MODULE 2: RESEARCH MISCONDUCT

Research misconduct policies provide guidance on responsible conduct in three areas. They:

- Establish definitions for misconduct in research
- Outline procedures for reporting and investigating misconduct and
- Provide protection for whistleblowers (persons who report misconduct) and persons accused of misconduct

2a. Federal research misconduct definitions and policies

To be considered research misconduct, actions must:

- Represent a “significant departure from accepted practice”
- Have been “committed intentionally, or knowingly, or recklessly;” and
- Be “proven by a preponderance of evidence”

The common Federal definition establishes a minimum standard for measuring acceptable behavior, not a standard for judging all research behavior. The definition of research misconduct is:

Fabrication
Falsification
Plagiarism

Research misconduct does not include difference of opinion; nor does it encompass criminal behavior, personal disputes, violations of grant management policies or other unacceptable behaviors not unique to research, such as discrimination of harassment.

Successful professional self-regulation depends on conscientious community participation. Every institution that receives Public Health Service (PHS) funding has procedures in place to receive and investigate reports of research misconduct. These procedures must include:

- The designation of individuals who are authorized to receive and investigate allegations of misconduct,
- Provisions for an intitial inquiry to determine whether the allegations have any merit,
- Provisions for a formal investigation to reach conclusions about the truth of the allocations,
- The designation of an individual who is authorized to weigh (adjudicate) the conclusions reached in the investigation and impose administrative actions to redress the misconduct (sanctions) or take steps to vindicate the person charged and
- Provisions for reporting findings to the Office of Research Integrity (ORI).

Basic protections are provided to the whistleblower and the respondent under the new common federal policy.

ACTIVITY: Discuss/debate several recent misconduct cases
Case 1: Reporting Research Progress for a No-Cost Extension

Case 2: Falsified Data by a Student for a Poster Presentation and Pre-Draft Manuscript Submission
(Source: http://ori.hhs.gov/content/case-summary-marija-manojlovic)

Case 3: “Turning a Blind Eye,” Mentor Responsibility and Trainee Responsibility
(Source: http://ori.hhs.gov/content/case-summary-lushington-gerald)

2b. Institutional research misconduct policies (vary across institutions; may include):
   - Violation of Federal rules
   - Abuse of confidentiality
   - Authorship and publication violations
   - Failure to report misconduct
   - Obstruction of investigations and retaliation
   - Other practices

2c. Putting research misconduct into perspective

Questions for Discussion
1. Should other practices besides fabrication, falsification, and plagiarism be considered misconduct in research?
2. Should researchers report misconduct if they are concerned that doing so could adversely impact their career?
3. What steps should someone take if they suspect that fabrication, falsification, and/or plagiarism has occurred?

Additional Resources
NIH misconduct site (http://ori.hhs.gov/)
The Office of Research Integrity web site (http://ori.hhs.gov) lists case summaries of closed inquiries and investigations (http://ori.hhs.gov/case_summary)
SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Calleen S. Zach, Creighton University: Based on evidence obtained from Creighton University (CU) and additional evidence gathered by the Office of Research Integrity (ORI) during its oversight review, ORI found that Ms. Calleen S. Zach, former Research Assistant and Data Base Manager, CU, engaged in research misconduct in research funded by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant R01 HD046991.

Specifically, ORI found that the Respondent provided falsified subject enrollment numbers in an application to NIH for continued funding of R01 HD046991 in 2008, a no-cost, one-year extension request for R01 HD046991 (April 8, 2009, letter to NICHD, NIH), and an application for additional funding of R01 HD046991 (June 30, 2009, to NICHD, NIH). In addition, she knowingly and intentionally provided falsified subject enrollment numbers in reports to the CU Institutional Review Board (IRB) in 2008 and 2009.

ORI concluded that Respondent's knowing and intentional falsification of data constitutes research misconduct as defined by 42 CFR 93.103. In addition, ORI found that Respondent's intentionally deceptive behavior, including false statements made to the CU institutional officials, forgery of petty cash receipts, and theft of NIH research grant funds establish a lack of trustworthiness and present responsibility to be a steward of Federal funds. 2 CFR 180.125, 180.800(d), 376.10.

