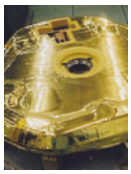

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Universities unnerved by revised rules for sharing NIH research

Charles Jennings

Memo to US researchers: read the small print carefully before filing your next grant application to the National Institutes of Health (NIH).

Unknown to many, the rules are changing on 1 October in a bid to encourage grant holders to share the fruits of their research. But university representatives fear that the new rules lack clarity and will cause confusion and delays for this year's applicants.

Come September, when people finalize their applications for autumn deadlines, "there's going to be a big crunch", says Robert Hardy, spokesman for the Council on Governmental Relations (COGR), which represents 150 US research universities in their dealings with funding agencies.

The NIH already expects grant holders to share materials and data with other researchers after publication, but from October, applicants must give explicit details on how they intend to do this. The policy is aimed at the sharing of model organisms, although it will also cover cell lines, associated reagents and protocols.

Under the new rules, applicants will be able to apply for extra funds to cover the sometimes substantial costs of sharing, such as depositing model organisms in public repositories. But a failure to share could lead to penalties: the NIH says that it will take sharing records into account when making future funding decisions.

K. GULDBRANDSEN/SPL

Open access: under new rules, researchers who seek an NIH grant must detail their plans for sharing model organisms.

Share deal

Eric Campbell of the Institute for Health Policy at Massachusetts General Hospital in Boston applauds the new policy. "The two fundamental underpinnings of science are replication and peer review," he says. "If you hamstring one of these, you are hurting science."

Campbell believes that funding organizations have a responsibility to promote a culture of sharing. Two years ago, he surveyed some 1,200 academic geneticists and found that almost half of them had been denied requests for information or materials in the previous three years — as a result, 28% of them were unable to replicate published findings (E. G. Campbell *et al. J. Am. Med. Assoc.* **287,** 473–480; 2002).

But the COGR is concerned about the way in which the NIH rules will be interpreted. When the changes were announced — fairly quietly in early May — the council wrote an open letter to the agency listing a number of concerns, including the lack of public consultation and a failure to deal with intellectual-property issues. Council president Katharina Phillips added that the NIH had not clarified what constitutes an acceptable sharing plan or the legal basis for the policy. Rather than insisting on detailed plans in grant applications, the COGR wants the NIH to accept a simple statement of intent to share materials.

The NIH has promised to clarify its policy in a document soon, but this has not yet been published, and the COGR says that the agency should delay its October deadline until the concerns have been resolved. The NIH says that it remains committed to its timetable.

The rule change is in line with a report published last year by the US National Research Council, part of the National Academies, which argued that stronger community standards for sharing were needed. "The NIH are moving in the right direction," says Thomas Cech, president of the Howard Hughes Medical Institute in Chevy Chase, Maryland, and chairman of the committee that produced the sharing report.

Balancing act

Observers, however, point out that there is an inherent tension between the NIH, which seeks to maximize the impact of the research it supports, and the universities, which are entitled to patent and profit from inventions made with government funds. In some cases, such as that of frequently requested reagents, it may be in all parties' interests to license the materials to companies that supply them to other researchers. Under the new policy, NIH reviewers will then have to consider the terms under which materials will be available and determine whether the price is fair.

Licensing decisions are normally the responsibility of universities rather than individual researchers, and the NIH policy statement also warns that institutions will be held accountable for the sharing behaviour of their investigators. The risk of losing NIH funding represents a considerable threat, but proponents of the policy see this as a last resort. "We will use discretion," says Norka Ruiz Bravo, deputy director for extramural research at the agency. "We don't want to use a hammer to swat flies." ■

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html