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Accountable and transparent

The US government has changed how biomedical scientists disclose their financial interests. The revised rules are welcome, but Internet access to the identified conflicts should be a requirement.

Toughened rules for how US biomedical scientists report financial interests came into force last month. The changes, which affect scientists who receive grants from the government, are welcome — although in one respect they do not go far enough.

About 38,000 researchers, most of them recipients of grants from the US National Institutes of Health (NIH), the world's largest medical-research funder, will need to comply with the beefed-up rules. The changes update regulations put in place in 1995 to ensure that investigator bias doesn't sway the design, conduct or reporting of research.

There are several important changes. First, investigators must now disclose to their institutions every "significant financial interest" belonging to themselves or their immediate family that is related to any of their institutional responsibilities — from teaching and seeing patients to lab research and service on ethics committees. This requirement appropriately casts a broader net than the previous rules, which generally asked for disclosure on only a project-specific basis.

The change ends ambiguity that, for instance, might have allowed a researcher to conclude that paid service on the board of a major pharmaceutical company drew only on clinical expertise, and therefore was not relevant to a government-funded research project that used one of the company's experimental compounds. Under the updated rules, there will be no question that such income must be disclosed, and institutions will have a more complete picture of their scientists' potentially relevant financial interests.

It takes only one example to drive home the significance of this change. Between January 2000 and January 2006, high-profile psychiatrist Charles Nemeroff, then at Emory University in Atlanta, Georgia, received more than US\$800,000 in payments from drug-maker GlaxoSmithKline for over 250 speeches that he gave to psychiatrists. He failed to disclose this income to Emory administrators. After being discovered, Nemeroff argued that the rules on whether such income was reportable were ambiguous.

The tougher rules, crucially, give institutions prime responsibility for determining whether a given financial interest — company-paid speaking honoraria, consulting fees, paid authorship, travel reimbursements and stock ownership all qualify — is related to a government-funded grant, and whether it constitutes a conflict. Under the old regime, the scientist was charged with deciding whether a given interest was related to the research and thus whether it was reportable. That arrangement did not inspire confidence — a problem in an era in which public trust in the medical enterprise is at risk and must be built, not undermined.

The updated rules also lower the threshold at which an interest is defined as significant, from \$10,000 under the old rules to \$5,000. In a moribund economy with many US taxpayers struggling to make ends meet, this is fitting.

The rules have also been strengthened in other important ways.

For instance, far more detail will now be reported by institutions to the NIH about each identified conflict, including the approximate dollar value of the interest and the measures being taken to manage or eliminate the conflict. There is also, importantly, an explicit exception to the disclosure requirements for income that scientists earn from universities or government agencies for teaching, serving on advisory or review panels and giving seminars or lectures.

The new rules fall down, however, in one significant regard. When it first published the proposed changes, the NIH described what it called "an important and significant new requirement to ... underscore our commitment to fostering transparency, accountability, and public trust".

That requirement was that institutions would post details of their investigators' financial conflicts of interest on a publicly accessible website that was updated every year. In the final iteration of the new rules, the website has been made optional, and institutions faced with requests for information may instead respond in writing, within five business days. This is an outdated approach to transparency. It will not advance the public's faith in timely, comprehensive and truly accessible disclosure, at a time when the boundary between academia and industry has become ever more porous, and when the average citizen's trust in government-funded medical research is ever more crucial. The NIH should revise the rules again to make the website mandatory. It is within the agency's power to insist on this standard, and it is the right thing to do. ■

"Public trust in the medical enterprise is at risk and must be built, not undermined."

Spinning threads

Publication of ENCODE data drives innovation in data mining.

There can be few scientists who have not used a brightly coloured highlighter pen to mark the most interesting parts of a research paper, report, proposal or (librarians look away) book. It is a natural reaction when faced with a swamp of information — to build islands of focus that can be identified and linked, both in print and in the mind.

This week, *Nature* introduces a new concept in the publishing and dissemination of scientific information: one that is a response to the increasing complexity of modern research, and one that draws heavily on the contribution of the humble highlighter.

Starting on page 45, we publish a package of material that centres

on the results from the ENCODE consortium, including 6 of the 30 papers the project has produced. The ENCODE — Encyclopedia of DNA Elements — consortium set out to describe all the functional elements in the human genome. Their headline conclusion: more than 80% of the human genome's components have now been assigned at least one biochemical function.

The six papers that *Nature* publishes (the others appear simultaneously in *Genome Research* and *Genome Biology*) may look like conventional research reports, but in the digital world they begin to take on new form — as themed threads. If you are reading this online, then click on the link. If you are reading it in print, then have a look at the version on *Nature's* ENCODE explorer website (www.nature.com/encode) or, better still, the iPad app.

