CORRESPONDENCE

We need to tackle the mismatch between supply and demand

SIR — Your Editorial 'Crisis of confidence' (*Nature* **457,** 635; 2009), about US graduates pursuing careers in biomedical research, hits the nail on the head. The problem is not that junior faculty careers are not fostered. Their crisis is predominantly due to perennial mismatches between supply and demand. The aura of an unstable career permeates the entire profession and has diverted the best students from seeking careers in biomedical sciences.

Strategically, there are two main issues facing the funding of US biomedical research, especially through the National Institutes of Health (NIH).

First, we all wish to see continued growth at this time of exciting developments in biomedical research. This goal seems to enjoy wide public support, and the new stimulus budget reflects a deep commitment to funding science. We need to convince all who will listen of the importance of this goal.

Second, we should be able to work with the hand that is dealt us: annual budgets from Congress. Why can't the NIH evolve mechanisms to regulate the impact of the upswings (increased congressional allocation) and downturns (periods of stagnant growth)? This is a key goal, as ensuring reliable growth is the best mechanism for getting new blood into biomedical research.

Here are some suggestions to consider. One is to modulate the amount of funding and grants depending on funding. Supplements can be used during periods of growth and taken away during downturns, which will tend to directly stabilize the number of grants, and thus the number of applicants and their success rates.

Another suggestion is to adjust the effort a principal investigator can charge to grants. This can be decreased during expansion; universities have to contribute more. This would impose on departments and universities a clear restraint on uncritical runaway hiring. Also, during periods of growth, funding should be diverted to infrastructure and programme activities: instrumentation, renovations and collaborative grants.

Approaches such as these and others, in aggregate, would reduce the incentive for rapid growth during periods of budgetary expansion at the NIH and would redirect funding to the R01 (research project grant) pool during periods of stagnation. Hence, they are likely to result in more 'steady state' growth that will reinvigorate career development in the biomedical and life sciences.

Yusuf A. Hannun Department of Biochemistry and Molecular Biology, Medical University of South Carolina, Charleston, South Carolina 29425, USA
e-mail: hannun@musc.edu

Review: important to prevent a return to abuses of the past

SIR — As a former chair of an institutional review board (IRB), I sympathize with the concern expressed in Scott Kim and colleagues' Commentary 'Pruning the regulatory tree' (*Nature* **457**, 534–535; 2009) about the heavy burden imposed by dealing with exempt research. Unfortunately, their fix won't work.

Many years ago, before the US National Institutes of Health clamped down, exemption was handled very casually at many institutions, even to the extent of researchers declaring themselves or their students exempt without any formal review. The result was a widespread culture of non-compliance with the common rule, with many dubious and improper claims of exemption. That is why IRBs at some institutions do not grant them — exemptions got a bad name.

A new regulation that "exempts minimal-risk research from IRB review" would certainly send a clear and unambiguous message: an invitation to return to the abusive practices of the past. If an IRB chair or a full review board feels the need to clamp down on exemption declarations to help researchers remain sensitive to their obligations to protect their human subjects, please give them your understanding and support. They are doing the right thing.

Kim's comments in Nature Network (http://tinyurl.com/am7l24) include an example of financial regulations that may seem too fussy. He is right on target with his choice of domain from which to draw analogies. I think most would agree that the streamlining of regulations in the financial industry — the undoing of rules requiring transparency and accountability, record-keeping and review — tempted people into excesses that have now severely damaged our economy. Let us not make a similar mistake with IRBs.

Without truly independent review of research protocols involving human subjects, at best preventable mistakes will happen because nobody looked and, at worst, significant harm may result.

Herbert J. Bernstein Department of Mathematics and Computer Science, Dowling College, Kramer Science Center, Oakdale, New York 11769, USA
e-mail: yaya@dowling.edu

Review: necessary for protection even in minimal-risk research

SIR — Although I am sympathetic to the suggestion made in Scott Kim and colleagues' Commentary (*Nature* **457**, 534–535; 2009) that we deregulate minimal-risk research by treating it as exempt from assessment by institutional review boards (IRBs), I do not believe that their proposal provides adequate protection for human subjects.

Most institutions require their researchers to submit a short application to the IRB requesting an exemption, but once an exemption is granted, the IRB need not ever see the research again (Center for Advanced Study *Improving the System for Protecting Human Subjects: Counteracting IRB 'Mission Creep';* CAS, 2006). The problem with treating minimal-risk research as exempt is that such studies are not risk-free. Researchers and institutions need to ensure that risks are adequately addressed. An independent body such as the IRB can make useful suggestions for minimizing risks, protecting confidentiality and interacting with human subjects. It can also provide continuing review and supervision of research, which is valuable when unanticipated problems arise or a study changes course.

Although minimal-risk studies do not call for as much scrutiny as more risky ones, they still require some independent overview. Minimal-risk social-science research, for example, can involve questioning people about sensitive topics such as sexuality, domestic violence or illicit drug use. And in minimal-risk biomedical research, risks may be associated with protecting the confidentiality of genomic samples or data.

A wiser proposal, which has received some attention in the literature, would be to make better use of the expedited review option for minimal-risk research; indeed, the CAS study above notes that IRBs are not making adequate use of this option. In expedited review, the IRB chair or another designated person conducts the review. Studies that are approved are subjected to the same review criteria that are applied to studies reviewed by the full board, as well as receiving continuing review. Expedited review can reduce the administrative burden without compromising the rights or welfare of human subjects.

David B. Resnik National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, North Carolina 27709, USA
e-mail: resnikd@niehs.nih.gov