Wanted: Fraud-buster with political antennae

A mild-mannered man's fiery resignation leaves a troubling vacancy at the world's largest office for investigating scientific fraud, says Colin Macilwain.

When David Wright leaves the Office of Research Integrity (ORI) at the US Public Health Service later this month, everyone will know just why he is walking out of the door. Wright's resignation letter to the assistant secretary of health, leaked last week, is unusually direct. "I'm offended as an American taxpayer that the federal bureaucracy — at least the part I've labored in — is so profoundly dysfunctional," he tells his former boss, in a note decorated with choice cuts of bureaucratic hubris. In one example, Wright says, he sought an evaluation of the support services available to the ORI, only to be told that "that had been tried a few years ago and the results were so negative that no further evaluations have been conducted".

Wright, a science historian and former research-integrity officer at Michigan State University in East Lansing, signs off with a cheery promise to publish a version of the daily log he kept at the ORI, "to share my experience and observations with my colleagues in government and with members of the regulated research community". That would be you, dear reader.

Anyone who has dealt with Wright professionally will be taken aback to see the guy nailing his colours to the mast in this way. He just isn't the rocking-the-boat type: a more courteous and polite official it would be difficult to meet. There is a profound feeling in circles interested in research misconduct that he is one of the good guys.

"A lot of us are wondering where we go from here," says Mark Frankel, head of the Scientific Responsibility, Human Rights and Law Program at the American Association for the Advancement of Science in Washington DC. As well one might, when the directorship of the world's largest and best-established research-misconduct office — which lacked a permanent director for two years before Wright's appointment in 2012 — has just imploded.

The ORI was established 22 years ago in the wake of the David Baltimore case, in which allegations of fraud (later dismissed) rocked the laboratory of one of America's most eminent biologists. The agency's 25 staff are supposed to educate tens of thousands of researchers on proper research conduct, as well as overseeing investigations into misconduct by researchers funded by the US National Institutes of Health (NIH), the world's largest research agency. But it was built to deal with the handful of cases that it was assumed would arise. According to research published last December by Daniele Fanelli at the University of Edinburgh, UK (D. Fanelli *PLoS Med.* **10**, e1001563; 2013), the proportion of allegations the ORI receives that are investigated and closed has halved over 20 years. Wright's resignation letter blows wide open long-standing doubts about its capacity to deal with a caseload that,

the available evidence suggests, should have expanded with the growth of the NIH itself.

The administration of US President Barack Obama needs to get a grip on this before an explosive high-profile case — such as that of Andrew Wakefield and MMR vaccines in the United Kingdom — turns up and the ORI can't cope. If the administration doesn't do this, Congress just might. Senator Chuck Grassley (Republican, Iowa) demanded in February that the ORI explain its lenient treatment of Dong-Pyou Han, a physician at Iowa State University in Ames, who was banned from seeking NIH funding for three years after falsifying data in AIDS vaccine trials that cost the agency US\$19 million.

It is not known how much Grassley's strident demand for answers contributed to Wright's departure. But attention from one of the most feared and respected voices on Capitol Hill can only intensify the political hot-house atmosphere that his resignation letter blames for the ORI's troubles.

These troubles go back a long way. The ORI sits under the assistant health secretary, instead of being properly independent like the inspector generals who keep an eye (imperfectly) on scientific fraud at the National Science Foundation (NSF) and other agencies. Its enforcement remit (of fabrication, falsification and plagiarism, or FFP) is too narrow, and its budget too small.

Canada has already shown the way. In 2011, it set up the Tri-Agency Framework: Responsible Conduct of Research. It has a relatively large staff of eight, for a research system one-tenth the size of that of the United States, a remit that reaches far

beyond FFP, and it is led by Susan Zimmerman, a tough lawyer unlikely to put up with dodgy academics whimpering about their "creativity".

Wright's resignation comes as a panel chaired by Robert Nerem, a bioengineer at the Georgia Institute of Technology in Atlanta, is in the final stages of the first National Academy of Sciences study on research integrity in 20 years. The report may recommend beefing up the ORI, broadening its remit beyond FFP and aligning its approach with that of the NSF and other agencies. But with the ORI leaderless, the academy report may be even more prone than usual to gathering dust.

I have been an optimist on misconduct: some 18 months ago, I wrote that the global community was starting to get a handle on it. Wright's appointment was progress, and his departure is a setback. His position must be filled promptly by someone respected by both ethicists and health researchers. They will also need the skills to build bridges with Congress: a peripatetic master, perhaps, but one who can prevent the ORI from getting kicked around. ■

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THE POSITION
MUST BE FILLED
PROMPTLY
BY SOMEONE
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HEALTH RESEARCHERS.

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