Department of Health and Human Services • Office of the Secretary • Office of Public Health and Science

Volume 16, No. 4 http://ori.hhs.gov September 2008

Office of Research Integrity

NEWSLETTER

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page.

IN THIS ISSUE

The ORI Newsletter *is interested in providing a forum for occasional commentary by outside experts. We thank Dr. Resnik for being the first to respond to ORI's invitation. Ideas can be submitted to ASKORI.*

COI Issues in Research Misconduct Inquiries and Investigations

David B. Resnik, J.D., Ph.D., Bioethicist, NIEHS/NIH, resnikd@niehs.nih.gov

Most of the literature on conflict of interest (COI) in research focuses on COIs in publication, authorship, peer review, or the oversight of human subjects research and does not mention COIs in misconduct inquiries or investigations (Shamoo and Resnik, 2009). To my knowledge, no articles have been published and abstracted in the PubMed database that examine COIs in research misconduct investigations. It is inevitable that COIs occur sometimes because people at the same institution tend to have personal, financial, or professional relationships with each other.

Consider the following hypothetical situation:

A prominent, well-funded molecular biology professor at a university faces an allegation of data fabrication and falsification from another molecular biology professor at the university. The person making the allegation (the complainant) had a falling-out with the person who is the target of the allegation (the respondent) several years ago over an intellectual property dispute. The complainant and respondent had been collaborating on

(See COI Issues, page 4)

ORI Study Finds Deficient Mentoring for Trainees in Misconduct Cases

A study, "Mentoring and Research Misconduct: An Analysis of Research Mentoring in Closed ORI Cases," was reported by David Wright, Sandra Titus, and Jered Cornelison in *Science and Engineering Ethics,* July 10, 2008. They examined the degree and type of involvement of faculty in ORI cases in which the trainee was found guilty of misconduct. Trainee misconduct accounts for one third of the ORI findings.

They found that "almost three quarters of the mentors had not reviewed the source data of the trainee and two thirds had not set research standards. These two behaviors are positively correlated."

The study reviewed ORI case files that were created by institutions in conducting their investigation. Also, ORI oversight added comments to the record in its evaluation of the case. Hence, these data did not rely on interviews, but on existing records. The authors point out that the value of using unobtrusive measures means that

(See ORI Study, page 5)

Update on Research Integrity Officer Study

In Phase I, over 90 Research Integrity Officers (RIOs) were interviewed. In Phase II, over 500 other RIOs have responded to the web-based survey that Research Triangle Institute conducted for ORI.

Preliminary analysis from Phase I shows that RIOs are rarely called the RIO, that they are trained in many fields, and that more than half of them are also engaged in human subject protections.

Since one of the jobs of the RIO is to ensure that researchers know about the misconduct policy, the survey asked whether RIOs had their researchers sign a statement that they were aware of their policy. Only 40 percent reported they did this. This raises the question: How does one assure their institution that the researchers are informed?

The role of the RIO for promoting responsible conduct of research (RCR) is not stipulated by regulations. Yet, over 30 percent said that they were involved in administering the RCR program.

18 European Misconduct Policies

In 2007, the European Science Foundation (ESF) and ORI hosted an international meeting in Portugal. Meeting attendees urged the ESF to collect information from European countries on their policies and procedures related to research integrity.

Recently, the ESF released its report, *Stewards of Integrity,* which provides an overview of approaches of major national research organizations promoting good research practice and handling allegations of suspected cases of research misconduct. See *http://www.esf.org/publications/corporate-publications.html*

The report is based on a survey conducted by the ESF in 32 European countries. Eighteen countries provided various details, such as guidelines, codes of conduct, and descriptions on mechanisms, to report allegations of misconduct and procedures used or proposed for use to investigate misconduct. (Although the ESF involves 32 countries, Europe is typically described as comprising 47 countries.)

RRI Conference at Niagara Falls Abstract Deadline: October 31, 2008

The Fifth Biannual Research on Research Integrity Conference will be held on May 15-17, 2009.

Sponsored by ORI and hosted by Roswell Park, the conference will be held at Niagara Falls Conference Center, Niagara Falls, NY. Accommodations will be at Crowne Plaza Hotel. Co-organizers are Cynthia Ricard and Nick Steneck.

Abstracts should be submitted to Cynthia Ricard, Director, Extramural Research, at cynthia.ricard@hhs. gov. The abstract deadline is October 31, 2008.

