ORI Newsletter

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REVIEW OF RCR POLICY BEGINS; ORI'S RCR EDUCATION PROGRAM PROCEEDS

Representatives from PHS agencies began meeting with ORI in March to review issues surrounding the PHS Policy on Instruction on the Responsible Conduct of Research (RCR), but a final resolution is not expected before an Assistant Secretary for Health (ASH) is appointed.

Meanwhile, ORI will continue to develop its RCR education program because "it is the right thing to do for biomedical research," Chris Pascal, Director, ORI, said. ORI will continue to facilitate the development of RCR resources, support research on RCR instruction, sponsor conferences and workshops to stimulate discussion, continue the development of the RCR web site, and promote the creation of a community of RCR instructors and interested persons.

As part of the review process, ORI plans to meet this summer with scientific societies and professional organizations that have commented on the policy on behalf of the research community to discuss ways to improve the policy. A public meeting is tentatively planned for late summer or early fall to receive additional comments. Advance notice of the public meeting will be published in the *Federal Register* and the ORI web site.

In addition, ORI staff will collect information about RCR programs being created by institutions that have decided to continue developing their programs even though the PHS policy has been suspended. Additional information on RCR programs is being solicited by PRIM&R in conjunction with the RCR conference scheduled for May 18-19 in Arlington, VA, through a Call for Content at the following address: **http://www.primr.org/rcr.html**.

Following a consideration of issues and options, ORI will make recommendations for further action on the policy to the Office of Public Health and Science, the PHS agencies, and the Department.

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QUALIFIED IMMUNITY UPHELD FOR OFFICIALS AT STATE UNIVERSITY

A Federal court dismissed a lawsuit brought by a professor at a State institution who sued the university and several employees for damages relating to a scientific misconduct investigation. *Kay* v. *Tolbert, et al.*, No. 290-TUC-JMR, slip op. (D.Az. March 30, 2001). The professor alleged, among other things, that as a result of being terminated from the university, she was denied property and liberty interests without substantive and procedural due process. The plaintiff also sought compensatory and punitive damages against several university employees, including the President, an attorney, several members of the investigation committee, and the university official who brought the charges.

The district court granted the defendants' motion for summary judgment and dismissed the case with prejudice. The judge held that many of the issues raised by the plaintiff were *res judicata* because of the decisions in prior lawsuits she had filed on the same or similar issues. Relying on *Harlow* v. *Fitzgerald*, 457 U.S. 800 (1982), the court also held that all the individual defendants were entitled to qualified immunity.

With respect to the plaintiff's substantive due process claims, the court held that the defendants were entitled to qualified immunity because at the time the plaintiff was terminated, the law on this matter was unclear and she had no clearly established constitutional right to substantive due process protection. With respect to the procedural due process claims, the court held that the individual defendants were entitled to qualified immunity because they either did not cause the due process violation (the termination without hearing) or they acted reasonably and relied in good faith on the termination process used on the advice of counsel.

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JOINT MEETING EXHIBITS SPONSORED BY ORI/OHRP

ORI and the Office of Human Research Protections (OHRP) are jointly sponsoring exhibits and poster sessions at meetings of scientific societies and professional associations to increase contact and generate dialogue with members of the research and academic communities.

Joint exhibits were held at the Experimental Biology 2001 meeting in Orlando from March 31 to April 4 and at the Association of Clinical Research Professionals meeting in San Francisco from April 30 to May 2. A poster session is scheduled for the American Psychological Society meeting in Toronto, June 14-17.

The exhibits and poster sessions allow ORI and OHRP staff to talk to researchers, research administrators, postdocs, graduate students, and association and society officials about the activities, mission and responsibilities of their offices and respond to questions and concerns. Society and association officials interested in having an ORI/OHRP exhibit or poster session at their meeting should contact Anita Ousley at 301-443-5300 or **aousley@osophs.dhhs.gov**.

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FEDERAL RESEARCH MISCONDUCT POLICY IMPLEMENTATION GROUP TO MEET

The interagency research misconduct policy implementation group, composed of representatives from the 19 Federal agencies that support intramural or extramural research programs, met May 22, 2001, to discuss the progress agencies are making in operationalizing the Federal Research Misconduct Policy by December 6, 2001.

