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Truth Telling: ORI Officials Offer Details On Case Settlements, Oversight Reviews

While investigators found guilty of research misconduct by the HHS Office of Research Integrity sometimes do not admit responsibility, the former director of the glycoimmunotherapy lab at the John Wayne Cancer Institute seemed to break new ground with the wording of his settlement with ORI.

The Aug. 28 *Federal Register* notice said Mepur Ravindranath accepted a three-year supervisory plan applicable if he is involved in Public Health Service-funded research "solely because contesting the findings would cause [him] undue financial hardship and stress, and [he] wished to seek finality."

"It is expressly understood that by entering into a voluntary settlement agreement, respondent is not admitting to any of the allegations made against him by JWCI and/or ORI, or any of their respective agents, employees, associates, or related persons, including but not limited to the findings made by ORI listed in the agreement," the notice added.

ORI gives investigators a measure of latitude in portraying their view of the transgressions, John Dahlberg, director of ORI's Division of Investigative Oversight, told *RRC* in an exclusive interview about ORI's policies and procedures, and some will go to the mat protesting their innocence. Nevertheless, "Our findings stand," added ORI Director David Wright, who also spoke to *RRC.* In a wide-ranging interview, Dahlberg and Wright also discussed how ORI conducts its "oversight review" of misconduct investigations, as well as how an investigator's sense of personal responsibility plays into ORI's determination of the sanctions or administrative actions imposed after a misconduct finding.

Misconduct is defined as fabrication, falsification and plagiarism, and it can occur in grant applications, poster presentations, published papers, grant progress notes and other documents, as well as be found in the conduct of the research itself. ORI recently found misconduct, for example, in an investigator's deliberate sabotage of a colleague's work (*RRC 6/11, p. 1).*

Institutions that receive PHS funding — NIH and the Centers for Disease Control and Prevention are among the largest granting agencies — are required to first conduct their own investigations when allegations of misconduct arise. Their findings are then presented to ORI, which conducts an oversight review and determines what administrative actions, if any, should be taken.

ORI has authority to impose a range of sanctions or administrative actions against an investigator. "Our regulation specifically notes that, in administrative law, our remedies are designed to be non-punitive," Dahlberg said, explaining ORI's use of the term administrative actions instead of sanctions. They are also meant to be "remedial" in nature, Wright added.

Possible actions include a requirement for supervision lasting one year or more if the researcher engages in PHS-funded research, or an outright debarment or exclusion from such research, which can be for life but more commonly extends for five or seven years.

The Department of Justice and ORI also work together to bring criminal charges against investigators, if warranted. ORI can request that an investigator retract a publication, especially if that is recommended in the institution's report.

Nine Cases So Far This Year

Eighty to 90% of cases in which misconduct is found result in settlements with investigators. "We try to settle every case if we think there is a chance because it is good for the respondent as well as everyone else to reach closure as soon as possible," said Dahlberg, who joined ORI in 1992. Wright joined ORI in January after many years as a research integrity officer (*RRC 1/12, p. 1*).

As Wright pointed out, "by concluding the agreement, you are accepting the findings." Those who don't settle "have an alternative, which is to litigate, first through the appeals process and then in court," he said.

Ravindranath's was ORI's eighth of nine misconduct findings issued so far this year, and actions imposed on him are fairly typical. He was one of four who agreed to a supervisory plan following findings that he falsified the results of research funded by two National Cancer Institute grants. The notice in the *Federal Register* said his actions included misreporting the number of subjects and the methodology used to achieve certain results, later described in grants' progress reports and papers published

in 2005 and 2007. Ravindranath did not respond to *RRC's* requests for comment.

Just one case this year involved a debarment — a ban of five years from participation in PHS-funded research. One investigator agreed to a seven-year exclusion, while another accepted a two-year exclusion. A third agreed to be excluded for one year, to be followed by a two-year period of supervision should he engage in PHS-funded research. ORI also imposed a year-long supervisory program upon one researcher.

All the actions taken are reported in the *Federal Register,* and most likely will have a significant and permanent impact on an investigator's career.

While the seriousness of the misconduct is certainly primary among the factors that influence ORI's choice of actions to take when it finds misconduct, it is evident from Wright and Dahlberg's comments that investigators who are truthful and accept responsibility — right from the start — will have a better outcome than those who don't.

How an investigator reacts before a case comes to ORI is important, because the agency only steps in after an institution conducts its own investigation.

