Responsible Conduct of Research (RCR)
For Graduate Students

I. Introduction

The material presented in this document was collated from *Introduction to the Responsible Conduct of Research*. This WSU document is supplementary, and the complete copy of this text, which can be downloaded, must be read (http://ori.hhs.gov/documents/rcrintro.pdf). Additional information: U.S. Dept of Health and Human Services Office of Research Integrity http://ori.hhs.gov/ and the International Committee of Medical Journal Editors (http://www.icmje.org/).

A. Research Responsibilities are Complex

Research responsibilities are promulgated by many different sources including professional codes, government regulations, institutional policies and procedures, and personal values.

B. Responsible Conduct of Research

The Responsible Conduct of Research (RCR) seeks to establish an environment that fosters open communication among colleagues, coworkers, and laboratory personnel in a research setting. A set of best practices for due diligence in accomplishing the research goals and objectives is accepted by everyone. Research personnel share ideas in various settings that are either informal or formal, such as regularly scheduled laboratory meetings. This sharing of ideas and open communication serves to increase all researchers' understanding of the project goals and objectives. Graduate students should understand the need for guidance on the responsible conduct of research and seek such guidance when necessary.

II. Core Instructional Areas

The Office of Research Integrity http://ori.hhs.gov/ supports programs that promote education and training in the responsible conduct of research. Topics include:

- **A.** Data Acquisition, Management, Sharing and Ownership
- **B.** Conflict of Interest and Commitment
- **C.** Use of Humans
- **D.** Use of Animals
- **E.** Research Misconduct
- **F.** Publishing Practices and Authorship
- **G.** Mentor/Trainee Relationships and Responsibilities
- **H.** Peer Review
- **I.** Collaborations

A. Data Acquisition, Management, Sharing, and Ownership

Research means data acquisition. Data management practices should be discussed before data are collected. These practices include collection, management, sharing, ownership, and intellectual property issues.

Data Acquisition considerations include:

1. Collection methods
2. Accuracy
3. Authorizations for use of:
    a. Humans (IRB http://www.irb.wsu.edu/)
    b. Animals (IACUC http://www.iacuc.wsu.edu/)
    c. Biological agents (IBC http://www.bio-safety.wsu.edu/)
    d. Radioactive materials (RSC http://www.rso.wsu.edu/)
    e. Hazardous Materials (EH&S http://www.ehs.wsu.edu/)
    f. Copyright (http://publishing.wsu.edu/copyright/)
    g. Intellectual Property (http://www.wsurf.org/)

All data must be original, accurate, and protected. In general, experiments are written and recorded in hard copy and must be dated and signed. E-data are in laboratory computer hard drives. These data must be in a safe place. Some data may be confidential and subject to privacy restrictions, such as data obtained from using Human Subjects or data for which Patent Protection is required. In general, retain data for 3 years after the completion of the research.

In general, the Principal Investigator of the project and the trainee and, on occasion, collaborators share the research data. Do not release preliminary data except under certain circumstances. Keep reproducible data confidential until its publication or presentation at scientific meetings or seminars. Publications permit the data to be freely available, and in some research fields, materials are to be made available upon request without the condition of co-authorship.

Research funding and data ownership are important areas of consideration by researchers. It is important to understand that when research funds (e.g., grants or contracts) are awarded to a researcher, these funds are committed to the institution, not to the individual researchers. The project leader (Principal Investigator) must submit reports, usually on an annual basis to the funding agencies, but the data remains with and belongs to the University (WSU). Contracts require a researcher to deliver a product or service, which is owned or controlled by the funding organization, unless otherwise indicated in the contract.

B. Conflicts of Interest and Commitment

Conflicts of Interest (COI) and Commitment Conflicts of Interest are not necessarily good or bad. What is important is how they are managed, and such conflicts must be acknowledged. A COI occurs when the personal and

professional interests of a researcher, trainees, and collaborators conflict in certain areas. For example, these areas may include financial gain, work commitments, Intellectual Property, and personal matters.

