To serve and protect research integrity

An interview with David Wright, Director of the US Office of Research Integrity

EMBO reports (ER): You started as the new Director of the Office of Research Integrity [ORI] this year; but you have been active in bioethics before this position.

David Wright: I'm not actually a bioethicist; my background is in the humanities. At Michigan State University I was the chair of the human subjects review committee and then I was also the research integrity officer for a little more than 11 years, responsible for administering the procedures to investigate misconduct.

ER: Given your experience, do you think you will bring a new vision to ORI, which so far is limited to investigating fraud, falsification and plagiarism, to include oversight of animal welfare, human subjects research or biosafety issues?

Wright: In the United States, the research regulations are fairly compartmentalized by regulating authority, and we have multiple agencies: the Office for Human Research Protections, for example, which oversees the protection of persons who participate in clinical trials. For animal welfare, there is a branch [the Office of Laboratory Animal Welfare] at NIH and a corresponding one at the Department of Agriculture. As research becomes more and more complex, sometimes our regulations will overlap on a specific case, in which case the agencies will consult with each other. At the same time, we try not to step on each other's toes. No, ORI will not expand into human research protections, although we are engaged, for example, in discussions with the Office for Human Research Protections about how to handle cases where both sets of regulations may apply.

ER: When it comes to human subjects and animal research, scientists need to obtain prior approval before they begin

their experiments. In contrast, a breach of research integrity is dealt with after publication. Would it be more efficient to implement greater oversight of research to prevent misconduct in the first place, rather than dealing with it after the event?

Wright: Actually, ORI already does that. ORI's oversight function, like police work, can only be conducted after something goes wrong. However, our regulations require all institutions that receive Public Health Service [operating divisions of the US Department of Health & Human Services] funding to "foster an environment that promotes research integrity and responsible conduct of research and prevents research misconduct." That's the proactive aspect of what ORI does. We fund the development of educational products and curricula to teach young scientists the responsible conduct of research, and we conduct conferences to discuss how to prevent misconduct. ORI has two divisions: the Division of Investigative Oversight—that's the one that oversees institutional investigations of misconduct and conducts its own independent review—and the Division of Education and Integrity, which, if you will, is the proactive one.

ER: Some scientists who investigate the causes of research misconduct have suggested that the highly competitive research environment, which results in part from training too many PhDs and postdocs, encourages researchers to cut corners. What else should be addressed to prevent misconduct?

Wright: There are a number of hypotheses about why misconduct occurs. One of them is increased competitiveness, particularly, the struggles of young faculty to get grants, to achieve tenure. There is also the hypothesis that a certain small proportion of every profession are sociopaths and there is nothing

we can do to stop them. Another hypothesis holds that, for some of the most successful scientists, arrogance is a factor; they don't need to do the experiments because they already know the answers. Another hypothesis is that, as the international research culture becomes more heterogeneous and as more and more foreign-born young scientists work in the United States, they may err through ignorance and lack of training if they haven't been carefully mentored in the American system. There is some evidence to support each of those hypotheses but, in fact, nobody knows exactly why misconduct occurs. Trying to investigate the causes of misconduct is like trying to investigate why people commit crime, which of course we can't do because of privacy laws. Of course, we have the records because we conduct investigative oversight but the records are not available to other scholars. Also, research misconduct is a very difficult subject to research: when people make admissions, you can't tell whether they are self-justifications or pre-emptory admissions to hide even greater misconduct. ORI supports research into research integrity, and trying to understand why misconduct occurs is an ongoing process. However, if we knew exactly why misconduct occurs, and whether it occurs for the same reasons in every case, it would be much easier to address.

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ER: At present, the institutions where the misconduct took place are also the ones to impose sanctions on researchers found guilty. Should ORI become an executive agency with the ability to impose sanctions on researchers?