As part of the publication process, the ENCODE authors asked for something extra: to select and package together the sections from each paper that will be of particular interest to scientists in various and varied fields. Just as a postdoctoral researcher looking at transcription factors would use a highlighter to mark up different bits of the papers from, say, a colleague looking at DNA methylation, so the ENCODE authors thought that researchers across the biological spectrum would want to be able to pull together pieces from each of the digital versions that were of specific interest to them. Our editors agreed, and the result is 13 online threads — biological themes that contain no original material but instead harvest and combine related paragraphs, figures and tables from the 30 papers.

The threads, we hope, will help readers to make sense of the dizzying amounts of data produced during the five years of the main ENCODE effort. And they should allow scientists to exploit more easily the information in their own studies, and that, after all, was the point of the project in the first place. Presented online, the threads are filled with links that allow readers to jump easily from paper to paper, to see where the information comes from and how the data are interconnected.

Alongside the thread concept, the ENCODE package introduces another technical innovation, at least one new to *Nature*. Using a 'virtual machine', online readers can access software designed to perform set computational functions on some of the ENCODE data.

The idea is to allow readers to recreate the analyses behind the specific aspects of the paper and to see how the outcome changes when specific parameters are tweaked. Think of it as a bridge that links the data, the analysis and the relevant description and discussion in the formal papers.

“Scientists who work on other data-rich and analysis-heavy projects should take note.”

We are eager to hear what readers and users of the material think of these approaches. If they are useful, and early feedback suggests that they will be, then scientists who work on other similarly data-rich and analysis-heavy projects should take note. Results from projects that aim to sequence the human microbiome or different forms of cancer, for example, produce piles of data that could be split along many different themes, and so divided into threads. In many cases the true hard work — the science — is done. Threads, then, are just a different way to package the results.

Some practical problems remain in applying these ideas more widely. The thread concept depends on cooperation between publishers, as well as open access to the papers and appropriate copyright agreements. And the virtual machine demands well curated data that are available to all.

Why are there 13 ENCODE threads? Good question, there could have been many more — as many as there are questions raised in the minds of scientists by the mass of information that the project has placed at their disposal. If your particular interest or angle is not already selected and presented as a theme, then apologies — there is always the old-fashioned route: print the papers and attack them with a highlighter. ■

Moonlight drive

The data from the ageing Voyager probes are illuminating the edge of the Solar System.

Someone in the NASA media-relations office knows their music. A press release from the agency last month stated that the twin Voyager spacecraft were poised to Break on Through to the Other Side — referring to the probes' approach to the edge of the Solar System, but also to a 1967 hit from the US band The Doors. NASA pointed out to journalists that the missions were launched 35 years ago and was no doubt hoping for some (more) positive coverage to mark the anniversary. What's more, on 13 August, Voyager 2 became the longest-operating spacecraft, beating the record of Pioneer 6, which was launched in December 1965 and returned its final signal some 12,758 days later. (Voyager 2, counterintuitively, was launched two weeks before Voyager 1, but the latter is now the farthest from the Sun.)

The spin doctors can be excused this time. Voyager is a truly great mission, and one that reporters still find hard to resist — some of them have been happily writing about its discoveries ever since the two craft launched in 1977. It is the science story that keeps on giving: the deep, hazy atmosphere of Saturn's moon Titan; the volcanoes of Jupiter's moon Io; the large, unusual magnetic field of Uranus; and the geysers of Triton, the frozen world that orbits Neptune — all discovered and lapped up by an eager public as the probes skimmed past the outer planets.

Still, their work is not done. Even though the probes are now more than 15 billion kilometres away from the Sun, their handlers on the ground remain in near-daily contact, as the spacecraft continue to

send back useful information — now about the farthest reaches of the Solar System. Last year, NASA even coaxed the ageing and radiation-blasted parts of Voyager 1 into performing a series of rolls to have a proper look around. It was curious because some of the data being sent back from the spacecraft seemed to suggest that the edge of the Solar System was nearby. Levels of high-energy cosmic rays, which originate far beyond our corner of space, had spiked. And the number of lower-energy particles that come from closer to home seemed to dip.

The results of the latest tests, which are published on page 124, have surprised many. If Voyager 1 truly is near the point where the heliosphere — the bubble of charged particles from the Sun — fades to interstellar grey, then it should have found solar particles that have been buffeted by the winds of deep space, generated by supernovae that exploded long ago elsewhere in the Galaxy. In fact, the particles it found had effectively been becalmed.

The implications of the discovery for our understanding of the structure of the Solar System, and how it changes as it whizzes through space, are profound. As a News story on page 20 explains, the find could mean that astronomers will have to rethink their models of the heliopause, the boundary at which the outward pressure of the heliosphere is balanced by the inward push of outer space. Or it could mean that Voyager 1 is still some distance from the heliopause.

That would no doubt disappoint the NASA press office, which is eager to announce that at least one probe has entered a new realm of discovery — and before the batteries of the spacecraft run out, in a decade or so. But it should not lose heart. Like the Voyager probes, The Doors are still going, albeit not as strongly and with their best work probably behind them. If the heliopause is farther away than we thought, and the reach of the solar wind longer than we realized, then the Voyager twins still have many years remaining as Riders on the Storm, and some way to go before they reach The End. ■

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