Research presentations as well as posters can be submitted for many different research areas. Please check the ORI web site at *http://ori.hhs.gov*

18 Seed Awards by National Postdoctoral Association

The National Postdoctoral Association, founded in 2003, is the only national organization devoted entirely to serving the needs of the postdoctoral research community. In 2007, ORI awarded a two-year contract to facilitate the development of a responsible conduct of research (RCR) program for postdoctoral fellows by institutional postdoc offices or associations. This program is termed "Bringing RCR Home."

A number of institutions have decided the first step is to survey their postdocs' previous training and needs. These efforts have provided useful data on the diversity of previous experiences in responsible conduct of research. (They have learned that many postdocs have no previous training at all.) The University of Pittsburgh, for example, will draft a white paper on the results of their surveys of participant opinions.

The RCR programs have catalyzed many new partnerships at their institutions. These partnerships have helped strengthen the RCR training but also have helped better integrate the postdocs into the institutional community. Some institutions will begin requiring RCR training for their postdocs as a result of their seed grant award, ensuring the future continuation of their training efforts.

Program Director Kathleen Flint said, "We're pleased to see 24 projects underway and so many institutions embracing the importance of tailoring RCR programming to suit the needs of the postdoc."

Three Awards Made for Research on Research Integrity

The goal of the Research on Research Integrity (RRI) program is to create a community of scholars who can study, draw attention to, and provide guidance on conducting responsible research. The three RRI awards are:

- RCR MULTI-COMPONENT MENTORING MODEL by Elizabeth Ripley at Virginia Commonwealth University
- PROPAGATING THE UNIFORM RESEARCH INTEGRITY CLIMATE ASSESSMENT (U-RICA) by Brian Martinson at HealthPartners Research Foundation
- INTEGRITY IN INTERNATIONAL RESEARCH COLLABORATIONS by Melissa Anderson at the University of Minnesota

Total funding for 2008 was $1.5 million. New grants received $500,000, while continuations received $1 million.

ORI contributed $1.5 million. The National Institutes of Health contributed $500,000. In addition, the National Institute of General Medical Services funded $200,000, and the National Library of Medicine funded $500,000, which also supported the grants.

The Center for Scientific Review provided grants management and review services.

The ORI-RRI program has now awarded 49 research studies; the published papers can be found at *http://ori.dhhs.gov/research/extra/rri_publications.shtml*

2009 RRI Plans

The format to apply for funding for 2009 will exclusively use the Exploratory/Developmental Grant (R21) mechanism.

The instructions and details will be found at the National Institutes of Health web site: *http://grants.nih.gov/grants/funding/phs398.html*

The proposed projects for the R21 mechanism must challenge existing paradigms, be developed around an innovative hypothesis, or address critical barriers to progress in understanding the multiple factors that underlie deviation from research integrity. Proposals must have clear relevance to biomedical, behavioral health sciences, or health services research. The deadline for applications will be January 2009.

2008 Annual Report on Possible Research Misconduct Approaching

ORI will send e-mail messages in December 2008 to officials responsible for submitting the 2008 Annual Report on Possible Research Misconduct. The messages will contain the password and IPF number for their institution to facilitate submission of their report by the March 1, 2009, deadline and will reduce the need to request them from ORI.

Institutions are required by regulation to submit the Annual Report to maintain their research misconduct assurance. If that assurance is not maintained, the institution becomes ineligible to receive PHS support for research, research training, and related research activities.

Filing the Annual Report requires officials to state whether their institution has a policy that conforms with the PHS Policies on Research Misconduct (42 C.F.R. 93), update their institutional contact information, and report the number of research misconduct allegations received involving PHS-supported research or research training and the subsequent number of inquiries and investigations conducted. All data fields in the institutional information and misconduct activity sections must be completed before the Annual Report can be submitted. ORI will automatically acknowledge receipt of the Annual Report.

ORI uses the contact information provided by institutions for mailing the *ORI Newsletter,* the ORI Annual Report, and other publications; for sending e-mail messages and updates on conferences, programs, and announcements; and for referring research misconduct allegations to appropriate officials.

The research misconduct activity data are reported to the research community in the *ORI Newsletter,* the ORI Annual Report, presentations at scientific meetings, special reports, and the ORI web site.

Reminders will be sent in January and February to institutions that have not already filed their 2008 Annual Report. Further information and assistance are available from Robin Parker at robin.parker@hhs.gov or (240) 453-8400.

COI Issues *(from page 1)*

the synthesis of an immune system protein with potential applications in cancer treatment.

