

New international guidelines for stem cell science

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The first international guidelines on human embryonic stem cell research, released on Thursday, echo public opinion in calling for a ban on human reproductive cloning. But they are already proving controversial in other angles.

Although the guidelines are not legally binding, they carry the weight of leading scientific opinion and are likely to be influential in many countries.

Written by a committee of leading stem cell scientists, the guidelines take a permissive stance on two key issues: paying women to donate eggs for research, and controls on projects involving human/animal chimeras.

Guidelines issued in 2005 by the US National Academy of Sciences (NAS) and laws in other countries, including the UK, prohibit using cash payments to induce women to donate eggs for research. But the new guidelines, issued by the International Society for Stem Cell Research (ISSCR), suggest that the question of payments should be left to local ethical committees.

"It's unfortunate that the ISSCR is choosing to water down what was becoming a *de facto* international standard of prohibiting the payment of women for eggs," says Jesse Reynolds, project director for biotechnology at the Center for Genetics and Society, an advocacy group in Oakland, California, US.

Cultural differences

However, George Daley, a stem cell biologist at the Children's Hospital Boston, US, and co-chair of the task force that drafted the new guidelines, argues that political and cultural differences between countries are too great to make a blanket global statement. The distinction between financial inducement and reimbursement for expenses is difficult to make, Daley notes.

"What you need to focus on is not the amount of money changing hands, but rather how the financial consideration is affecting the decision the woman goes through," Daley says. "If it would make [the potential donor] trivialise any of the risks then it constitutes an undue inducement."

Egg donation for stem cell research is a controversial issue, especially in light of the scandal involving Woo Suk Hwang's research on stem cell cloning in South Korea. Egg donors in that study were paid in spite of national laws prohibiting the practice. "It shows that guidelines and laws are not enough. You need effective oversight," says Reynolds.

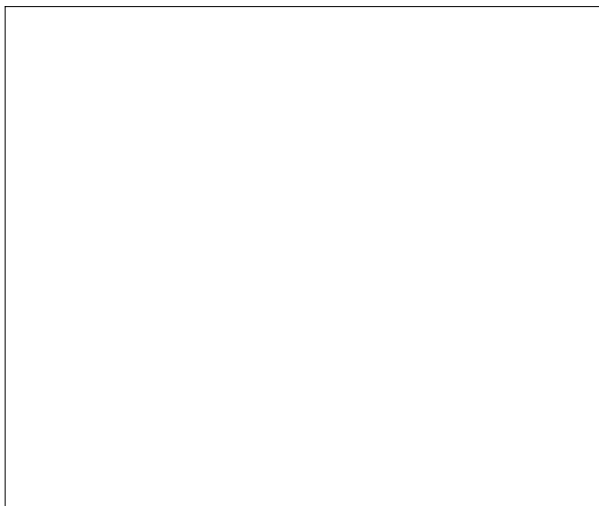
Mating chimeras

The ISSCR guidelines also diverge from those issued by the NAS on the subject of creating chimeras by injecting animals with human embryonic stem cells. This is necessary for testing potential stem cell therapies. But if injected early in an animal's development, the cells could differentiate into any tissue, including ovaries and testes.

Both the NAS and the ISSCR want to prohibit mating chimeras with each other for fear of accidentally creating a human embryo inside an animal. But the NAS guidelines also oppose mating them with non-chimeras (see *Half human half beast*). The ISSCR calls for strict local review of these types of experiments, but does not rule them out. "You need to figure out a way to write guidelines that maintain flexibility so the science can evolve," Daley argues.

The UK Human Fertilisation and Embryology Authority is currently drafting regulations on research involving human/animal chimeras. It is expected to take a stance similar to the NAS, and its rulings will be enforceable by law.

David Magnus, a bioethicist at Stanford University in Palo Alto, California, US, believes the ISSCR missed an opportunity, by revisiting the same topics covered by the NAS. He wishes the guidelines



addressed other developments, such how to regulate clinical trials of new therapies: "It would have been nice if they had tried to break new ground."

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