since 1997. Martínez-Alonso told *Nature Medicine*, "We recommended restructuring and the introduction of new equipment such as a confocal and laser microscopy as well as updating genomics, proteomics and cell biology programs." And Costa explained, "Evaluations by external scientific advisory boards are rather new to Spanish institutions and represent a change in culture. I expect it will take some time for all those concerned to learn how to respond and benefit from constructive criticism."

Félix Rueda, one of the scientists facing the sack, says that a few days after the evaluation ended, eight of the thirteen researchers at the center were told "without notice" that they had to leave. According to Rueda, he and his colleagues were not told how well each program had performed in scientific and economic terms. "The sackings would have meant the closure of publicly funded projects, some of which had been positively evaluated and approved by the National Agency of Evaluation and Prospective," he adds.

Projects to be terminated included the development of anti-tumor vaccines, cancer immunology and genetics, metastasis research and research on leukemias and lymphomas. "Sacking of the 8 scientists would also have meant a net loss of 30 people among staff, fellows and lab technicians," claims Rueda.

He says that so far the board of directors has not explained what the new direction of research will be, apart from a division into two fundamental groups: Molecular Oncology and Molecular Genetics. He says "the research staff does support a redefinition of the institute's objectives," but requests the introduction of "a new internal committee which can work with the research director and the external evaluation panel to restructure current programs without job loss."

Borrás admits "there were problems of internal coordination of research at IRO, including some inequalities in access to internal funds, which was based mainly on historical, and not scientific, criteria." He points out that, as a result of the evaluation, "non-productive and non-innovative lines will be rationally restructured," and is planning to appoint a director for the new department of molecular oncology. He says he will now reorientate the main fields of research to create a more unified department of molecular oncology.

Xavier Bosch, Barcelona

UK speculated to permit stem cell research

After protracted delays, Britain's government finally looks set to allow research on stem cells with the aim of developing treatments for spinal injury, diabetes and other diseases. A chorus of scientific bodies has advised ministers to permit the use of these cells, taken from embryos or from fetal tissue, to explore techniques for future therapies, arguing that the potential benefits outweigh any remaining ethical concerns.

The report of an expert group set up by the government last August to weigh the pros and cons of therapeutic cloning was known to be complete as *Nature Medicine* went to press. A national newspaper seemed

to have been leaked information that the government was about to give therapeutic cloning the go-ahead, but a health department official insisted that ministers had not yet seen the expert group's report and would say only that an announcement would be made "within weeks," and that the newspaper report was "speculative."

But no one seems willing to deny the newspaper article. Sir Robert May, the government's Chief Scientific Adviser, and a member of the expert group, refused to say more about the report but made his personal views clear: "We ought to be pursuing the kind of stem cell research that in the

New measures introduced to monitor gene therapy trials

James M. Wilson, director of the Institute for Human Gene Therapy (IHGT), which made headlines last year for operating a clinical trial that involved the first-ever death of a patient due to gene therapy (*Nature Med.* 6, 6; 2000), has responded to the Food and Drug Administration's (FDA) January shutdown of his institute's eight clinical trials by reorganizing his institute to ensure compliance with FDA requirements.

Chief among the changes at the institute is the hiring of a clinical research organization (CRO), Parexel International, to monitor procedures and documentation of all its future gene therapy trials. IHGT will also hire a chief operating officer to be in charge of clinical trials, toxicology and vector manufacture. And standard operating procedures have been established for amending investigational new drug protocols, confirming trial participant eligibility and ensuring informed consent—all matters criticized by the FDA.

IHGT will not be the only gene therapy organization to reexamine its monitoring procedures. The FDA recently announced that all gene therapy trial sponsors will be routinely required to submit their monitoring plans for inspection. Plans for monitoring clinical trials are already required of sponsors, but now the FDA will begin examining them for adequacy and completeness.

Clinical trial monitoring has become a hot topic of conversation among academic gene therapists. Hiring a CRO, as IHGT is doing, or as the pharmaceutical industry does routinely, is beyond the means of an individual university investigator. According to leading gene therapist French Anderson, some medical schools are considering hiring CROs to inspect all trials, including gene therapy trials, taking place at their institutions. Anderson suggests CROs are not necessary for all academic trials, but that every academic investigator needs to appoint someone to monitor procedures.

In another effort to improve the safety of gene therapy, FDA announced it is stepping up on-site inspections of clinical trials to make sure they are being adequately monitored. The NIH, likewise, is planning site visits; the NIH wants to be sure investigators understand its reporting requirements for gene therapy-related adverse events. The NIH intends to complete a database of these events by the end of the year.

The database remains controversial, however, because some investigators are not yet convinced the data will be organized so that meaningful information can be extracted. The FDA and NIH have joined hands for another safety initiative—a series of Gene Transfer Safety Symposia, to be held at meetings of the NIH's Recombinant DNA Advisory Committee or the FDA's Biological Response Modifier Advisory Committee. The symposia are planned as a forum for investigators to discuss matters regarding safety monitoring, gene therapy side effects and good clinical research practice with different types of gene therapy vectors.

A senior FDA official says that when the FDA is satisfied it has a complete response to all issues raised by its inspection of the Gelsinger trial, it will consider reopening the institute's clinical trials.

Tom Hollon, Bethesda