NIH Funding Mechanisms Need Appraisal

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The National Institutes of Health (NIH) is a jewel among U.S. federal agencies. Its enlightened funding practices, which award scientific merit, are responsible for many of the most spectacular successes of biomedical research in the United States. This pride in NIH's accomplishments should renew the U.S. commitment to review NIH funding mechanisms periodically so that NIH supports the very best research in the most cost-effective manner. I hope to stimulate such an evaluation by presenting my opinions on the relative merits of several granting mechanisms.

Individual Versus Group Grants

The fundamental logic that collects multiple projects under a group grant states, in effect, that the product of individuals working on related projects, if brought together under a group grant, is greater than the sum of its parts. Yet, many superb science departments have prospered with the philosophy that bringing together the very finest interactive individuals studying unrelated problems and organisms with different methods is greater than the sum of the parts. The cohesion and interaction of scientists is, above all, their own responsibility, but certainly more the concern of their department and their university than their granting agency. If diverse groups can be as effective as focused groups, it is reasonable to support individuals on the basis of the quality of their research and reward groups of high-quality researchers that compose a close-knit unit, such as a department, by providing them with shared facilities and equipment by means of a core group grant of the kind that I will describe.

What Should and Should Not be Funded by Group Grants

Group grants should not fund a collection of research projects. Individual research projects should be evaluated and funded separately. If multiple investigators wish to collaborate on a single research project, they can do so as co–principal investigators. Furthermore, administrative components should be allowed only under special circumstances in a group grant. Currently, program project and center grants pay an administrative component out of direct costs. A collection of grants does not justify additional administration beyond what already exists in a department or university and what is supported by indirect costs.

However, group grants should fund the improvement of facilities and the purchase of expensive, multi-user equipment that is shared by multiple, individually funded investigators in a single location. The grants should pay for the purchase of the equipment, renovations needed to house it, and perhaps 3 to 5 years of training and salary for a technician needed to run the facility. These group grants (similar to the current P30 core grants) need not be renewable if shared expenses are allowable on individual (RO1) grants.

The Need for Regional Centers

Material, equipment, and facilities for the conduct of research ought to be divided by cost into those that can be purchased with RO1 grants, those requiring group grants, and those that are too expensive or difficult for a local unit to set up with a group grant and maintain through RO1 grants. I would include in the latter category transgenic mouse facilities and, in some cases, a core facility that includes DNA and protein sequencers and synthesizers for scientists dispersed throughout a particular region. Facilities for animals, with their ever-increasing regulatory expenses, are falling into this category. Many scientists now contract with companies to make antibodies to avoid keeping a rabbit or mouse colony. There is precedent for purchasing or maintaining on a regional basis by contract cell culture centers, extremely expensive equipment such as synchrotrons, and some of the above-mentioned services. Not every institution should be permitted to duplicate every essential but expensive facility. Regional centers paid for on a fee-for-service basis would save money and could even improve the quality of these specialized services. The same service that would be supported by a group grant in one department of a research-intensive university might be provided through a regional center in parts of the country where there are fewer and more dispersed users. Such centers should be reevaluated at least every 5 years to be certain that their work remains of high quality and that the community of users continues to need their services.

MERIT Awards (R37) and FIRST Awards (R29)

Despite all the evidence that researchers become less imaginative and productive as they grow older, most institutes insist on rewarding their most distinguished senior scientists with extended grants called MERIT Awards (Method to Extend Research in Time Awards). I believe that these extended grants cover too much time and that the maximum length of any grant should be 5 years before a competitive renewal is required. If institutes want to reward their most notable senior scientists who receive favorable grant ratings, they should do so with a 5-year renewal, plus a certificate suitable for framing.

The FIRST (First Independent Research Support and Transition) Award, which is reserved for young first-time grantees, is an excellent grant. Institutes can and should fund these at a more liberal success rate than the competitive renewals with which they must compete. According to the *NIH Data Book* (*1*), in 1991 more money was spent on MERIT Awards than on FIRST Awards.

Big Science Versus Small Science

The direct cost of a grant is recommended by the study section, but the actual amount of an award is decided by the institute administration. Two years ago, one institute, the National Institute of General Medical Sciences (NIGMS), decided to take an extra look at any fundable grant that caused a principal investigator to receive more than $500,000 in direct costs in any year. The importance, novelty, and quality of that grant are compared with a grant representing the sole funding for another applicant that just missed the pay line. In 1992, 79% of NIH grantees received just a single grant averaging $140,600 in direct costs. The 5.7% of grantees who received more than $500,000 from the Research Project Grants (RPG) budget alone collected 27% of the total, direct-cost money awarded for research projects. When center grants are combined with RPG awards, 7.7% of all grantees received more than $500,000 and consumed 36% of the combined RPG and center funds. If investigators had been held to $500,000, $400 million or $680 million in direct costs alone could have been reallocated from the RPG or the combined RPG and center budgets, respectively. These figures include the costs of particu-

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larly expensive clinical trials as well as the costs of individual scientists who supervise the research of large groups of graduate students and postdoctoral fellows requiring funding by multiple RO1 and group grants. Important but unavoidably costly studies would not be compromised if every institute applied the NIGMS criteria to big science.