The policy, developed by the National Science and Technology Council, requires each Federal agency that sponsors research to establish a policy and procedures for responding to allegations of research misconduct in their research programs. The policy is on the ORI web site under

Federal Policies in the Policies/Regs/Statutes section. If available, a report on the meeting will be posted on the ORI web site.

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FUNDING STILL AVAILABLE FOR DEVELOPING RCR RESOURCES

Two more opportunities exist this year for submitting grant applications to support the development of resources for education in the responsible conduct of research (RCR) under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs, August 1 and December 1.

Information on the RCR solicitation is available at **http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf**. Select the Office of Public Health and Science under X. Grants-Program Descriptions and Research Topics in the index. The SBIR program is only open to small businesses. The STTR program allows collaboration between a small business and an academic institution.

Funding for SBIR/STTR projects occurs in two phases. In Phase I, the technical/scientific merit and feasibility of the project must be established along with the ability of the organization to carry the project through Phase II. Successful Phase I projects may apply for Phase II support to continue the work begun in Phase I.

Each program offers a maximum of $100,000 in total costs for Phase I projects. The SBIR program expects Phase I projects to be completed in 6 months; the STTR program, 1 year. The SBIR program offers a maximum of $750,000 for Phase II projects; the STTR program, $500,000. Each program expects the projects to be completed in 2 years.

Areas in which resource development is needed include: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee relationships; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) protection of human research subjects; (7) use of animals in research; (8) research misconduct; and (9) conflicts of interest and commitment.

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REPORTED MISCONDUCT ACTIVITY INCREASES FOR 2ND CONSECUTIVE YEAR

Institutions reported increased misconduct activity in their Annual Report on Possible Research Misconduct for the second consecutive year following a 3-year decline.

Eighty-two institutions reported misconduct activity in 2000 compared with 72 in 1999 and 67 in 1998. New cases were opened by 60 institutions in 2000 compared with 46 in 1999 and 41 in 1998.

New cases resulted in 59 inquiries in 2000 compared with 51 in 1999 and 38 in 1998. The new

cases also resulted in 18 investigations in 2000 compared with 9 in 1999 and 7 in 1998.

The 103 new allegations received in 2000 were more than the 89 received in 1999 and the 69 received in 1998. The 62 new cases opened in 2000 was 1 less than in 1999, but 8 more than in 1998. Cases frequently involve more than one allegation.

In their submission, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

The 103 new allegations included 24 of falsification, 37 of fabrication, 19 of plagiarism, and 23 others. Institutions reporting new cases include 45 in higher education, 7 research organizations, 5 independent hospitals, 2 small businesses, and 1 health organization.

The 82 institutions reporting misconduct activity in 2000 conducted 80 inquiries and 38 investigations in response to allegations made in 2000 and before. Sixty institutions opened new cases; 30 were completing old cases, and 8 were handling new and old cases. The number of inquiries conducted by an institution ranged from 0 to 2. The number of investigations conducted by an institution also ranged from 0 to 2.

Table 1: Frequency of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations and New Cases Opened, 1994-2000.

Annual Report	Institutions Reporting Activity	Institutions Reporting New Cases	New Allegations	New Cases
2000	82	60	103	62
1999	72	46	89	63
1998	67	41	69	54
1997	73	48	92	64
1996	88	54	127	70
1995	96	61	104	81
1994	79	50	89	64

Table 2: Frequency of Inquiries and Investigations Conducted in Response to New Allegations, 1994-2000.

Annual Report	Inquiries	Investigations
2000	59	18
1999	51	9
1998	38	7
1997	56	19
1996	61	25
1995	70	31
1994	56	20

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BAD FAITH ALLEGATIONS REPORTED BY INSTITUTIONS

Two institutions received one bad faith allegation each during 2000 according to their Annual Report on Possible Research Misconduct. Four allegations have now been reported by institutions since the question concerning these allegations was initially included in the 1997 Annual Report.

One institution determined that all six allegations included in a complaint "have possibly been filed in bad faith." The allegations were dismissed during the preliminary assessment. No action was taken against the employee who left the institution prior to the bad faith determination. The other institution placed the final report of the research ethics committee that concluded the allegation was made in bad faith in the personnel file of the whistleblower.