Once a misconduct allegation has been made, researchers have "time to consider and prepare their responses," Wright said. "There is sometimes, not in every case, but there is sometimes a process in which they start in denial and slowly come to accept and admit responsibility."

Institutions engage in an "inquiry" when allegations are raised, which "takes 60 days and then, if warranted, [conduct] an investigation that takes 120 days," Wright explained.

Institutions' Investigations Come First

Dahlberg stressed that ORI's review is based on the investigation that the institution has already conducted. "That's important because so many individuals believe that we can, if they are angry about the outcome of the process at their institution, that ORI can come in and do it all over again, and the answer is we cannot do that," Dahlberg said.

When the Office of Scientific Integrity, the predecessor to ORI, was founded in 1989, "we had authority to conduct investigations when institutions didn't do it right or when there were multiple institutions involved in a case. That was taken away in the mid-90s," Dalhberg said. "But once the institution has completed its investigation and we start our oversight review, we do have very broad authority" under that review.

ORI's activities can include "interviewing witnesses, asking for more information and making separate and additional findings. That's one of the reasons why we developed such a strong forensics program is that DIO has a lot of authority to augment the findings of the institution," Dahlberg said (see box, below). Generally, ORI's review pertains to possible misconduct or a pattern of misconduct over the previous six years, as that is the statute of limitations on misconduct. But under some circumstances, the look-back can be longer.

Under the concept of continuing use, "If the respondent relies on that falsified data [prior] to six years ago then we can still go back more than six years," Dahlberg said. "A paper published 10 years ago [that] is now used in part as the basis for a current grant application by the same person" would be one such example.

The action "has to be done knowingly, of course, because anybody can cite false data or a false record and not know it is false, and, therefore, [is] not intentionally committing an act of misconduct," Dahlberg added.

Once misconduct is deemed to have occurred, ORI determines the administrative and other actions that need to be taken. One goal of such actions is to "prevent [investigators] from misspending taxpayer dollars for a reasonable period of time" when necessary, Dahlberg said.

ORI considers "quite a list of factors" when deciding what action to take, Dahlberg said. "They range from the seniority of the individual committing the misconduct, the degree and significance of the misconduct, and the time frame over which the misconduct took place. Those are the primary factors. Obviously any of those could be nuanced, and lead to consideration of aggravating and mitigating circumstances which, for example, could take into account admission or cooperativity during the course of the investigation and other such factors."

'Damage' and Truthfulness Are Considerations

While ORI takes into account what the institutional committee recommends, Dahlberg makes it clear that "the institution and ORI have separate interests."

"For this reason we do not consult with the institution about ORI's administrative actions," Dahlberg said, nor with "the funding component about our proposed findings; they are notified of the findings" as these agencies maintain lists of investigators who are restricted from involvement in certain PHS activities.

Beyond holding scientists accountable for misconduct, "an at least equally important goal in these proceedings is to protect the integrity of the research record," said Wright.

"It's the impact of the misconduct on the research record that is critical," Wright said. "Whether it can be impacted severely by tables or images or plagiarism, that isn't the point. The point is, how severe is the impact on the record?"

To help make that assessment, ORI consults with "subject matter experts at institutions" and at funding agencies, Dahlberg said.

If a researcher makes a misconduct "admission, and it's complete, that goes a long way toward being a mitigating circumstance," Dahlberg said. "In particular, it can also lead toward a voluntary agreement rather than having to go through a costly and time-consuming litigation process."

Referring to "aggravating circumstances," if the investigator "continues to misrepresent the truth during the process of the investigation and even later when they are interacting with the DIO during its oversight review of

ORI Investigators Share Some 'Tricks of the Trade'

The HHS Office of Research Integrity is charged with conducting "oversight reviews" of investigations that grantee institutions undertake if an investigator is accused or suspected of committing misconduct in research supported by funding from the Public Health Service. Federal regulations define research misconduct as fabrication, falsification and plagiarism.

If misconduct is found, investigators face actions ranging from a lifetime ban on involvement in PHS-funded research to a several-year supervisory requirement.

ORI Director David Wright and John Dahlberg, director of ORI's Division of Investigative Oversight, recently shared with *RRC* the factors that go into determining what actions are taken against investigators when misconduct is found (see story, p. 1).

Dalhberg, who joined ORI in 1992, also described the "tricks of that trade that we have learned over the years" that are used to find evidence of misconduct.