The respondent patented the protein, and the complainant was not named on the patent application. The complainant believes that he should have been named as a co-inventor on the patent. The university owns the patent and has agreed to give the respondent 50 percent of the royalties from it. The respondent has started a company, with the university's backing, to manufacture and market the protein. Clinical trials are planned for next year. The university has a 40 percent interest in the company. The vice president for research at the university is the institution's Research Integrity Officer and is a co-inventor on the disputed patent. He is responsible for deciding whether the allegation is a serious one that merits further inquiry, and whether a committee should be appointed to look into the allegation. Most of the people at the university who would be qualified to look into the allegation know both the complainant and respondent well.

In the scenario, the complainant, the respondent, the Research Integrity Officer, and the university have professional and financial relationships. It may be difficult to manage these COIs and reach a fair resolution of this case.

The Public Health Service (PHS) research misconduct policies include specific provisions for dealing with COIs. According to the PHS policies described below, institutions have a responsibility to respond fairly and follow procedures to deal with biases and act in good faith.

Institutions must: "Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective, and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial COIs with the complainant, respondent, or witnesses" (45 C.F.R. 93.300b).

"Institutions must also have policies and procedures to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses or with the subject matter" (45 C.F.R. 93.304).

The PHS policies also state that "members of committees that conduct inquiries or investigations have an obligation to act in good faith and that a committee member who has a conflict of interest is not acting in good faith" (45 C.F.R. 93.210).

The Office of Research Integrity (ORI) Sample Policy and Procedures also include provisions for dealing with COIs in misconduct inquiries and investigations (ORI, 2005).

The PHS requires that institutions identify and deal with COIs related to misconduct inquiries and investigations since COIs can bias judgment and undermine objectivity, integrity, and trustworthiness in research (Shamoo and Resnik, 2009). It follows that COIs can threaten the fairness, integrity, and privacy of a misconduct inquiry or an investigation and can cause considerable harm to the parties involved or to the institution.

COIs are a common problem in scientific research. However, without empirical research on this topic, we simply do not know how often COIs may occur during misconduct inquiries and investigations and whether or not outcomes have been adversely affected. Regardless of the prevalence of these varying ways that COIs compromise the process, institutions should introduce specific language into their guidelines in order to guard against them.

The views expressed herein represent those of the author and are not necessarily the views of the National Institute of Health Science or the U.S. Department of Health and Human Services.

References

Office of Research Integrity. 2005. Sample Policy and Procedures for Responding to Allegations of Research Misconduct. Available at: *http://ori.dhhs.gov/policies/documents/SamplePolicyandProcedures-5-07.doc*

Office of Research Integrity. 2008. About ORI – History. See *http://ori.dhhs.gov/about/history.shtml*

Public Health Service. 2005. Public Health Service Policies on Research Misconduct; Final Rule; 45 C.F.R. 50 and 93. See *http://ori.dhhs.gov/documents/FR_Doc_05-9643.shtml*

Shamoo A and Resnik D. 2009, in press. *Responsible Conduct of Research,* 2nd ed. New York: Oxford University Press.

ORI Study *(from page 1)*

the data are less likely to introduce the social desirability factor that is a problem when conducting interviews.

A case example from the paper highlighting the lack of review of data:

ORI reported on the oversight within the laboratory: *There appeared to have been a lack of oversight as evidenced from the selection of raw tracings appropriated for publication. DIO [ORI Division of Investigative Oversight] noted that the coauthors had the opportunity to review a total of six versions of the questioned manuscript; at no time did any one of them observe errors or mistakes in the raw tracings, even though some had far greater experience with the [...] technique [than the trainee].*

An example of the lack of standards:

The Investigation Committee states: *There also were concerns about how data on research records were handled in the laboratory; each investigator used his own individual approach to record keeping. ORI noted that the direct oversight and supervision was the responsibility of the laboratory chief.*

The authors also found that 18 of the 49 institutional Investigation Committees had begun to ask the same question about the mentors' role in a case of misconduct. Another finding of the study noted that these 18 institutions were also concerned with whether the mentors had failed to train and supervise their students. In addition, the committees often instructed faculty members about remedial actions they needed to undertake.

One such Investigation Committee recommended:

Mentor/PIs should provide a more formal process of initial training for their graduate students as they join a research project. This should include coverage of Institutional Review Board regulations and the responsibility inherent in maintaining the integrity of research. The Board also recommends that [Mentor/PIs] should have more contact.

