.
- 27. Overestimating the significance of research in order to obtain economic benefit.

V. References

Sinclair Community College: *Research Misconduct* (ppt presentation) Department of Health and Human Services 42 CFR 50 and 93 National Science Foundation 45 CFR 689 University of Arkansas: *Research and Scholarly Misconduct Policy* University of Minnesota: *A Guide to Research Ethics* National Institute of Environmental Health Sciences (David B. Resnik): *What is Ethics in Research and Why is It Important?*