The "ORI Model Policy for Responding to Allegations of Scientific Misconduct" states, "an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation." Although institutions are not required to determine whether an allegation was made in bad faith, ORI requests data on bad faith allegations because of the concern within the scientific community about such allegations and because many institutional misconduct policies state that these acts are subject to disciplinary action.

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REGIONAL CONFERENCE ON TEACHING RCR NOVEMBER 16-17, 2001

ORI is co-sponsoring a regional conference with the University of Alabama at Birmingham (UAB), East Carolina University, Meharry Medical College, Vanderbilt University, and Charles Stuart University, Canberra, Australia, on teaching responsible conduct in research. The conference will be held at the Continuing Education Center, UAB campus, November 16-17, 2001.

Conference participants will learn about data access and ownership, authorship issues, managing conflicts of interest, protecting human subjects in research, and defining and identifying research misconduct. Substantive presentations on the issues will be made by experts in the area, and then smaller breakout groups will focus specifically on techniques for teaching these topics.

The conference will fulfill an important need for those responsible for teaching students and others at their respective institutions about research ethics. Participants will also receive a wide variety of resource materials, including case studies and suggested ideas for using them in RCR training.

For further information, contact Dr. Harold Kincaid, Director, Center for Ethics and Values in the Sciences, UAB, 900 13 St. So., HB423, Birmingham, AL 35294-1260; Phone: 205-934-4805; Fax: 205-975-6639; E-mail: **kincaid@uab.edu.**

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NOTABLE QUOTE

"The importance of research productivity in academic promotion exacerbates scientific competitiveness; it would help if institutional rules emphasized quality over quantity." Donald Kennedy. *Science* 289:1137, 2000.

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STATISTICAL FORENSICS: ONE DIGIT TOO MANY!

When the original handwritten data contain only *three* decimal places, and the same data entered into a Microsoft Excel® spreadsheet appear with *four* decimal places, there is cause for suspicion. Where did that extra digit come from? And when that fourth digit is either a *zero* or a *five*, (and no other digit, e.g., *one* or *nine*) the suspicion is that division by *two* produced the fourth decimal digit. Thus, division by *two* of a decimal number whose last digit is *odd* leaves a remainder of *one-half* which produces an extra decimal digit, *five*. In contrast, when the last digit is even, there is no remainder and the extra digit is *zero*. Division by two yields no other extra digits.

In one case, these clues led investigators of ORI's Division of Investigative Oversight (DIO) to determine that the data for a third rat were fabricated by averaging the data for two others. This case concerned a study of the effect of rhythmic contractions of skeletal muscle in the hind limbs of rats where blood flow was measured at rest and during nerve stimulation. Measurements of blood flow and muscle weight were recorded.

The respondent presented results for six rats in a lab seminar. Sometime after that, a co-worker discovered that the original data sheets for two rats were blank. The respondent furnished the university with copies of tracings of continuous measurements, handwritten recorded data for muscles for six rats, and printouts of a Microsoft Excel® spreadsheet that contained blood pressure measurements and muscle weights for six rats.

DIO investigators concentrated on the measurements of muscle weight. The investigators observed that the entries in the spreadsheet for Rat-3 and Rat-6, purportedly copied from the handwritten data sheets, had an extra decimal digit. Therefore, the spreadsheet numbers had not been copied from the handwritten sheets. They further observed that the extra digit was either *five* or *zero*. This observation led to the hypothesis that the Rat-3 and Rat-6 measurements were the average of two measurements. Investigators then verified that the purported measurements for "Rat-3" and "Rat-6" were the averages of the corresponding measurements, respectively, for Rat-1 with Rat-2, and Rat-4 with Rat-5. This irrefutable demonstration that the weights for both Rat-3 and Rat-6 were fabricated by calculation facilitated the voluntary exclusion of the respondent from receiving Federal funds for 3 years.

