

Office of Research Integrity

N E W S L E T T E R

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.



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Workshop on Responsible Research Practices in a Changing Research Environment

Mark S. Frankel, Ph.D., and Rebecca Carlson, American Association for the Advancement of Science, Washington, DC

On February 17, 2011, in conjunction with its Annual Meeting, the American Association for the Advancement of Science (AAAS) convened a one-day workshop on *Responsible Research Practices in a Changing Research Environment*, supported with funding from ORI and the National Science Foundation (NSF) Office of Inspector General. More than 80 people from diverse professional backgrounds attended

a series of five sessions. The first session focused on fostering an ethical research environment. Presenters observed that research ethics education has evolved to include information not only about the rules and regulations of the conduct of science, but also about the fundamental values and ethics of research. One presenter stressed the importance of virtues and character in cultivating (See **Responsible Research**, page 3)

Dual Use Research and the Societal Responsibilities of Researchers

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Advances in the life sciences are critical to the development of safe, effective treatments for disease and have yielded improvements in human, animal and plant health, the food supply, and the environment. But the resulting knowledge and the technologies can also be used to threaten the health and safety of humans and other forms of life. Research generating valuable knowledge that can also be put to malevolent purposes is “dual use research.” Such research challenges scientists to become aware of and diligent about their societal responsibilities.

The dual use dilemma is exemplified in several papers that were pub-

lished in well-known scientific journals. In 2001, the *Journal of Virology* published “Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox,”¹ wherein the authors described how the insertion of the mouse IL-4 gene into the mousepox virus produced a viral strain that killed mice that were naturally resistant to, and had been vaccinated against, ordinary mousepox. The paper generated anxieties that the same techniques might enable the production of vaccine-resistant smallpox for use against human hosts. In 2005, the (See **Societal Responsibilities**, page 4)

Court Finds Qualified Immunity for Whistleblower

Samantha Weidner, J.D., Presidential Management Fellow, National Cancer Institute

The United States Court of Appeals for the Second Circuit recently found that statements made to report possible scientific misconduct are protected against defamation claims by certain qualified privileges. In *Chandok v. Klessig*, Dr. Meena Chandok sued Dr. Daniel Klessig for allegedly defamatory statements that Klessig made regarding Chandok's reports of the results of her biomedical research. (Nos. 09-4120-cv(L), 09-4121-cv(xap), 2011 WL 108729 [2d Cir. January 12, 2011].)

The scientists worked together at the Boyce Thompson Institute for Plant Research (BTI), an affiliate of Cornell University, where Klessig was a senior scientist. He directed a research team focusing on immune response mechanisms in plants and on the production of nitric oxide by plants to offset attacks by pathogens. Chandok was tasked with working to find and purify nitric oxide synthase (NOS). In 2002, Chandok sent Klessig data indicating that she was successful in developing a recombinant protein with NOS activity. The reported results were widely publicized, and as a result of the reported data, Klessig's laboratory received a grant from NIH of more than \$1 million to fund further NOS research.

In 2004, Chandok resigned from BTI. Subsequent to her departure, the other scientists in Klessig's lab were unable to replicate the results that Chandok reported. Chandok declined to return to BTI to assist in replicating the results, and Klessig

became concerned that Chandok had engaged in scientific misconduct. Klessig proceeded to notify BTI, NIH, NSF, and the Office of Research Integrity (ORI) of the potential misconduct. Klessig also retracted articles published in *Cell* and in the *Proceedings of the National Academy of Sciences of the United States (PNAS)* regarding the reported results. Klessig e-mailed fellow scientists interested in NOS research to inform them that the *Cell* and *PNAS* articles were retracted in light of the inability to replicate or confirm Chandok's reported NOS results.

Chandok sued Klessig in August 2005 for defamation, claiming that Klessig made numerous false statements about the accuracy or veracity of her NOS research, thereby causing significant damage to her reputation in the scientific community. The district court granted Klessig's motion for summary judgment dismissing Chandok's defamation claim and Chandok appealed.