David Wright, the Director of the Office of Research Integrity (ORI) since January 2012, is a historian of science by training: he received his bachelor's degree in English from Princeton University and a PhD in American Studies from Michigan State University. Wright was Professor and Chairperson of Michigan State University's Department of Community, Agriculture, Recreation, and Resource Studies, where he taught and wrote on the history of science and technology and the responsible conduct of research. From 1993 to 2004, he served as Michigan State University's Assistant Vice President for Research Ethics and Standards and as its Intellectual Integrity Officer; he also chaired the University's Committee on Research Involving Human Subjects for 11 years. Wright has been an expert consultant to ORI since 2001, working with both the Division of Investigative Oversight and the Division of Education and Integrity.

Wright: The US research regulations have developed through a long negotiation among the Congress, the research community, the oversight agencies, and the press and public. The upshot is a shared responsibility between the institutions that receive federal funding and the federal oversight agencies when it comes to dealing with things like animal welfare, which was one of the first subjects of regulation, dating from the mid 60s, human subjects, research misconduct, financial conflicts of interest. Institutions perform the first review through the peer review process. If they fail to get it right, a federal oversight agency will try to correct the problem. So, ORI deals with alleged misconduct that already has occurred. We ask institutions to conduct their own investigations, and ORI then reviews those investigations and, as necessary, performs its own *de novo* review of the allegations. ORI can make its own findings on behalf of the Public Health Service. For example, an institution might find one of its members guilty of research misconduct and might, at the severe end of the continuum, fire that person; alternatively, at the lenient end, they might put the individual on probation for a period of time. The federal government in the form of ORI might, at the mild end, require that a person's research be supervised for a period of time to guarantee integrity or, at the severe end, suggest that the individual be debarred for a period of time from receiving federal funding for research.

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ER: The USA is more stringent, in terms of both laws and enforcement, than most European countries. Nicholas Steneck, Director of the Research Ethics and Integrity Program of the Michigan Institute for Clinical and Health Research, once commented that research into research integrity itself is probably about a decade ahead in the United States compared to Europe. Can you explain why the US is more advanced in both researching and dealing with research misconduct?

Wright: I want to say first that, whereas I have attended the world conference on research integrity and spoken from time to time to European colleagues, I don't consider myself an expert on other systems. The US research enterprise is huge, much more homogenous than in Europe, and our investigative press made a very big deal about waste of federal funding during the 1980s. We have a congressional system that makes it easy to hold hearings. I think it's fair to say that our processes and procedures for investigating misconduct are more legally oriented and comparatively sophisticated, for example, in sequestering evidence or safeguarding and protecting it so that the record can't be tainted before adjudication

occurs. At the same time, when the regulations were first being debated, people in the research community and some of their allies in Congress made a point of emphasizing prevention. That opened the doors to funding research into research integrity. The major, initial emphasis was on the detection and prosecution of misconduct; over time, our emphases have become more balanced between detecting and sanctioning alleged misconduct, and preventing misconduct and promoting research integrity.

ER: There are obviously grey areas in research misconduct, in particular when it comes to plagiarism and the 'beautification' of data. As more American scientists are cooperating with colleagues in Asia, South America and Europe, do you think that cultural differences, in particular in regard to plagiarism, could become a greater problem?

Wright: I have done a little personal research on that, so I am familiar with the literature and have observed that the views of scholars and regulators vary greatly concerning the weight that should be accorded to various types of plagiarism. Some are concerned about what's sometimes called micro-plagiarism—little bits and phrases here and there, others about so-called sausage publication—repeating little bits of previous publications of one's own. Both are objectionable ethically. The question is whether one or the other or both rise to a level at which they should be officially

sanctioned. The ORI traditionally has confined its interest to serious cases of possible plagiarism. We don't look at the number of words, for example, but at the significance of those words. If the alleged plagiarism concerns a central finding, for example, or a novel procedure or technique, then we would very likely pursue that allegation. If the allegation concerns only modest plagiarism of an article or standard methods, then we probably wouldn't take it on. That doesn't mean that universities aren't free to make their own, more expansive findings of misconduct. When they do, although ORI may not make findings of its own, we certainly support those of the institutions.

“The journals are not responsible for the increasing competition; nor are the funding agencies”

ER: And if you have to investigate a case that involves researchers from abroad?

