NIH may choose to award title to another party or to license the invention itself. The committee wants a clearer definition of circumstances in which NIH might exercise this "march-in right," as it is called by patent attorneys.

Industry is apparently troubled by the provision because it has no certainty that a title to an invention it nursed through the research stage is protected if the patent remains undeveloped. Hutt said that industry needs assurances that its investment is secure. NIH has never used the march-in right, although it has brandished it on occasion to prompt action on a patent.

Setting aside the issue of patent policy, the advisory committee was worried about NIH's investment in academic research on yet another front and pondered how much the government should pay for indirect costs on research grants. The question is age-old, but, as NIH appropriations remain level, the agency wants to make sure that its money is being used for research rather than for university overhead costs or activities unrelated to research, such as curriculum development.

Fredrickson said that NIH may decide to pay a flat sum for total costs, rather than continuing with the current policy of placing a cap on indirect costs, and let researchers and campus administrators figure it out for themselves how to divide up expenses. Joseph Perpich, associate director of program planning and evaluation, predicts that there may now be some movement on the issue because of the new Administration's general belt tightening. One of the most vulnerable areas is departmental administration costs, which cover student and faculty recruitment, lecture series committees, and budget committees.

One proposal that the advisory committee is weighing that might enhance the quality of research is a grant system called a fixed obligation grant (FOG). Fredrickson said, "I'm beginning to glow about this. I think we may have something."

Such a grant would eliminate time-and-effort accounting by researchers, and the work would be graded on technical reports submitted periodically. The new system would also allow spillover of grant money from one year to the next to prevent the spending sprees with left-over federal money at the end of each fiscal year. The forecast is unclear if or when the FOG will roll into the nation's campuses.—MARJORIE SUN

Team Research: Responsibility at the Top

A debate develops over whether senior scientists should answer for the misconduct of junior colleagues

Few precepts of laboratory ethics seem more straightforward than the notion that a scientist should take responsibility for his research, accepting both praise and blame.

It is therefore noteworthy that a minor debate has emerged during the past year over whether a senior researcher should be held responsible for the work of junior members of a research team, especially for unethical work. So far, there seems to be anything but consensus.

In sharp contrast, the sharing of rewards is governed by long-standing tradition: it is common practice for a senior researcher to share coauthorship even when his specific contribution is more inspirational than substantial. An emerging debate over risk and reward for senior researchers may bode ill for collaborative research. Junior researchers joining the debate have voiced strong grievances.

The responsibility debate, overheard at various hearings called by presidential commissions and in Congress, was touched off by reports of misconduct and data falsification in collaborative research. Perhaps one of the more noted incidents centered on responsibilities of Yale senior researcher Philip Felig for the data falsification of a junior colleague (*Science*, 3 October 1980, p. 38). The dimensions of the debate at this point are quite broad: issues include how much responsibility a principal investigator should take for patient welfare in clinical studies, for the integrity of data in a multi-authored paper, for the integrity of data generated by research aides who may not have a stake in the publication process, and so on. Effects of the debate may be far reaching. The explosive growth of collaborative research in the postwar era has brought with it a variety of organizational tensions that are not as a rule examined in public. However, as federal officials and deliberative bodies make recommendations on how to avoid some of the ethical and administrative tangles that have recently emerged, what heretofore has been informal by way of dividing up various responsibilities in the lab might well be mandated by law.

The responsibility issue was most recently debated at a special meeting in Boston of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The focus was the case of Marc J. Straus (*Science*, 19 June, p. 1367). In 1978 Straus was the principal investigator of a large research team at Boston University (BU) that submitted falsified data to a multi-institutional clinical study. Team members reported the misconduct to BU officials and said they falsified patient data on orders from Straus and because of "general anxiety" that there might be a shortage of statistically acceptable patients for their studies. Straus denied the charges and quit the school.

Publicly commenting on the case for the first time in 3 years, Straus at the hearing differentiated realms of responsibility. He said he took "full responsibility" for all aspects of patient care, but that paper work was a different story. "We had 40 full-time people, including eight nurses and data managers, and we had a series of very good checks and balances. . . . [But] there are certain types of studies that are almost beyond the ability for absolute surveillance. . . . You must rely on the integrity of people who are going to fill in those multiplicity of little boxes correctly. . . . There is a certain level of surveillance in any operation, medicine or otherwise, that requires the belief that the persons under you are acting properly."

Straus's attorney, Andrew Good of Boston, lamented the lack of uniform and clear federal guidelines on the responsibility issue. Good noted that the case is currently under investigation by the Food and Drug Administration and the National Institutes of Health, and

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said there was a "dire need" for federal statutes on the liability of a principal investigator. This was necessary for "people in the field, and so that . . . [in dealing with] these problems we all know what rules we are operating with."