David Wright, the lead author, said: "These findings do not mean that if mentors pay attention to source data and sets standards that they can totally prevent misconduct in their trainees. However, the mentors set the tone of the group and provide the social structure and rules on how to conduct trustworthy research. Their involvement can reduce questionable research practices as well as research misconduct. If we are striving to build a culture of integrity, then it is imperative to pay attention to helping mentors and advisors. Most faculty have never received any specific training on being a good mentor or advisor, and I think this is where we need to focus more resources. Institutions need to educate research mentors instead of assuming everyone knows how to be a mentor."

Dealing with COIs: The ORI Perspective

How do conflict of interest (COI) issues "play out" in ORI cases? First, most institutions have a COI affidavit that, to ensure confidentiality, is best provided to committee members before the allegations are revealed to them. Also, it is important that the complainant and respondent be given a reasonable opportunity to vet the appointment of the committee members. Unless there was a concern registered at the outset, alleged COIs made after the release of the investigation report tend to ring hollow.

Even with such precautions, perceptions of COI in the fact finders may be identified during the investigation, such as the discovery of a research or business collaboration with the spouse of a committee member. In these situations, one can simply inform the participants, a substitute committee member can be named (if warranted), and the process can be completed without delay.

An obvious appearance of a COI in fact finding occurs when the allegations involve a small business, but in this case their Small Organization Statement (42 C.F.R. 93.303) permits the investigation to be assigned to another entity.

The identification of the appearance of a COI has triggered ORI actions before an investigation has occurred in two ironic situations. In one instance, ORI asked without explanation that the institution appoint a different ORI contact, since the institution was unaware that its contact had been found guilty of PHS scientific misconduct at his previous institution.

In the second instance, a primary concern for ORI is whether an unidentified COI has inhibited the thoroughness and scope of fact finding, in which case an institution can be asked to reopen the investigation. If identified in oversight, a COI may affect the weight given to the evidence rather than its admissibility.

Case Summaries

J. Keith Hampton, St. Luke's Hospital (SLH) in Chesterfield, MO:

Based on the report of an investigation conducted by St. Luke's Hospital (SLH) in Chesterfield, MO, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that J. Keith Hampton, MSN, APRN, former Clinical Research Associate, SLH, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, and U10 CA33601. PHS found that Mr. Hampton engaged in scientific misconduct by falsifying and fabricating data that were reported to the National Surgical Adjuvant Breast & Bowel Project (NSABP) and Cancer and Leukemia Group B (CALGB) cooperative research groups. Specifically, PHS found that:

1. For protocol CALGB 90206, Respondent: (a) falsified a patient's CT scan reports and registration forms and reported the falsified CT scan reports and registration worksheet to CALGB, and (b) falsified a patient's performance status records (giving 80% performance status) and registration forms and reported the falsified performance status report and registration form to CALGB.

2. For protocol NSABP B-35, Respondent: (a) falsified eligibility data related to hematology and chemistry assays and to the performance of a pelvic exam on one patient's registration form and reported the falsified registration forms to the National Cancer Institute Cancer Trial Support Unit (CTSU), (b) falsified pelvic exam eligibility on a second patient's registration form and reported the falsified registration form to the CTSU, and (c) falsified hematology and chemistry assay eligibility on a third patient's registration form and reported the falsified registration form to the CTSU.

3. For protocol NSABP B-36, Respondent falsified a patient's multigated acquisition test (MUGA—a test of heart function) records, cardiac function, and registration forms, certified the patient's eligibility, and reported the falsified MUGA test, cardiac function, and registration forms to the CTSU.

4. For protocol NSABP B-38, Respondent falsified hematology, chemistry, and MUGA eligibility for a patient on the registration form and reported the falsified registration form to the CTSU.

5. For protocol NSABP C-08, Respondent: (a) falsified urine protein/creatinine ratio eligibility for one patient on the registration form and reported the falsified registration form to the CTSU, (b) falsified urine protein/creatinine ratio eligibility for a second patient on the registration form and reported the falsified registration form to the CTSU, and (c) falsified claims of the urine protein/creatinine ratio and PT(INR) eligibility for a third patient on the registration form and reported the falsified registration form to the CTSU.

6. For protocol NSABP R-04, Respondent falsified a patient's colonoscopy report and eligibility at registration and reported the falsified colonoscopy report and registration form to the CTSU.

Mr. Hampton has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on June 17, 2008: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR part 376 et seq.) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR part 180); and (2) 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 or contractor to PHS.

