governing human subjects protections that would apply to all organizations, public and private, conducting any kind of research involving human subjects. Specifically, subjects who should be covered by these laws include those who "1) are exposed to manipulations, interventions, observations, or other types of interactions with investigators or 2) are identifiable through research using biological materials, medical and other records, or databases."

The two key means of ensuring protection of subjects, the Commission finds, are risk and benefit analysis and informed consent. Regarding the former, NBAC advocates distinction between various grades of risk, from minimal to greater than minimal risk, so that the appropriate level of protection may be provided to the subject. When considering the issue of informed consent, they stress that laws should focus on the "process . . . rather than the form of its documentation."

To ensure that these goals are met, the report goes on to propose that Institutional Review Board (IRB) members be required to undergo certification and that institutions conducting or reviewing research involving human subjects should be required to obtain accreditation. Also, criteria should be developed for the selection of IRB members, and at least 25% of the members of a given IRB should be those "who represent the perspectives of participants, . . . who are unaffiliated with the institution, and . . . whose primary concerns are in nonscientific areas."

Although most of the recommendations made by the Commission are concerned entirely with the welfare of the patient, at least one suggested measure would benefit the researcher: the allowance of a single "lead" IRB to provide review of a study conducted at multiple institutions.

A hearing scheduled for May 23 by Senator Bill Frist (R-Tenn), Chair of the Senate Subcommittee on Public Health, to discuss human subjects concerns was cancelled because of a scheduling conflict with a vote on Bush's tax cut package, sources say. The NBAC report would likely have been a key topic. The hearing had not been rescheduled as of the time this article went to press.

Letters to Kirschstein Voice Concerns Over Implementation of Loan Repayment Program

Two letters sent in April to Ruth Kirschstein, Acting Director of the National Institutes of Health (NIH), express concern over reports that the NIH planned to exclude non–NIH-supported researchers and trainees from the eligibility criteria for application to the loan repayment program established by the Clinical Research Enhancement Act (CREA), which was signed into law late last year.

Kevin O'Brien, AFMR President, in his letter dated April 25, and House Representatives James C. Greenwood (R-Pa), Nita Lowey (D-NY), Nancy Johnson (R-Conn), and Sherrod Brown (D-Ohio), in their letter dated April 18, objected to a policy that would make clinical investigators and trainees who are funded by other Federal agencies or private organizations ineligible to apply for the loan repayment awards.

Regarding the exclusion of researchers funded by sources other than the NIH, Representatives Greenwood, Lowey, Johnson, and Brown emphasized that this was not intended by the Congress.

Dr O'Brien's letter took particular issue with a policy that would exclude students/trainees in advanced degree clinical research programs, most of whom do not receive support from the NIH and would be ineligible, therefore, to apply to the loan repayment program. As Dr O'Brien states, "The availability of the loan repayment incentive will strengthen the ability of programs to attract students to participate in the type of didactic training most likely to produce a successful investigator."

In discussions with senior NIH officials, Dr O'Brien expressed support for efforts to assure that clinical research tuition loan repayment funds are allocated wisely. He emphasized that, rather than strict limits on the potential pool of eligible applicants, the focus should be on establishing an appropriate review process that will discriminate between those most worthy of the awards and those who are less likely to pursue productive careers as clinical investigators.

The NIH is continuing deliberations regarding application criteria for the clinical research loan repayment program and expects to announce the availability of awards some time in July.