The Court of Appeals for the Second Circuit found that there were three categories of qualified privileges, which protected the statements made by Klessig and prevented the imposition of liability in a defamation action. First, the Court found that Klessig had a legal obligation to inform the company for which he worked and other pertinent agencies of his suspicions of Chandok's research. As such, statements made by Klessig to the Committee, NIH, and NSF were protected by the qualified privilege and were not defamatory. Second, the

Court noted that even if there were no legal duty, Klessig had a moral obligation to inform NIH, BTI, and coauthors of the *Cell* and *PNAS* papers, as well as members of the faculty at Cornell, about his concerns regarding Dr. Chandok's research. Third, the Court found that several of Klessig's statements fell within the scope of New York's qualified privilege for statements on a matter of common interest among communicants, including those statements made to BTI staff, coauthors, and members of the Cornell faculty. Other statements protected by this privilege were e-mails sent by Klessig to fellow scientists who were interested in NOS research.

On the basis of the application of the qualified privileges, and the fact that Chandok was not able to overcome the privileges by showing either actual malice (knowledge of a statement's falsity or reckless disregard about whether it was false) or common law malice (spite or ill will toward the plaintiff) on the part of Klessig, the Court affirmed the district court's dismissal of the defamation claims.

ORI THANKS THE FOLLOWING AUTHORS:

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Responsible Research Practices Workshop *(from page 1)*

an ethical researcher. Despite this broadening understanding of research ethics, the past decade has seen a marked increase in cases of research misconduct. A second presenter discussed the importance of also having a regulatory scheme in place to complement education in ethics and other professional best practices.

The second session offered guidance on how to communicate with the media. The presenter took the audience through the “do’s and don’ts” of communicating with journalists. Tips included (1) requesting a specific time for an interview to enable the scientist to prepare for it; (2) speaking with authority about your research, keeping answers short and precise, while avoiding speculation about the facts or implications; (3) suggesting questions the journalist might want to ask; (4) reviewing the thrust of the interview at its conclusion to avoid misunderstandings and misquoting; and (5) never attempting to be “off the record,” since anything you say to a reporter is fair game.

Using an interactive format, which included two professional actors from The Second City, the third session addressed some of the challenges for research collaborations. By acting out situations highlighting language barriers, problems with informed consent, and miscommunication, the audience was given insights into the importance of harmonization, communication, tolerance, and oversight by collaborators—whether it be multi-institutional, international, inter-laboratory, within

local communities, or with industry, policymakers, or educators.

While the number of research proposals for federal funding has been on the rise, there are fewer funding sources available. Moreover, proposals are often interdisciplinary and include larger research teams. Funding agencies also are instituting new accountability mechanisms for researchers and their institutions. To address these matters, the fourth session had representatives from the National Institutes of Health (NIH) and NSF describe some of the increasing requirements that scientists face in the funding process. Examples from NSF included the Post-Doc Mentoring Plan, which reviewers have often found to be too perfunctory, the new 2011 requirement for a Data Management Plan, and the broader impacts and intellectual merit requirements at the core of the agency’s peer review system. One NSF presenter noted that “the difference between a good proposal and a great proposal that gets funding is often the broader impact of the science.” While similar requirements also exist at NIH, its ethics education requirements typically apply only to trainees, thereby omitting many other young scientists. NIH has emphasized ethics education for those engaged in human subjects research as well as the inclusion of diverse populations in the research unless there are solid reasons not to do so.

The final session of the day focused on advocacy by scientists. When a scientist’s research enters the policy arena, it is critical to understand that

presentation of the “facts” about a particular scientific matter does not necessarily translate into sound policy. Presenters stressed that science is just one of many components of decisionmaking for public policy.

It is critical to know your audience (its political ideology, voting history, political pressures, etc.) and to communicate effectively with it. Scientists should be prepared to both offer concrete examples of how their research contributes to better public outcomes and be sensitive to the potential ethical pitfalls when engaging in advocacy.

AAAS plans to convene another workshop at its February 2012 Annual Meeting in Vancouver, Canada. For more information about the workshop, visit: <http://www.aaas.org/spp/sfrrl/workshop-on-responsible-research-practices-2011.shtml>

An Upcoming Event

The “Quest for Research Excellence Conference 2011” is being held in Washington, DC, August 29-30, 2011. The conference is co-sponsored by ORI and the Georgetown-Howard Universities Center for Clinical Translational Science.

