warranted". Designed to allow companies such as Novartis to import transgenic pigs, this loophole could lead to use of virus-laden wild animals, says Allan.

The document does not go into detail on the viruses that need to be considered in risk assessment, or species-specific differences, leaving this for the FDA to consider for each protocol. Difficulty in assessing the risk is the major caveat to proceeding. Although the guidelines emphasize the need to assay tissues for viruses, in reality most new viruses are only detected after the event.

Most research on pig viruses has focused on those that cause losses to pig farmers. Little is known about viruses, such as herpes and retroviruses, that cause low-lying infections that might be dangerous to humans.

"I still worry about the infectious disease risks," says Allan. "But if there are promising therapies, such as pig neuronal cells to treat Parkinson's disease, that could benefit millions it changes your notion of how to go forward." Such cells may be less dangerous than whole-organ transplants. But more work is needed to develop primate models for viral infection.

Abdullah Daar, a surgeon and bioethicist at Sultan Qaboos University in Oman, says the new guidelines are "much tougher", but is sceptical as to how they will be implemented. They require sponsors of trials to ensure informed consent of patients, their families and close contacts, for example, and long-term surveillance of subjects. But several observers doubt that this is feasible.

The PHS also recommends that blood and tissues samples and all records of trials be kept for 50 years. Salomon wonders who will pay for such a proposed national database: "Industry will be reluctant, and there is certainly no evidence that the FDA could budget such a project."

"The PHS is determined to go ahead with clinical trials, but if we are putting the public at risk then broad public consultation is needed, and not decisions by experts," says Fritz Bach, a xenotransplant researcher at Harvard Medical School, Boston, who has called for a moratorium on trials.

But André La Prairie, an official at Health Canada, the country's equivalent of the FDA, says that "the guidelines are a clear message that limited controlled trials in xenotransplantation will continue". ■

... and sets up a body to oversee trials

Paul Smaglik, Washington

The US Department of Health and Human Services is to augment the panoply of government regulatory bodies by setting up a Secretary's Advisory Committee on Xenotransplantation (SACX) to oversee the technology.

The new committee will review proposed clinical trials and monitor ongoing trials, much as the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH) endorses novel gene-therapy protocols and monitors 'adverse events' in trials already under way.

But the role of the SACX in deciding which trials go ahead remains unclear. "There's been no decision yet on how it will work in terms of reviewing protocols," says Mary Groesch, a policy officer at the NIH's Office of Biotechnology Activities who is handling nominations for the SACX.

The Food and Drug Administration (FDA) will have the final say in approving clinical trials. In gene therapy, it is the NIH director, and ultimately the FDA, which has the last word.

In the early 1980s, the RAC approved the first human clinical gene-therapy trial. By the 1990s, its responsibility was restricted to approving new types of protocol (see *Nature* **384**, 297;1996).

More recently, some critics have called for the RAC to stop examining new protocols altogether to focus on education, as the oversight of gene therapy by both the FDA and NIH has led to confusion, especially over reporting adverse events.

Researchers hope that, by sticking to a narrow mission, the SACX will attract less critical flak than the RAC. ■