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CONCERNS ABOUT USING SET-UP EXPERIMENTS IN INSTITUTIONAL INVESTIGATIONS

Several investigation reports transmitted to ORI from research institutions in recent years have included descriptions of experiments that were set up to try to detect additional fabrication or falsification of research results by the respondents. The set-up experiments (S-UEs) were arranged by complainants or institutional officials. Setting up experiments or asking respondents to repeat the experiments resulted in misconduct findings in the first three case examples given here. However, in other cases, the S-UEs failed to include safeguards, so the results were not useful in supporting an ORI finding of scientific misconduct. Furthermore, "repeating" the originally-claimed results in an experiment does not alone disprove an allegation that the original work was fabricated.

Most findings of scientific misconduct are not based on the implementation of S-UEs and S-UEs are not necessary to confirm scientific misconduct. The results of S-UEs will not be useful in confirming misconduct unless adequate safeguards are imposed to monitor the situation and document any evidence.

Case #1
An M.D./Ph.D. graduate student was suspected of fabricating data on experiments over several years. When asked to return to the laboratory to repeat the work on blinded samples, the student repeated the results in the presence of a coworker. However, when the laboratory director evaluated the materials used in the repeat experiments, the director found changes indicating the student had surreptitiously determined the contents of the "blinded" tubes before doing the new experiments. The student admitted doing so when challenged, and ORI obtained a debarment of the respondent from receiving Federal funds.

Case #2
A postdoctoral fellow was observed pipetting material into labeled scintillation vials before conducting an experiment. The complainant secretly counted the vials and found they had been "spiked" with radioactive material. The respondent apparently was conducting the research with unlabeled cells and discarding them. The complainant went to the laboratory director, who set

up experiments with animals deliberately mis-identified as being transgenic, but the fellow got the results that he had predicted if they were transgenic. The institution found scientific misconduct in this case and retracted four papers. Based on the institution's report, ORI obtained a debarment agreement.

Case #3
The institution found substantial evidence of falsification of data by a graduate student who had finished a doctoral thesis. The officials delayed awarding the degree, but allowed the student a year to try to repeat the allegedly falsified results in another laboratory. ORI informed the institution that getting the expected results would not constitute proof that the original experiments were actually done, since the student might have correctly predicted the results without actually conducting the original experiments. But the institution insisted that the student have the opportunity to repeat the protocol. However, the student ultimately was unable to do so (there was evidence the student had changed the labels on the new materials, too). ORI found sufficient evidence of multiple falsifications in the student's original research to warrant debarment.

Case #4
A group of postdoctoral and graduate students had individually raised concerns about some of the work that their professor did to complete the assays and report the results of the experiments that the students had initiated. So the students set up several experiments in which the biological samples were non-positive controls, but they told the professor that they were actual test samples. The professor got results that were consistent with those predicted by his theoretical model, but were impossible to achieve based on the actual samples. Unfortunately, the students did not inform the chairman, dean, or counsel in advance, and they could not prove later what the samples had contained. Although the evidence of other falsifications by the professor was sufficient for ORI to get a debarment agreement, ORI was not able to use the results of the S-UE to confirm scientific misconduct.

Case #5
A professor and a senior scientist suspected that a graduate student had spiked biological samples before testing, to guarantee achieving the predicted results. They notified university officials, and they arranged for the student to return to their laboratory to conduct controlled, blinded experiments under their close supervision. However, because they learned later that the student could have had overnight access to the room with the "blinded" samples, the student could have tested and decoded the samples before the supervised runs. In the end, the institution found that the evidence was insufficient to conclude that the student had committed scientific misconduct, and ORI agreed.

Case #6
A postdoctoral fellow was accused of manipulating instruments to get results that were "almost perfect" in physiological experiments on patient tissues. The laboratory chief set up experiments in which water was substituted for the biological agent in the solution that he planned for the fellow to use. When the new results came out as expected, he accused the fellow of falsifying all

the results, and the fellow left the laboratory without responding. However, the investigation committee found that none of the new stock solution, made up to a standard volume, appeared to have been used. The fellow's notebooks indicated that a new vial of agent had been prepared, and the fellow testified that this new solution had been used for the repeat experiments. The institution found insufficient evidence of misconduct, and ORI agreed.

ORI concludes from these examples that set-up experiments have sometimes been problematic, especially when the members of the laboratory conducting the S-UEs have not sufficiently documented the evidence or informed institutional officials who could independently monitor or confirm the actions. However, in other cases, the S-UEs have been used successfully to confirm suspicions about scientific misconduct and to obtain an admission from the respondent.