Wright: If we—the Public Health Service, including NIH—funds part of the research, then our regulations apply. We would have to insist that any review of alleged misconduct meet our standards. Probably, we would try to negotiate within the guidelines and procedures of host entities but we might conduct our own separate review of the evidence. Of course, ORI might recommend debarment of a respondent from HHS funding independent of decisions by other entities.

ER: Do you think that journals also play a role in creating the pressures that lead to research misconduct since scientists need to get a paper into *Nature*, *Science* or *Cell* to obtain research grants?

Wright: Actually, I don't blame journals. The journals are not responsible for the increasing competition; nor are the funding agencies. All would agree that we would like to give more money to promising scientists and journals don't like the competitive situation any better than the young scientists. As the technology of research has tended to make research findings, especially as reported in journals, more visual, falsification and fabrication more often tend to involve images. In fact, of the fabrication and falsification cases that ORI receives, at least 70% involve image manipulation. Journals have become very good at detecting such manipulation.

Many have part-time editors whose only job is to make sure that images are proper and verifiable and don't show signs of manipulation. It was once the case that journals, perhaps for fear of liability, were reluctant to work with universities and oversight agencies and, when they detected something, they'd simply report it back to the senior author, which from our point of view could be asking the fox to guard the henhouse. Journals are now much more likely to talk to the research integrity officer or to ORI.

ER: Do you think that journals generally should also apply more rigorous checks?

Wright: I think the journals are actually doing a good job and have been leaders in this field. Twenty-five years ago, very few of the practices that many journals now use were in place: asking that the original data be submitted to be made visible to other researchers as some biomedical journals do; requiring clear conflict of interest statements; demanding evidence of human subjects protection approvals; having editors look for image manipulation—that's all gold-standard behaviour, in my opinion. Journals have evolved along with universities and oversight agencies like ours. Not every journal is as good as the leaders, but the standards have been set by the leading journals and I think they are very high, very good and very helpful.

ER: Is there a risk that we could end up being too strict about less critical issues, such as ignoring data outliers?

Wright: I think that over-regulation and over-interpretation of any regulation or law tends to promote contempt and disobedience of that regulation. It is already the case in the US and in the ESF [European Science Foundation] Code of Conduct, that we sometimes contemplate ethical issues that do not rise to the level of misconduct. In the US, these are called questionable research practices, such as prettying an image or deleting outliers, not to hide or to deliberately falsify, but to make an image look better or to make the results seem more powerful. Such practices don't change the overall findings but, nevertheless, are ethically wrong. I think most people agree that these practices can be a slippery slope to something worse and should be the subject of mentoring and counselling of young investigators, but do not warrant a full-scale

prosecution for misconduct. We must be judicious and balanced in the enforcement of any regulations to make them work.

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ER: Do you think we are just seeing the tip of the misconduct iceberg? If so, how deep does it go?

Wright: I think there is, if not universal agreement, at least strong agreement among people in this field that research misconduct is underreported. Twenty to twenty-five years ago, when this discussion started, people said there was one instance of misconduct in 10,000–100,000 cases. Then, slowly, over time, research by Brian Martinson and others suggested that misconduct may occur in as many as 1% of funded studies. Now, people are talking about an upper level of 3%. If you look at the number of misconduct findings by, let's say, NSF or ORI, compared with the number of article retractions, the number of retractions would suggest a much higher rate of misconduct. I would say that, although most research is honest, misconduct is a non-trivial problem in the research community. We could do a much better job of training young investigators to adhere to rigorous standards. For example, if lab chiefs and mentors were regularly looking at raw data, as opposed to summary data or data on PowerPoint slides, it would be far more difficult for fabricated or falsified data to ever leave a laboratory in a grant proposal or manuscript.

ER: Raymond de Vries and Nick Stenek, both leading scholars in research integrity, come from Michigan, as do you. Why do so many research integrity experts come from Michigan?

Wright: That's a very good question. I suppose it's just because it's a great state.

ER: Dr Wright, thank you for the interview.

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