The following administrative actions have been implemented for a period of five (5) years, beginning on January 23, 2012:

(1) Ms. Zach is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government, referred to as "covered transactions" as defined in 2 CFR 180.200, 376.10; and

(2) Ms. Zach is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.
Case 2: Falsified Data by a Student for a Poster Presentation and Pre-Draft Manuscript Submission
(Source: http://ori.hhs.gov/content/case-summary-marija-manojlovic)

Case Summary: Marija Manojlovic
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Findings of Research Misconduct
AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Marija Manojlovic, University of Pittsburgh: Based on an inquiry conducted and written admission obtained by the University of Pittsburgh (UP) and additional analysis conducted by ORI in its oversight review, ORI found that Ms. Marija Manojlovic, former graduate student, Department of Chemistry, UP, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant P50 GM067082, National Cancer Institute (NCI), NIH, grant P01 CA078039, National Institute of Mental Health (NIMH), NIH, grant U54 MH074411, and National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI033506.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating the synthesis and spectral data that were included in one (1) poster presentation and in one (1) pre-submission draft of a paper to be submitted for publication.

Specifically, ORI found that the Respondent knowingly falsified and fabricated the synthesis and characterization, largely in the form of manipulated 1H- and 13C-NMR spectral data, for five intermediate steps and the final product, 9-desmethylpleurotin, and presented these false results in a poster, "Efforts Towards the Total Synthesis of Pleurotin," presented at the 2011 National Organic Symposium, and in a manuscript, "Total Synthesis of 9-desmethylpleurotin," prepared for submission to Angewandte Chemie International Edition.

Ms. Manojlovic has voluntarily agreed for a period of three (3) years, beginning on September 26, 2011:

(1) To have her U.S. Public Health Service (PHS)-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, she shall ensure that a plan for supervision of
her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) That any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which she is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) To exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.
Case 3: “Turning a Blind Eye,” Mentor Responsibility and Trainee Responsibility
(Source: http://ori.hhs.gov/content/case-summary-lushington-gerald)

Case Summary: Lushington, Gerald
[Federal Register Volume 76, Number 247 (Friday, December 23, 2011)]
[Pages 80371-80372].

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Findings of Research Misconduct
AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Gerald Lushington, Ph.D., Kansas University: Based on an inquiry conducted and written admission obtained by Kansas University (KU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Gerald Lushington, Director of the K-INBRE Bioinformatics Core Facility, KU, and Director of the Molecular Graphics and Modeling Lab, KU, engaged in research misconduct in research supported by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grant P20 RR016475.

\1\ K-INBRE: The KansasIDeA Network of Biomedical Research Excellence, which is a consortium of a number of schools and centers in Kansas.
Specifically, ORI found that Respondent engaged in research misconduct by approving publication of three articles and one abstract he knew contained significant amounts of plagiarized text without attribution or citation from other writers' published papers. The specific published documents as well as the relevant source documents are:

Retracted: Retracted administratively by IEEE on Jan 5, 2011
http://ieeexplore.ieee.org/xpl/freeabs_all.jsp?arnumber=5260432
Dr. Lushington has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on December 6, 2011:

(1) To have any U.S. Public Health Service (PHS)-supported research supervised; ORI acknowledges that Respondent's research is currently being supervised by KU; Respondent shall ensure that a plan for supervision of his PHS-related duties is submitted to ORI for approval either within two weeks of this Agreement becoming final or prior to receiving or applying for PHS funds if such support is not current at the time this Agreement is completed; the supervision plan must be designed to ensure the scientific integrity of his research contribution; because of the ongoing review of Respondent's research by KU, ORI will only require a summary report on the first and second anniversary of the Agreement detailing how KU has ensured that Respondent's research and language in PHS grant applications and reports of PHS-supported research have been verified to be his own and accurately reported; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that this annual summary, provided by any institution employing him, shall provide assurance that each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent was involved, was based on actual experiments or was otherwise legitimately derived, that the data, procedures, and methodology were accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions was his own or properly cited the source of copied language and ideas; and (3) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.
Case 4: Plagiarism
(Source: http://ori.hhs.gov/content/case-summary-jagannathan-jayant)

Case Summary: Jagannathan, Jayant
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Findings of Research Misconduct
AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Jayant Jagannathan, M.D., University of Virginia Medical Center: Based on the report of an investigation conducted by the University of Virginia (UVA) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Jayant Jagannathan, former Resident Physician at UVA Medical Center, engaged in research misconduct by plagiarizing research supported by National Institutes of Health (NIH) research and training awards and by NIH intramural research funds from the National Institute of Neurological Disorders and Stroke (NINDS), Surgical Neurosurgery Branch (NSB), and from the National Institute of Dental and Craniofacial Research (NIDCR).