Erased Files Can Be Found

Once an institution submits its findings to ORI, the agency reviews the report but also frequently requests the institution's source material. Typically universities have all the backup data that relate to the allegations, Dahlberg said.

"It's standard practice nowadays" that institutions will "go to their information technology people and get a copy of their own hard drives, backups of server information, emails, visual information from computer instruments such as microscopes and other kinds of instruments," Dahlberg said. ORI may request all of this to conduct its oversight review.

"We also have become more and more adept at using forensic software to look at sequestered digital data, such as hard drives, flash drives, CDs and so forth for erased files or altered file names, looking at email attachments," Dalhberg said.

"And the nice thing about this software is it prevents you from making any changes to the hard drive once it's sequestered. So it's considered appropriate for presentation as evidence in a courtroom," he added.

Dahlberg recalled that in one case, "we had 15 or 20 hard drives to look at." ORI officials can also re-interview witnesses involved in the institution's investigation, as well as contact new ones.

Over time, ORI has developed its own tools to find evidence of misconduct. John Krueger, currently a scientist-investigator in DIO, "came in with a vast knowledge of image analysis using the Macintosh system and he has continued to develop that technology on the PC system as well, using Photoshop and other programs," Dahlberg said. "And most of the DIO staff are very adept at detecting manipulated images using Photoshop primarily, but with augmented tool sets that we have purchased commercially."

Dahlberg and a biostatistician, now retired from ORI, "developed procedures for detecting fabricated numbers," he recalled. "We developed some computer-aided systems for, for example, looking at questioned sets of numbers and seeing whether they may have been made up, or to look at graphs, and, using computer software, to convert the data points, or bar values… back into spreadsheet values and then see how that compares with the original data in spreadsheets."

Spreadsheet Analysis Proves Revealing

Dahlberg adds that ORI can look "at the spreadsheets themselves, because we've had three or four cases in which people have used formulas inappropriately in spreadsheets. It is possible to view the formulas rather than the actual derived data values, and often enough we've seen examples where formulas are in a cell or in a column that's supposed to [contain] the data."

ORI also uses "advanced plagiarism detection software," Wright added. "We use a number of tools. One of the most powerful ones is IThenticate, which is commercially available." (See http://www.ithenticate.com.)

IThenticate "is actually a service," Dahlberg said. "You purchase a license that allows you to review X number of pages per year."

ORI also makes forensic tools available on its website. See http://ori.hhs.gov/forensic-tools.

that, that's a very strong aggravating factor because it's [a respondent] being continually unreliable," Dahlberg said.

Investigators would do well not to underestimate the DIO staff, he warned. "DIO staff have always been a pretty bright bunch, even though a lot of people out of the office think that we must be dummies because we work for the government," Dahlberg said. "And it has actually worked to our advantage a number of times where a respondent has come in thinking they can convince us of their innocence, and they give us evidence that proves their guilt. That may have happened just a few months ago, actually."

Seemingly paradoxically, an admission of guilt may "come about because they get an attorney. Sometimes attorneys are actually very helpful," Dahlberg said, "because the attorneys will recognize the quality of the evidence against their client and realize it's to no one's advantage other than their own pocketbooks to draw the process indefinitely, and then to end up losing."

Wright shared that "one attorney said to me once, it's important to help a client recognize a bad set of facts." As an aside, he added that not all researchers who are accused of misconduct are represented by an attorney. "They are not obligated to have one. They may," Wright said.

"The regulation actually is very clear that, at any stage of the game, respondents are entitled to counsel," Dahlberg explained.

This issue of truthfulness goes beyond the accused individual, Dahlberg pointed out. "It's obviously an issue for everybody involved in the process to be able to adequately assess the credibility of the respondent — and the witnesses," Dahlberg said, "because there are a lot of cases in which no one is credible. And other cases where everyone says one thing and the respondent says another. It's easy in that situation to say that 'it appears that the respondent is not being truthful.'"

Blaming Others Is Not a Great Idea

Yet truthfulness comes in shades of "gray," Dahlberg said. "There are cases in which the complainant themselves may have been involved in the misconduct. There are a lot of cases we've had historically where people were collaborators for years, their relationship falls apart for one reason or another, and all of a sudden they are accusing each other of misconduct, and it turns out they are both right," Dahlberg said.