For more information about the “Quest for Research Excellence Conference 2011,” please visit the following web site: <http://ori.hhs.gov/conferences>

Societal Responsibilities (from page 1)

Proceedings of the National Academy of Sciences of the United States of America (PNAS) published “Analyzing a bioterror attack on the food supply: The case of botulinum toxin in milk,” wherein the authors mathematically modeled the substantial harm that could result from an intentional contamination of the milk supply.² After extensive review, the editors of *PNAS* decided that the benefits of publishing the paper outweighed the risks.

Publications such as these have highlighted the urgent need to develop effective strategies for managing the risk of misuse without hampering scientific progress. In 2004, the U.S. Government established the National Science Advisory Board for Biosecurity (NSABB) to recommend strategies for the oversight of life sciences research with dual use potential. From its inception, the NSABB has recognized that researchers are critical to any effort to address and mitigate the risks of dual use research. The rationale is simple: Researchers are in a good position to anticipate the types of knowledge, products, or technologies that their work might generate and the potential for their misuse.

Because of their specialized knowledge and position, scientists have a heightened responsibility to prevent malignant dual use. The norms of science mandate that researchers accept responsibility for the integrity and safety of their investigations—for ensuring that their research is methodologically rigorous; that their data are accurately recorded, analyzed, and reported; and that they safeguard the health and well-being of others,

including society at large. But in light of their unique position, they also have the responsibility to be alert to the risk that their own research findings might be misused for malevolent purposes and to take appropriate steps to minimize these risks. Though their responsibilities for methodological rigor and for the unbiased, honest reporting of results serve the goal of truth, these latter responsibilities—for recognizing and managing the risks associated with the dual use potential of their work—serve the critical aim of preventing harm to the public and to the environment.

To fulfill these societal responsibilities, scientists first have to make themselves aware of the dual use potential of their own work by educating themselves, their laboratory workers, and their students about the concept of dual use research and about the dual use potential of their investigations. Second, scientists have to take thoughtful, deliberate steps to manage and mitigate the risks associated with the dual use potential of their research—beginning with the design and conduct of their studies through communication of their results.

The NSABB is working on multiple fronts to help scientists meet these challenges. Through its work on codes of conduct for dual use research, it has sought to identify and clarify the responsibilities of individual scientists and to offer suggestions for how these responsibilities might be promoted and inculcated through the adoption of codes—by professional societies, institutions, and others. Through its work with scien-

tific journals, the Board is developing suggested policies and practices for authors, reviewers, and editorial boards to consider when grappling with the challenges of whether and how to communicate research findings of dual use potential effectively and responsibly. And through its outreach and education activities, the Board has advised on an array of educational tools and modalities, which have informed NIH efforts to develop exhibits, materials, an educational brochure for investigators, and a video that presents an overview of the issue.

Life sciences research is a vital undertaking that yields innumerable and immeasurably important benefits. In recognizing the value of this research, we must also be mindful that even a single misuse of certain information, knowledge, or technology could have devastating effects. Therefore, scientists, the public, and policymakers have a shared interest in working together to minimize the risk of misuse while fostering the continued progress of science.

Endnotes

¹ Ronald J. Jackson et al., “Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox,” *Journal of Virology*, 75, No. 3 (February 1, 2001):1205-1210. Available at <http://jvi.asm.org/cgi/content/abstract/75/3/1205>. Accessed Feb. 16, 2011.

² Lawrence M. Wein and Yifan Liu, “Analyzing a bioterror attack on the food supply: The case of botulinum toxin in milk,” *Proceedings of the National Academy of Sciences of the United States of America*, 102, No. 28 (July 12, 2005):9984-9989.

Dual Use Research, Biosecurity, and the Responsible Conduct of Research

Malcolm Dando, Ph.D., Professor, International Security-Dept. of Peace Studies, University of Bradford, UK, and Simon Whitby, Ph.D., Director, Bradford Disarmament Research Centre, University of Bradford, UK

In recent years, security concerns about dual use research and biosecurity have produced constructive responses from the scientific community.¹

The third edition of *On Being a Scientist: A Guide to the Responsible Conduct of Research* has a final substantive chapter titled “The Researcher in Society.”² This chapter contains a case study titled “Ending the Use of Agent Orange.” The study records Dr. Arthur Galston’s (1920-1988) discovery of plant herbicides, his opposition to their use in the Vietnam War, and his belief that scientists can prevent the negative consequences of science. This case study also highlights important issues related to the responsible conduct of research (RCR) including the treatment of data, mistakes, negligence, and dual use.