ORI found that the Respondent engaged in research misconduct by including, in five publications, large amounts of text and an illustration that he plagiarized from publications supported by the following NIH grant awards: T32 CA09677, P01 HL024136, R01 HL059157, P50 CA090270, M01 RR01346, R01 CA075979, R01 DK064169, R01 NS027544, R01 NS052406, and K08 NS002197, and by intramural funds from the Surgical Neurosurgery Branch, NINDS, and from NIDCR.

T32 CA09677, Radiation Biology Training Grant," A. Kennedy, P.I.

P01 HL024136, "Mechanisms of Remodeling in Chronic Airway Inflammation," G. Caughey, P.I.

HL059157, "Angioproteins in Airway Vascular Leak and Angiogenesis," D. McDonald, P.I.

P50 CA090270, "UTMDACC Cancer Center SPORE in prostate cancer," C. Logothetis, P.I.

M01 RR01346, "UTHSC GCRC," R. Clark, P.I.

R01 CA075979, "Mechanisms for Pituitary Tumorigenesis," S. Melmed, P.I.
R01 DK064169, "Metabolic Consequences of Sccurin Disruption," S. Melmed, P.I.

R01 NS027544, "Loss of Developmental Plasticity after Head Injury," D.A. Hovda, P.I.

R01 NS052406, "Age-dependent Ketone Metabolism after Brain Injury," M.L. Prims, P.I.

K08 NS002197, "NMDA Receptor Dysfunction after Traumatic Brain Injury," C.C. Christopher, P.I.

Publications in which Respondent reported plagiarized material were:

1. Jagannathan, J., Li, J., Szerlip, N., Vortmeyer, A.O., Lonser, R.R., Oldfield, E.H., Zhuang, Z. "Application and implementation of selective tissue microdissection and proteomic profiling in neurological disease." Neurosurgery 64:4-14, 2009 (to be retracted);


Dr. Jagannathan has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of four (4) years, beginning on October 20, 2011:

(1) To have his research supervised; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of his duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he will not participate in any PHS-supported research after sixty (60) days from the effective date of the Agreement until a plan for supervision is submitted to and approved
by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) That any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) To submit a letter to the journal editor for publication 3 (Neurosurgical Clinics of North America) listed above, requesting that the paper be retracted because Respondent had plagiarized portions of text reported in it; the letter must be sent to ORI for approval prior to being sent to the editor; and

(4) To exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.
Additional Illustrative Examples

Raphael B. Stricker, M.D., University of California at San Francisco. An investigation conducted by the University found that Dr. Stricker falsified data for a manuscript and a PHS-supported publication reporting research on AIDS. In the manuscript, Dr. Stricker selectively suppressed data that did not support his hypothesis, and reported consistently positive data whereas only one of four experiments had produced positive results. In the publication, Dr. Stricker reported that an antibody was found in 29 of 30 homosexuals, but not found in non-homosexuals. However, Dr. Stricker’s control data, which he suppressed, showed the antibody in 33 of 65 non-homosexuals. The falsified data was used as the basis for a grant application to the National Institutes of Health. The ORI concurred in the University’s finding. Dr. Stricker executed a Voluntary Exclusion and Settlement Agreement in which he has agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three year period beginning April 1, 1993. The publication "Target platelet antigen in homosexual men with immune thrombocytopenia" in the New England Journal of Medicine, 313: 1315-1380, 1985 has been retracted (New England Journal of Medicine, 325: 1487,1991).

Leo A. Paquette, Ph.D., Ohio State University. An investigation conducted by the University found that Dr. Paquette had submitted a grant application to the National Institutes of Health in which sections of the research design were plagiarized from an unfunded grant application written by another scientist. Dr. Paquette had received the other scientist’s application in confidence as a peer reviewer for the NIH. Dr. Paquette claimed that inclusion of the other scientist’s text was inadvertent, he said that he had given the other scientist’s application to a postdoctoral fellow, whom Dr. Paquette refused to name, for an educational exercise, and that text had somehow been inadvertently used in his own application. The ORI concurred in the University’s finding of misconduct. Dr. Paquette stated that he was accepting full responsibility for this occurrence. The ORI has required institutional certification of proper attribution in any future grant proposals to the PHS from Dr. Paquette and has prohibited him from serving on Public Health Service Advisory Committees, Boards, or review groups. These actions are effective for a ten year period beginning December 31, 1992.