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Japan's embryo experts beg for faster ethical reviews

TOKYO

Zealous review committees are crippling Japanese research on human embryonic stem cells, according to a plea about to be lodged at the country's science ministry.

Japan is a world leader in embryonic stem-cell research involving mice and monkeys, but work involving human cell lines is another matter. That is because review committees regularly take far longer to approve such projects than other countries do, researchers charge.

Norio Nakatsuji of Kyoto University will send anecdotal data about Japan's lag to the science ministry this month, with a request to simplify the system. "We cannot wait long, because already Japan is greatly behind other countries," he says.

In 2001, Japan decided to allow research on human embryonic stem cells and issued guidelines for researchers. Three years later, Nakatsuji, who created all three of Japan's current cell lines, began distributing them. Yet so far only 15 laboratories in Japan work on human embryonic stem cells. In a rough survey of the scientific literature for 2004 and 2005, Nakatsuji found that, of 259 papers with titles mentioning human embryonic stem cells, only three had Japanese first authors. The United States had 90 first authors and Britain had 25.

Scientific expertise with stem cells does not seem to be the problem. Japanese researchers account for more than a quarter of first authors on the 204 papers involving mouse embryonic stem cells, and more than a third of the 21 involving primates that Nakatsuji looked at. There is also no lack of funding — for example, the Ministry for Economy, Trade and Industry recently promised annual sums of ¥250 million (US\$2.1 million) for the next five years to investigate the use of human embryonic stem cells in clinical work.

Nakatsuji blames the review process, which requires approval first by an institutional review board (IRB) and then by the science ministry.

Last month he sent an informal questionnaire to 20 researchers, all of

whom complained of the time-consuming approval process, which averaged 12.5 months. Most vexing, it seems, were the questions about researchers' personal beliefs. "The boards want to know exactly how important you think the cells are. It's as if they have a soul, but they are just a bunch of cells in culture," Nakatsuji says.

"The people on the IRB seem to think of the cell lines as just as sacred as the embryos used to establish cell lines," adds Issei Komuro, a cardiovascular specialist at Chiba University. It took a year for his review board to tell him that he needed to exhaust all relevant mouse and monkey studies before moving on to humans. Eventually he gave up his plans and

decided to stick with mice.

"Review boards want to know exactly how important you think stem cells are — as if they have a soul."

Researchers contacted in other countries, where there is usually only one level of approval, say it generally takes a fraction of the time — two to three months in Singapore, South Korea,

Australia and Britain. In the United States, despite its reputation for restrictive policy, approval to work with permitted stem-cell lines can take as little as a few weeks.

Officials at Japan's science ministry say they are trying to improve the system. "Ministry guidelines were not clearly communicated to the institutional review boards," says Yasuhiko Ishii, director of the ministry's bioethics and biosafety office. At a meeting on 11 November he says officials discussed ways to streamline the process. They also decided to make it clear that thorough monkey studies are not always necessary before moving to human cells. "We don't want to be an obstacle to research," says Ishii. "But we need to know that proper ethical considerations are being made."

Meanwhile, Nakatsuji, who is co-hosting an international symposium on embryonic stem cells in Kyoto this week, is undeterred. He plans to create ten more human embryonic stem-cell lines in the next year, and to build a cell-processing centre to produce clinical-grade lines in the next five years. ■
David Cyranoski

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REASONS

Korean scientists are calling for an independent investigation, but it is not clear whether this will happen (see page 257). In the meantime, researchers are left wondering what caused Schatten's sudden change of heart.

Until recently, Hwang and Schatten had been getting on famously. "They seemed as close as they could be," says Hyun, who spent this summer studying the Korean team's ethical practices. "Gerry kept referring to Dr Hwang as his brother, and Dr Hwang's public toast to Gerry at a formal dinner was so effusive, it was almost embarrassing."

Eggen adds that just last week the two were as chummy as ever at a conference in New York. "They seemed to have every intention of continuing to collaborate in the future," he says.

Evan Snyder, a neuroscientist from the Burnham Institute in La Jolla, California, says that he received an e-mail from Schatten just before he issued his statement. "Whatever prompted this he found so exceedingly disturbing, he could not sit on it," says Snyder. "You have to realize this is a major part of his research programme as well, so to do something this precipitously, it must have been terribly shocking." ■

David Cyranoski and Erika Check