Our extensive discussions with practicing life scientists in numerous countries have involved efforts to find out what is being taught on dual use and biosecurity. These efforts have led to the development of educational materials (see also <http://tinyurl.com/472tqea>). We believe that for there to be a culture of responsibility that prevents misuse, scientists should be able to answer the following kinds of questions:

1. Would you be able to spot an experiment of real dual use concern?
2. Is there a mechanism in place in which you could raise concerns about a particular dual use experiment of interest with your superiors?
3. Are dual use and biosecurity policy developments (nationally and

internationally) being carefully followed, and are you being kept informed so that you can contribute your expertise to finding solutions?

4. Are you well informed about the national laws and regulations that could affect your country’s obligations under the Biological Weapons Convention? (See also <http://www.state.gov/t/isn/bw/>.)

These questions acknowledge the importance of raising awareness and developing educational provisions about dual use, biosecurity, and RCR that take us far beyond the laboratory doors. Reflecting a broad biosecurity agenda, they could also form the basis for establishing complementary global biosafety and biosecurity professional competency standards (see also the International Federation of Biosafety Associations (IFBA)).^{3,4} At the Seventh Review Conference of the Biological Weapons Convention, such issues may also have implications for national and international regulations.^{5,6}

It is likely that the Review Conference State Parties in Geneva, Switzerland, in December 2011, will follow previous discussions from 2008 (see also <http://www.opbw.org/>).

The Presidential Commission for the Study of Bioethical Issues notes that the creation of a culture of responsibility through ethics education in synthetic biology “could do more to promote responsible stewardship in synthetic biology than any other single strategy.”⁷ It is time for scien-

tists interested in the moral and ethical integrity of their work to discuss the implications of scientific research, to prevent misuse, and to assist in building a culture of responsibility.

Endnotes

- ¹ Department of Health and Human Services, National Science Advisory Board for Biosecurity Charter, March 4, 2004. See also Department of Health and Human Services, National Science Advisory Board for Biosecurity Charter—Revised, March 16, 2006.
- ² *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*, Committee on Science, Engineering, and Public Policy. National Academies Press, 2009.
- ³ 2011 – The Year of Building International Biosafety Communities. <http://internationalbiosafety.org/English/pdf/2010/IFBA-Year-activities-October-2010.pdf>. Accessed Jan. 21, 2011.
- ⁴ IFBA web site. <http://tinyurl.com/45kvq9t>. Accessed Jan. 21, 2011.
- ⁵ The Biological Weapons Convention Treaty prohibits the development, production, stockpiling, acquisition, or retention of weaponized disease agents such as anthrax, smallpox, and plague.
- ⁶ “Biological Weapons Convention Meeting of States Parties Concludes in Geneva.” <http://tinyurl.com/4ste5tf>. Accessed Jan. 21, 2011.
- ⁷ *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, Presidential Commission for the Study of Bioethical Issues, Washington, DC, December 2010. Available at <http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12-16-10.pdf>

Case Summaries

Sagar S. Mungekar, Ph.D. **New York University School of Medicine**

Based on the Respondent's written admission as set forth below, the New York University School of Medicine (NYUSOM) and the Office of Research Integrity (ORI) found that Sagar S. Mungekar, Ph.D., former M.D./Ph.D. student in the Sackler Institute of Graduate Biomedical Sciences at NYUSOM, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants R01 GM35769, R01 GM55624, and T32 GM07308, and National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant T32 AI007180.

Dr. Mungekar admitted that in his Ph.D. thesis he "increased statistical significance of the calculated means and standards of deviation [*sic*] of the UV spectrophotometric [*sic*] data presented by discarding certain experimental data and thus presented data that was falsified. In addition, as the repression ratios calculated and conclusions reached based on these data that included falsified data, those values and conclusions are fabricated. Approximately 60-75% of the [Respondent's] Ph.D. research data was changed or falsified." Dr. Mungekar also admitted "while doing these experiments, I did not sequence all of the constructs that I constructed; thus, I could not be certain of the exact identity of the plasmids in question."