Financial COIs are serious and must be managed. Prospects of financial gain can compromise a researcher, and this may be evident through the overemphasis of research findings, falsification of data, or misinterpretation of data. This COI may also include delaying a competitor's work or publication to secure a patent or be the first to publish. Managing this financial COI requires that a researcher report any significant financial interests ($10,000 per year or equity interest in a company >5%) and conflicts before the research is done. The researcher must disclose to the WSU COI Committee such conflicts and develop a COI management plan. Finally, you may find the WSU policy in Executive Policy #27 (http://www.wsu.edu/~forms/manuals.html) and the Office of Grants and Research Development Memorandum #3 (http://www.ogrd.wsu.edu/policies.asp).

Conflicts of Commitment occur from the competing demands on a researcher's time and loyalties. A researcher must learn how to deal with all of his/her responsibilities. Researchers are writing proposals and publications while performing their academic responsibilities, which include lecturing, attending and presenting at scientific meetings, reviewing papers for journals, and serving on government boards and panels. Researchers may consult for companies or form their own companies, again adding to potential financial COIs. Therefore, researchers have numerous concerns needing attention. These include the proper allocation of time on multiple projects, the amount of time spent on trainees, and the appropriate use of grant monies for the projects. Care must be taken with students performing research that is part of a company venture. Importantly, a researcher must disclose his/her affiliations on grants, reports, and publications.

C. Human Subjects

Research involving human subjects has many specific requirements set by federal regulations and requires approval by the WSU Institutional Review Board (IRB) before the research begins. The IRB Committee must ensure that all risks to humans are minimized and reasonable in relation to anticipated benefits. Selection of subjects must be justified, and informed consent is required from each subject or authorized representative and must be appropriately documented. The data must be kept confidential to secure the privacy of subjects. Importantly, there is education and training on human subjects in research that is provided by many granting agencies. More information is available to you at http://www.irb.wsu.edu/.

D. Animal Welfare

The use of animals in research requires careful planning and Institutional approval, and the WSU Institutional Animal Care and Use Committee (IACUC - http://www.iacuc.wsu.edu/) reviews all research involving animals. IACUC and the Office of the Campus Veterinarian (http://campusvet.wsu.edu/) are concerned with many principles for the responsible use of animals in research, such as the humane use of animals and the use of appropriate numbers and species. IACUC makes researchers aware of the use of non-animal models, the need to reduce the number of animals, and to eliminate and/or reduce unnecessary pain and distress.

E. Research Misconduct

Research misconduct is serious and receives considerable public attention. Researchers who act dishonestly waste public funds and seriously erode the integrity of the research process to undermine the trust the public places in the University. Such misconduct may adversely affect public health and safety.

Research misconduct arises through fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results. Fabrication is the making up of data or results and in recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving them appropriate credit. Research misconduct does not include honest errors, differences of opinion, or honest differences in interpretations or judgments of data.

Report research misconduct to your immediate supervisor or chair of the department. You can also report misconduct to the Vice President for Research. The following URL has the WSU policy on reporting research misconduct: http://research.wsu.edu/faculty_resources/policies.html. There are laws and policies meant to protect both the individual who makes the complaint and the individual accused of misconduct. Importantly, inquiries and investigations are handled with extreme confidentiality.

F. Publication Practices and Responsible Authorship

You should read the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org/) regardless of the nature of your particular research project. Researchers share results of their activities through

publications. Such scientific articles must meet journal requirements and are stand-alone bodies of knowledge. A publication has full descriptions of the methods, results, and discussion of the significance of the data. Publications should avoid including individuals as honorary authors who do not contribute to the work. Authors listed on papers should accurately represent the individuals responsible for the work. Most journals now have much stronger and more detailed descriptions regarding the conditions that must be satisfied to permit authorship. According to the ICMJE, authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published, and 4) ability to explain and defend the study in public or scholarly settings. Authors should meet all 1 through 4 conditions. A claim of authorship by persons who may have been associated in some way with a study but do not meet the four criteria may constitute an unethical research practice. Authors are in order of importance with respect to their contribution to research, and the senior author is generally defined as the person who leads a study and makes a major contribution to the work. In many fields, the research Principal Investigator always has his name listed last. Corresponding author(s) assume responsibility for the work. Except where permitted, such as chapters in books, publishing the same information more than once is not allowed. Faculty should be especially aware of their responsibility to safeguard the rights of graduate students to publish the results of their research. Contributions that do not justify authorship should be acknowledged separately in the manuscript. There is now concern about the “doctoring” of figures for scientific articles, and journals are using methods to detect Photoshop-doctored figures. Graduate students and laboratory workers must avoid any falsification of data. As mentioned earlier, upon publication and in the biological sciences, for example, all research materials must now be made available upon request without the condition of co-authorship. Many biomedical journals ask authors to transfer copyright to the journal. Increasing number of “open access” journals do not require authors to transfer copyright to the journal.