The President's commission has also noted the lack of clear statutes on these issues, and in September 1980 commission chairman Morris B. Abram wrote to the Secretary of the Department of Health and Human Services, asking for clarification. The commission has yet to receive an answer.

For at least one witness, there was no question about the lines of responsibility. Robert J. Polachwich, a physician on the Straus team who had reported alleged misconduct to BU officials, had a short response to a long question about the extent to which a principal investigator should be held responsible for data entered or for the actions of junior people on his research team. A senior investigator, he said, "should be held responsible."

One place where unambiguous statutes on investigator responsibility do exist is at the state level, according to James F. McDonough, chairman of the Massachusetts Board of Registration and Discipline in Medicine. Testifying at the commission hearing, he said that in Massachusetts a principal investigator on a clinical research project is held responsible for the conduct of aides. One result can be the cancellation of the certificate of registration which allows a physician to practice in the state. He also testified, however, that because of a lack of funds, the board is not actively investigating the Straus case, and is waiting for the decision of federal investigators. In any event, the board no longer has authority over Straus, who is a clinical oncologist at the New York Medical College in Valhalla.

Arguing that a principal investigator should be held accountable but not absolutely so was Kenneth J. Ryan, of Harvard Medical School and the former chairman of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the predecessor committee to the President's commission. Ryan drew the analogy of a president of a large company who discovers that an accountant is fudging the books. "Do you blame the president?" he asked, and then followed with a long list of questions to further define a president's responsibility. "Did he exercise care in the selection of personnel for this activity, and were they properly instructed? Were appropriate audits made? How often? Did the president, or the principal investigator if you will, keep up to date on what was going on? . . . It becomes almost Machiavellian in terms of what one would expect a principal investigator to do."

Commission member Albert R. Jonsen, of the University of California at San Francisco, noted that principal investigators usually have to "ad hoc it when it comes to devising an accounting system to carry out their responsibilities" and wondered if a written, standardized system might not be better. Ryan responded that this is precisely the duty of a group that sets up a multicenter study (such as the Eastern Cooperative Oncology Group, to which the Straus team had submitted bad data). "They ought to get together and set up protocols so the types of controls, the surveillance of data, and the input is standardized within all the institutions and very rigorously controlled. They are going to discredit their entire enterprise if they don't do this." Further, if these responsibilities were more clearly spelled out, Ryan said, it would be easier to determine whether a principal investigator had been "innocently wronged" by a data-fudging junior colleague. Jonsen agreed with this recommendation, saying that an incident "like the Felig case at Yale would be dealt with by Dr. Felig assuring that he had fullfilled all of his responsibilities, and the falsification that took place was something that he had no control over."

> "It becomes almost Machiavellian in terms of what one would expect a principal investigator to do."

The case of Philip Felig and the falsification of data by a junior associate of his at Yale has thrown some of the responsibility issues into high relief. At a recent congressional hearing, Felig himself testified about some of the responsibilities he may have neglected, and made some general recommendations about how to avoid such pitfalls.

The problems for Felig started when he coauthored a paper with a data-fudging junior associate, Vijay Soman. Felig claimed no responsibility for the finagling, but a faculty committee at the Columbia College of Physicians and Surgeons, where Felig had taken up a senior faculty position, forced his resignation when they learned of the details of the Yale affair. One of their complaints was his handling of the responsibility issue. "In conversations with the Committee," they wrote in a seven-page single-spaced report, "Dr. Felig has mentioned that he was not fully conversant with the methodology of Dr. Soman. The committee cannot accept this as an excuse. The tenets must be upheld that a principal investigator has responsibility for the research in his laboratory, and he should not co-author without understanding and taking responsibility for that paper."

Felig in a written response charged the committee with holding false standards. "The committee is, in fact, applying a standard to which they do not subscribe. I have published a paper (in *Diabetes*) with Dr. [Keith] Reemtsma, a member of this committee, in which my laboratory provided plasma glucagon measurements. Dr. Reemtsma never discussed the methodology with me nor would I expect him to fully understand it."

Testifying this spring at a House hearing, Felig, who after the tempest returned to Yale, said in principle he now agrees with his critics at Columbia on this point. "When a senior scientist is not too familiar [with the techniques of a junior researcher], he or she should exercise even greater care in reviewing the original data . . . or his or her name should not be included on the paper. I further deem it advisable that consultation from outside experts be sought before permitting the material to be published with the senior scientist's name."

Needless to say, if Felig's suggestion were taken to heart it would revolutionize the oftentimes more informal ways that senior researchers verify the validity of methods with which they are not familiar. Whether this outside review would be a healthy development or an unseemly encumbrance to the already complex process of publishing will no doubt be debated in the coming months. In any event, an examination of this and other questions in the arena of responsibility cannot help but clarify issues that have been raised by the explosive postwar growth in collaborative research and the concomitant rise in coauthorships. Clarification is important, since these issues lie at the heart of the research enterprise.—WILLIAM J. BROAD