# NIHRAC proposes faster gene-therapy reviews

Faster reviews will allow NIHRAC to focus on the "sticky issues and the difficult protocols."

WASHINGTON, D.C.—During its March meeting, the National Institutes of Health Recombinant DNA Advisory Committee (NIHRAC, Bethesda, MD) recommended a new approach to streamlining the review of gene-transfer protocols, many of which are now considered routine. The NIHRAC also recommended approving six gene-transfer protocols, including four for cancer patients, one for individuals with AIDS, and one for individuals with an inherited deficiency of alpha-antitrypsin, a deficiency that can lead to emphysema. Of these six protocols, NIHRAC officials note, two might have been approved more expediently had the new accelerated-review process been in place.

The NIHRAC's recommendations for streamlining the review of gene-transfer protocols will take effect as soon as NIH Director Harold Varmus approves them, says Nelson Wivel, director of the NIH's Office of Recombinant DNA Activities (ORDA, Bethesda, MD). The revised system will "allow the committee to focus on new developments—the sticky issues and the difficult protocols—instead of spending time on straightforward applications," says Wivel, adding that streamlining is "the only way for the committee to survive as the number of protocols keeps increasing." Wivel notes, moreover, that these efforts may free up some of the committee's time to again consider the question of procedures involving germline genetic changes.

Among the NIHRAC recommendations for speeding the review of gene-transfer protocols is a scheme for the ORDA staff to follow in classifying such protocols. Under this scheme, the ORDA could approve some gene-transfer protocols for accelerated review without taking them to the full NIHRAC, although the ORDA could consult with various NIHRAC members before going ahead with such approvals. In all of these cases, though, the ORDA would provide a report of its actions at the next NIHRAC meeting.

The NIHRAC also recommended several categories of gene-transfer protocols for accelerated reviews. Protocols that involve lethally irradiated tumor cells and that do not use replication-competent viruses will qualify for simplified review. In addition, gene-marking procedures where gene-transfer techniques are used in an analytical, rather than a therapeutic, capacity are eligible for streamlined review.

Some NIHRAC recommendations dealt with simplifying administrative procedures. Previously, when an investigator moved to a different university, his or her gene-transfer application required another full NIHRAC review. Similarly, if investigators at different institutions wanted to collaborate in conducting a multisite gene-transfer protocol, each of them needed separate, full NIHRAC reviews. The new scheme eliminates those cumbersome practices. **—Jeffrey L. Fox**