Another "important" factor is "have they engaged in retaliatory behavior against anybody who presented an allegation, or collaborators who testified against them?" said Wright.

"Or blamed others for their misdeeds?" Dahlberg added. "That's a biggie for us, particularly when you've got a senior person who not only doesn't take responsibility but continues to blame others for his or her misconduct. It's hard for those innocent bystanders to restore their reputations sometimes. Collateral damage, as I put it, is often a big factor."

"Another [factor] that might relate to seniority is a pattern of misconduct," Wright said. "How long the misconduct is going on and the impact of it.…A senior person who had the capacity to cause damage to the work of subordinates and students — we would likely view that as more serious."

"[If] abuse of animal or human subjects were involved," this would be another aggravating circumstance that could lead to a more severe action, Dahlberg added.

Among mitigating factors could be a lack of mentorship, the ORI officials said.

Debarment is the most severe administrative action, which is applied when ORI officials determine that the investigator cannot be trusted to be "responsible to do PHS-funded research," Wright added.

ORI May Pen Retraction Requests

The administrative actions and settlement requirements may include having the investigator request that an article is retracted.

"Our regulation doesn't discuss [retractions] in those specific terms," Dahlberg said. "What we do in a case where misconduct is related to publications, if it's a voluntary agreement that we reach with the respondent, [ORI will] require the respondent to agree to those demands by the committee" at the investigator's institution.

The investigative committee at the institution determines if a paper "warrants retraction or correction," Dahlberg said. Sometimes a retraction "is accomplished before we even reach a settlement."

ORI may give special scrutiny to retractions of papers with multiple authors.

In the last three to four years, ORI has experienced more cases that involved "multiple respondents" and "in certain cases a whole lab has been accused of falsification of papers over, say, anywhere from five to 10 years, as if it's kind of a cultural expectation in that lab," Dahlberg said. "These are situations that we haven't seen in the past, and it's not clear what the explanation for that is."

How the retraction request is worded matters to ORI. "We are prepared to write letters for the respondent" requesting a retraction, Dahlberg said. "In our experience respondents' letters, if they are allowed to write their own, are so self-serving and misleading that it's a disservice to [their] collaborators, in particular."

Discussions will also involve what the public settlement agreement and *Federal Register* notice will say. Ravindranath, the cancer researcher, was not the only

investigator recently found guilty of misconduct who did not admit to it. In fact, he was one of three just this summer.

An Aug. 2 *Federal Register* notice said that Shane Mayack, a former postdoctoral fellow at Joslin Diabetes Center, committed research misconduct by falsely presenting images and figures in two published papers, since retracted, that resulted from research funded by three NIH grants, of which one was a prestigious "young innovator" award. "Both [Mayack and] HHS want to conclude this matter without further expenditure of time or other resources," the notice said.

And last month, Marc Hauser, an evolutionary psychologist who resigned from Harvard University in August 2011, agreed to settle allegations that he engaged in research misconduct in published and unpublished papers as far back as 2002 by falsifying data, including claiming monkeys had responded to certain stimuli when they had not been exposed to it.

ORI's Sept. 6 *Federal Register* notice described at least 10 instances of questionable, false or manipulated data stemming from a variety of Hauser's experiments. These actions have led to the retraction of one paper to date and corrections to others. The notice said Hauser admitted in one instance "that his coding was incorrect and that the study failed to provide support for the initial hypothesis." In another, he "accepts responsibility for a false statement in the methodology section for one experiment reported in the paper."

Despite Wording, Findings Are Unaltered

Yet, Hauser "neither admits nor denies committing research misconduct but accepts ORI has found evidence of research misconduct," the notice states, even though he agreed to a three-year supervisory plan and to exclude himself from serving as an advisor to any PHS agencies for three years.

ORI staff have been "told by our attorneys we can pretty much say anything we want in our agreements," Dahlberg said. "What we will not budge on is that ORI makes findings of misconduct, and that they are the result of falsifications and/or fabrications and/or plagiarism, in one thing or another. But we allow attorneys and their clients some latitude in terms of what they claim or admit to. That's standard practice in the legal world."

"The findings stand as evidenced in administrative action," said Wright. "That's the bottom line in the *Register* notice, whether it's debarment or supervision."

Dahlberg said he doesn't think what investigators "say in a voluntary agreement is going to have a positive impact on their future. But they think it will."

Links: http://ori.hhs.gov/case_summary; http://ori.hhs.gov/meet-directors ✧