The RFA Mechanism

The request for application (RFA) mechanism at NIH dates back about 10 years. Some institutes do not use it, or use it sparingly, whereas others award substantial fractions of their budgets through RFAs. The decision to target funds to specific research topics is made by the administration of each institute. The assumption behind an RFA is that a particular research area has been ignored and needs the stimulation of set-aside funds. There are specific funds mandated by Congress, such as those used to investigate the cause of and a cure for acquired immunodeficiency syndrome (AIDS), that cannot be spent entirely through the traditional investigator-initiated mechanism. Even in this case, a basic scientist would say that it is impossible to determine from whence will come the next great breakthrough that will lead to a cure for AIDS, thus justifying the use of funds designated for AIDS for related basic research. However, the use of RFAs goes well beyond these special cases and has permeated deeply into the granting system. Basic science topics are now subjects for RFAs in some institutes. Such direction and distortion of research emphasis by the institutes is inappropriate, and this practice should be eliminated.

Training

The various mechanisms used to support training influence the biomedical research enterprise. In two such mechanisms, NIGMS administers the entire Medical Scientist Training Program (MSTP) (M.D.-Ph.D.) program, whereas other institutes use physician-scientist awards (K11) to encourage M.D.'s to enter research after several years of residency. The decision of how and when M.D.'s should be trained for research is certain to have a profound impact on the research proficiency of future leaders in academic medicine. Both training mechanisms have been around long enough for data to accumulate on the success rate of these individuals as independent scientists. The relative value of these two funding mechanisms should be evaluated.

Another valuable group grant is the institutional training grant (T32). The most effective of these grants reward institutions that attract the best graduate students by having the best graduate programs. Graduate education is the final level of training for which competition for support should be left in the hands of institutions. Postdoctoral fellows should compete for individual fellowships (F32) based on their own merit or they should be paid by the principal investigator's grant or home institution. Yet, some training grants support more postdoctoral fellows than they do graduate students.

Clinical Trials

In 1991, the cost to NIH for subsidizing clinical trials was $745 million, an increase of 22% from the cost in 1990 (*1*). Who benefits financially when NIH's imprimatur is given to a drug or a specific treatment regime? Are all of the trials that NIH pays for and supervises appropriate, or should some of these be conducted by the pharmaceutical industry, which stands to benefit from them financially? A clear set of guidelines should be established that describes trials that NIH should and should not conduct.

Study Section Revision

The quality and judgement of the peer-review process is essential to the success of NIH-funded science. A panel of NIH administrators and extramural scientists that was convened as part of NIH's strategic plan last summer made excellent suggestions on how to improve and update the peer-review system. They emphasized the importance of revising periodically the subject matter categories into which grants are grouped and the need to appoint the very highest quality and up-to-date scientific panels and administrators. This process needs an oversight body that relies heavily on active scientists.

There are two kinds of outside committees that advise NIH on extramural policies—the members of study sections and the advisory councils to the director and to each of the institutes. The principle of peer review by study sections of highly qualified scientists is an exemplary use by NIH of the scientific community. Institutes are not required but generally do take the advice of the study sections. The advisory councils to institutes have enormous authority by law. All grants funded by an institute must be approved by a quorum of its advisory council. However, councils do not have enough information, time, or expertise to question the decisions of study sections, so they correctly accept the judgment of study sections on the ratings of grants for funding priority. Councils meet three times a year for a day and a half. An agenda is provided for them, and they leave after rubber-stamping the grant portfolio that the institutes present to them for approval. As they are constituted, these advisory councils cannot provide the kind of ongoing critical evaluation of NIH's funding mechanisms that is needed.

Conclusion and Recommendation

The mechanisms by which research is evaluated and funded have an enormous impact on the quality and cost effectiveness of the scientific product. Currently, these choices rest disproportionately in the hands of the institute administrators at NIH. The relative value of granting mechanisms should be evaluated by a committee that would include not only members of the NIH administration but, more importantly, a broad selection of our country's most distinguished scientists and clinicians.

REFERENCES

1. *NIH Data Book 1992* (U.S. Department of Health and Human Services, National Institutes of Health, Washington, DC, 1992).