ORI found that Dr. Mungekar engaged in research misconduct (42

C.F.R. 93.103) by fabricating and falsifying data. Specifically, ORI found that Dr. Mungekar falsified five tables and five figures (Tables 2-1, 2-2, 3-1, 4-1, and 4-2 and Figures 2-3, 3-1, 3-2, 4-3, and 4-4) in his Ph.D. thesis entitled "Autoregulation of Ribonuclease E," by discarding certain spectrophotometric data, to increase statistical significance, used to calculate repression ratios and RNA decay rates. Dr. Mungekar also claimed to have constructed 53 different reporter plasmids with RNase E mutants, when sequencing data did not exist to support this claim.

Dr. Mungekar has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 22, 2010:

(1) that any institution that submits an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution. Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI;

(2) that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-funded research in

which he is involved, a certification to ORI that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report; and

(3) to exclude himself voluntarily 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.

Meleik Goodwill, Ph.D. **Wadsworth Center, N.Y.S.** **Department of Health**

Based on the Wadsworth Center report and the oversight review conducted by the Office of Research Integrity (ORI), the U.S. Public Health Service (PHS) found that Meleik Goodwill, Ph.D., former postdoctoral fellow, Wadsworth Center, New York State Department of Health, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R21 ES013269-02.

Specifically, ORI found that the Respondent engaged in research misconduct by the fabrication of data for growth curves presented in Figure 1 in the 2007 *Journal of Neuroimmunology* article (Goodwill, M.K., Lawrence, D.A., & Seegal, R.F. "Polychlorinated biphenyls induce proinflammatory cytokine release and dopaminergic dysfunction: Protection in interleukin-6 knockout mice." *Journal of Neuroimmunology*

Case Summaries *(continued)*

183 (1-2):125-132, 2007), and by the use of composite images of Western-blot bands from unrelated experiments done in 2005 that were falsely labeled as if from different experiments to construct Figure 4A in the 2007 *Journal of Neuroimmunology* article. Figure 4B of the article also was falsified by use of identical sets of numbers for different treatments. The 2007 *Journal of Neuroimmunology* article was retracted in *J. Neuroimmunol.* 197 (1):197, 2008.

Dr. Goodwill has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on January 21, 2011:

(1) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution. Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;

(2) that any institution employing her submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-funded research in which she was involved, a certification to ORI that the data provided are based on actual experiments or are otherwise legitimately derived and that the data,

procedures, and methodology are accurately reported in the application or report; and

(3) to exclude herself voluntarily from service 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.

Bengu Sezen, Ph.D. Columbia University

Based on the findings of an investigation by Columbia University (CU) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, ORI found that Bengu Sezen, former graduate student, Department of Chemistry, CU, engaged in misconduct in science in research funded by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM60326.

Specifically, ORI made twenty-one (21) findings of scientific misconduct against Dr. Sezen based on evidence that she knowingly and intentionally falsified and fabricated, and in one instance plagiarized, data reported in three (3) papers¹ and her doctoral thesis.

The following administrative actions have been implemented for a period of five (5) years, beginning on December 13, 2010:

(1) Dr. Sezen is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United

States Government, referred to as "covered transactions," pursuant to HHS's Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 C.F.R. 376 *et seq.*); and

(2) Dr. Sezen 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.

Endnote

¹ Sezen, B., Franz, R., & Sames, D. "C-C bond formation via C-H bond activations: Catalytic arylation and alkenation of alkane segments." *J. Am. Chem. Soc.* 124:13372-13373, 2002. Retracted in *J. Am. Chem. Soc.* 128:8364, 2006.

Sezen, B., & Sames, D. "Oxidative C-arylation of free (NH)-heterocycles via direct (sp³) C-H bond functionalization." *J. Am. Chem. Soc.* 126:13244-13246, 2004. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.

Sezen, B., & Sames, D. "Selective and catalytic arylation of N-phenylpyrrolidine: sp³ C-H bond functionalization in the absence of a directing group." *J. Am. Chem. Soc.* 127:5284-5285, 2005. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.

*"It takes less time to do
a thing right than
it does to explain
why you did it wrong."*

**Henry Wadsworth
Longfellow**

American Poet and Educator
Feb. 27, 1807 - Mar. 24, 1882

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DATED MATERIAL

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