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CASE SUMMARY

Malabika Sarker, M.B.B.S., M.P.H., University of Alabama at Birmingham (UAB): Based on the report of an investigation conducted by the UAB and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Sarker, former doctoral fellow, Department of Epidemiology, School of Public Health, UAB, engaged in scientific misconduct by falsifying questionnaire data for risk factors for sexually transmitted diseases (STDs) in Bangladesh for her dissertation. The research was supported by the Fogerty International Center, National Institutes of Health (NIH), grant D43 TW01035, "UAB AIDS/HIV International Training & Research." The purpose of the research was to determine from questionnaires the lifestyle and personal history factors of subjects and correlate them to infection rates for STDs from use of laboratory tests. Dr. Sarker admitted that she falsified the coding of the questionnaire data relating to the occupations of the subjects and of their sexual partners to present statistically significant data regarding the risk factors for STDs. Dr. Sarker accepted the PHS finding and entered into a Voluntary Exclusion Agreement with PHS in which she voluntarily agreed for a 3-year period beginning on April17, 2001, to exclude herself from serving in any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision requirements.

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QUOTE

"The honesty is established by not calling upon trust, but demonstrating that one did what one said one did." Jonathan King, Professor of Molecular Biology, M.I.T. *Science and Engineering Ethics* 5:216, 1999.

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NCI ADDS ETHICS TRACK TO FELLOWSHIP PROGRAM

The National Cancer Institute (NCI) and the Cancer Prevention Fellowship Program (CPFP) have a new postdoctoral fellowship track in the Ethics of Public Health and Prevention. This program will provide an opportunity for ethicists, philosophers, physicians, and scientists to study ethical issues in cancer prevention research and their application in public health and

clinical medical practice.

Completion of the program results in a Master of Public Health degree. Fellows with doctorate degrees are accepted for up to 5 years of training. Applications are due September 1 for entry into the program the following July 1. For catalog, contact: Dr. Douglas L. Weed, Director, CPFP, NCI, 6120 Executive Boulevard (EPS), Suite T-41, MSC 7105, Bethesda, MD 20892, Inquiries: Barbara Redding Phone: 301-496-8640; FAX: 301-402-4863; E-mail: br24v@nih.gov.

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2ND RFA FOR RESEARCH ON RESEARCH INTEGRITY

A second request for applications (RFA) for the research program on research integrity was published in the *NIH Guide for Grants and Contracts*. See **http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-02-005.html**

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INT'L. CONFERENCE TO ADDRESSES CONFLICT OF INTEREST PROBLEM

An international conference is being organized to address the impact of conflicts of interest on the conduct of basic and clinical research, current governmental and institutional policies regulating their management, and possible national and international standards for handling the problem. The "Conflict of Interest and Its Significance in Science and Medicine" conference will be held in Warsaw, Poland, on April 6-7, 2002, under the sponsorship of the Polish Academy of Science, Council of Europe, the S. Batory Foundation, and the State Committee for Research in Poland.

For additional information contact: Conference Secretariat, c/o IITD PAN, 53114 Wroclaw 15, Poland. Phone: 071-337-3491; Fax: 071-337-2171; E-mail: **secret@immuno.iitd.pan.wroc.pl**. A conference web site is under construction at http://surfer.iitd.pan.wroc.pl/events/conferenceApril2002.html.

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CONFERENCE PROPOSALS DUE OCTOBER 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on promoting research integrity or handling scientific misconduct allegations. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country. The amount of funding available generally ranges from $5,000 to $20,000.

October 1, 2001, is the next target date for the receipt of applications. Proposal instructions and an application form are available on ORI's web site, **http://ori.hhs.gov**, by calling 301-443-5300, or sending an e-mail to **askori@osophs.dhhs.gov**

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RCR RESOURCES

"Teaching The Responsible Conduct of Research Through A Case Study Approach: A Handbook for Instructors" may be purchased from the Association of American Medical Colleges. See **http://www.aamc.org/publications/research.htm.**

"Integrity in Scientific Research-Five Video Vignettes" may be purchased from the American Association for the Advancement of Science. See **http://www.aaas.org/spp/video/video.htm**.

Resources are also listed on the ORI web site.

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