Roxana Gonzalez, Carnegie Mellon University (CMU):

Based on reports submitted by Carnegie Mellon University's (CMU) inquiry and investigation committees, the Respondent's own admission in sworn testimony, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Roxana Gonzalez, graduate student, Department of Social and Decision Sciences and Psychology, CMU, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH56880, R03 MH62376, and R24 MH67346. Specifically, PHS found that Ms. Gonzalez engaged in the following acts of scientific misconduct:

1. Respondent altered the main dependent variable (life events; life expectation) in the electronic file and the

Case Summaries *(continued)*

manipulation check variables for ease-of-thought generation so that the reported study results are largely unsupported in:

(a) Publication: Lerner, J.S., & Gonzalez, R.M. "Forecasting one's future based on fleeting subjective experiences." *Personality and Social Psychology Bulletin* 31:454-466, 2005; (b) 2005 Manuscript: Lerner, J.S., & Gonzalez, R.M. "On perceiving the self as triumphant when happy or angry"; and (c) Review Article: Lerner J.S., Tiedens, L.Z., & Gonzalez, R.M. "Portrait of the angry decision maker: How appraisal tendencies shape anger's influence on cognition." *Journal of Behavioral Decision Making: Special Issue on Emotion and Decision Making*.

2. Respondent falsified cortisol values, and possibly cardiovascular measures and optimistic appraisals (as measured by LOT), so that a large portion of the mediation analyses of Table 3 does not reflect the data actually collected and analyzed for the study reported in a publication (Lerner, J.S., Gonzalez, R.M., Dahl, R.E., Hariri, A.R., & Taylor, S.E. "Facial expressions of emotion reveal neuroendocrine and cardiovascular stress responses." *Biological Psychiatry* 58:743-750, 2005). Respondent further allowed one of her collaborators to report the results from this study at the Annual Meeting of the American Psychological Society held in Los Angeles, California in May 2005, although Respondent's collaborator did not know at the time that the results were tainted by Respondent's acts of research misconduct.

3. Respondent falsified the analyses based on participants' responses to the manipulation check items (including the data for self reported fear) in a study reported in a publication (Fischhoff, B., Gonzalez, R.M., Lerner, J.S., & Small, D.A. "Evolving judgments of terrorism's risks: Foresight, hindsight, and emotion." *Journal of Experimental Psychology: Applied* 11:124-139, 2005).

4. Respondent falsified the main dependent variable (reservation price, BDM) in the electronic file for 48 of the 175 subjects participating in a study reported in a 2005 manuscript (Lerner, J.S., Gonzalez, R.M., Small, D.A., Lowenstein, G., & Dahl, R.E. "Emotional influence on economic behavior among adolescents"). Respondent directed the alteration of the paper files for those subjects in order to match the altered electronic file. One of Respondent's collaborators included a qualitative description of the results of the research that is the subject of this study in an NIH grant application, although Respondent's collaborator did not know at the time that the results were tainted by the Respondent's acts of research misconduct. ORI acknowledges Ms. Gonzalez' extensive cooperation with CMU's research misconduct proceedings.

Ms. Gonzalez has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, beginning on June 26, 2008: (1) 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 or contractor to PHS, for a period of three (3) years; (2) That for a period of three (3) years, any insititution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses the Respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution; Respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution; Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; (3) for a period of three (3) years to ensure that any institution employing her submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the Respondent is involved, a certification that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, analyses, and methodology are accurately reported in the application, report, manuscript or abstract; the Respondent must ensure that the institution sends a copy of the certification to ORI; and (4) to write ORI-approved letters to (a) collaborators/coauthors of the manuscripts and published papers cited above, stating what she falsified/fabricated and offering restitution; and (b) editors of the journals in which papers were published (even if they have been retracted/corrected) to state that her falsifications/fabrications were the underlying reason for the retraction/correction.

Upcoming Conferences

A Research Integrity Education Conference for the Federal Nursing Community

September 17, 2008
Uniformed Services University

The conference will focus on professionalism in nursing research in relationship to clinical trials; challenges in informed consent; emerging issues in human subjects protections; and issues of authorship, collaboration, and mentoring.

http://www.thechiefinformationgroup.com/conference/091708/index.htm

Challenges and Tensions in International Collaborations

October 2-3, 2008
University of Minnesota

The conference will address questions on international differences in education, laws, regulations, and cultural expectations as well as ways to develop research relationships between countries, individuals, and patients. Over 30 international speakers will discuss their own research and share what they have learned about conducting international research.

http://www.international.umn.edu/oriconf/index.html

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