G. Mentor/Trainee

Successful, experienced, established, and/or senior researchers often assume the role of mentor to trainees. The mentor/trainee relationship is complex and may harbor conflicts, such as who gets credit, who owns the results, and when the trainee is independent. The mentor should communicate the basic responsibilities to the trainee. For example, trainees need to know the extent and amount of time they are expected to work on the project. The student should know the standards by which his/her performance will be judged. Teamwork within a laboratory may require shared responsibilities. The student should become aware of the standard operating procedures for data collection

and maintenance. There should be discussions regarding assignment of credit, authorship issues, and ownership of data.

Likewise, the mentor should know that the trainee(s) would do assigned work conscientiously, respect co-workers, follow all rules and regulations, and abide by authorship and ownership agreements. The research environment is important. It must be respectful and equitable to all trainees. There should be regular meetings to discuss data and laboratory issues needing attention. Above all, the mentor must provide information and be a role model on the responsible conduct of research.

H. Peer Review (http://www.icmje.org/)

Unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific process. Peer review is the critical assessment of manuscripts submitted to journals by experts who are not part of the editorial staff. Peer review can therefore be viewed as an important extension of the scientific process. Peer review helps editors decide which manuscripts are suitable for their journals, and helps authors and editors in their efforts to improve the quality of reporting. A peer-reviewed journal is one that submits most of its published research articles for outside review. (ICMJE; http://www.icmje.org/). Peer review is the evaluation of your work by colleagues with similar knowledge and experience. It occurs in the reviews of grant applications, submitted manuscripts, work performance, and expert testimony. There are deadlines associated with reviews. Public trust in the peer review process and the credibility of published articles depend in part on how well Conflict of Interest (COI) is handled during writing, peer review, and editorial decision-making. All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential COI. Disclosure of these relationships is also important in connection with editorials and review articles. Editors may use information disclosed in COI and financial interest statements (discussed above in Section B) as a basis for editorial decisions. Manuscripts must be reviewed with due respect for authors' confidentiality. Authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details of the review of their manuscript. Reviewers also have rights to confidentiality.

I. Collaborative Research

While most researchers have devoted their career to one field of study and spend their time talking to colleagues with similar interests, collaborative projects encourage researchers to pursue interdisciplinary work. Collaborations with colleagues who have expertise and/or resources to contribute to a project

are normal. Some collaborations may be complex. Federal agencies and universities now foster interdisciplinary and multidisciplinary research. However, it is important that the roles and responsibilities of each collaborator are known. The Principal Investigator who manages the project must be transparent. Everyone must appreciate the disparate interests and the personnel cultural differences in projects involving collaborating researchers.

Collaborations require an understanding of important issues. For example, such issues that must be addressed include the precise goals and outcomes by each partner, the methods for obtaining, sharing, and securing data, the presentation of results and writing of papers and authorship, ownership of Intellectual Property, and mechanisms for termination of relationships. Effective management of collaborations must include good fiscal management in accordance with federal rules (A-21 and A-110). There must be training and supervision of research staff and students.

III. Assistance and Resources

A. In general questions on any of this material should be discussed with your faculty advisor or Principal Investigator who is directing your research activities.

B. Questions on use of humans, animals, and/or biological material used in research may be directed to the Office of Research Assurances (335-7138) http://www.ora.wsu.edu/.

C. The federal Office of Research Integrity has a significant amount of material available on their website http://ori.hhs.gov/.

D. *Introduction to the Responsible Conduct of Research*. A complete copy of this text can be downloaded from: http://ori.hhs.gov/documents/rcrintro.pdf.

E. International Committee of Medical Journal Editors (http://www.icmje.org/).