

day's more invasive methods. Clinical developments are still a long way off, however, cautions Nancy Brackett, a neuroscientist who works with men with spinal cord injuries at the University of Miami School of Medicine in Florida.

All the same, the study is certain to stimulate more research from scientists curious about sex. One intriguing line of investigation: What do LSt cells do in females? "It's a great question," Coolen says. "That's a study we're planning to do."

—GREG MILLER

## HUMAN SUBJECTS

### Ethicists Fault Review Of Children's Study

The ethics panels that assess proposed experiments on human subjects by U.S. researchers traditionally operate behind closed doors. A recently dusted-off federal rule governing certain children's studies is opening that process to the light of public review, however, and some bioethicists don't like what they see.

The specific rule involves studies in which healthy children would be exposed to greater than minimal risks. Under a 19-year-old standard, a university's Institutional Review Board (IRB) must pass such a research hot potato to the Department of Health and Human Services (HHS), which then seeks advice from an expert panel. Last year HHS's expert panel, acting on the first of what appears to be a new wave of such proposals, opted to allow a group of healthy Japanese-American and Caucasian children to be exposed to above-minimal-risk procedures, such as the use of a catheter for glucose tests. The children would be studied because Asian Americans are believed to be at elevated risk for developing type II diabetes around puberty.

On 7 August the responsible HHS agency, the Office for Human Research Protections (OHRP), put out a request for public comments on its proposal to proceed, but some bioethicists believe that the agency isn't giving the public enough time or information. "The way this has been handled is atrocious," says Robert Nelson, who oversees ethics reviews at The Children's Hospital of Philadelphia.

HHS had previously been sent only two studies under the rule, 45 CFR 46.407. But the cancellation of a National Institutes of Health study on obesity in children nearly 2 years ago (*Science*, 17 November 2000, p. 1281) led OHRP to clarify the rule, and seven such studies are now in the pipeline, accord-

ing to OHRP spokesperson Pat El-Hinnawy. A 1998 law requiring companies to test drugs on children might be a contributing factor, along with added caution by IRBs.

Shining more light on the IRB process is good, says medical ethicist Loretta Kopelman of East Carolina University in Greenville, North Carolina, especially given recent shutdowns of trials at several institutions (including the University of Washington, which proposed the diabetes study). Kopelman says that openly discussing the study could help explore questions such as what risks to children are acceptable, and when the overall benefits to society from research on healthy children outweigh the risks to individuals. Such issues are not aired often, because IRB reviews normally remain confidential.

Kopelman and others are sharply critical of how OHRP is seeking comments, however. The notice says the expert panel's summary report is available upon request but doesn't



**No pain, no gain.** Government panel weighs value of performing procedures such as imaging on healthy children.

offer anything else—such as individual panelists' reports or the protocol. Of 10 comments received by OHRP, three viewed by *Science* called for more time and more sharing of information. "What gives moral credibility to [rule] 407 is the public nature of the discussion," and "a 2-week comment period falls far short," says Nelson, who was a member of the panel that reviewed the University of Washington study.

The protocol is available under the Freedom of Information Act, but some have suggested that OHRP should post it on the Web. IRBs consider protocols confidential, notes Mary Faith Marshall of the University of Kansas Medical Center in Kansas City, because they usually haven't received federal funding, and they contain information that could be used by a competitor.

The OHRP spokesperson declined to say how the agency plans to proceed once it has finished reviewing the comments. The rule sets no time period for a final decision.

—JOCELYN KAISER

## ScienceScope

**Stem Cell Slowdown** Australian scientists will have to wait a little longer for national legislation endorsing research on human embryonic stem (ES) cells. Researchers had hoped that federal legislators would finalize a long-debated law (*Science*, 12 April, p. 238) by the end of August, but the Senate last week ordered another committee review, delaying action until at least December.

The delay won't disrupt existing research, scientists say. But "we really do need the endorsement of the legislation to get on with our work," says cell biologist Martin Pera of the Monash Institute of Reproduction and Development in Melbourne and chief science officer of the new Centre for Stem Cells and Tissue Repair. The bill would ban human cloning but allow researchers to use and derive certain human ES cell lines.

Researchers are cautiously optimistic that the bill will pass this year. But if it fails, at least three of the nation's six state governments—which have the power to regulate health research—have vowed to enact similar laws.

**It's in the Mail** U.S. efforts to implement a major new bioterrorism law have hit a glitch—infuriating some university officials who are scrambling to meet a looming deadline. Under the law, universities and thousands of other facilities must notify the Centers for Disease Control and Prevention (CDC) in Atlanta by 10 September if they possess any of about 40 potential bioterror agents. But when a CDC contractor mailed out 190,000 special notification forms earlier this month, it somehow missed the nation's 3000 or so colleges and universities—one of the major targets of the law.

"Given more time, we certainly could have had a more accurate list," the contractor, Analytical Sciences Inc. of Durham, North Carolina, told academic officials in a note posted on an Internet bulletin board. It promised to have the forms—which are printed with special machine-readable ink and paper—in the mail to academia by this week. But if one doesn't show up, the company advises campus officials to "go looking for it!"

The oversight "is helping making a hard job for universities even more confusing and difficult," says Cheri Hildreth, who is managing compliance for the University of Louisville, Kentucky. Even institutions that don't get the forms, she notes, could face penalties for missing the deadline. Help seekers can call 866-567-4232.

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