NIH approves 13 embryonic stem-cell lines for funding; more expected

WASHINGTON – Thirteen human embryonic stem-cell lines have been approved for use in federally funded research and approval of many more lines is expected to follow, the head of the National Institutes of Health announced Dec. 2.

Dr. Francis S. Collins, who took over as NIH director in August, said in a telephone briefing with the media that it was a "significant day" in the efforts to achieve President Barack Obama's goal of "a loosening up of what had been considered too stringent requirements" for federal funding of research involving human embryonic stem cells.

Collins said the 13 stem-cell lines – 11 developed at Children's Hospital Boston and two at Rockefeller University in New York – were approved after NIH staff determined that the scientists who created the lines had followed the "very detailed informed consent process" outlined in NIH guidelines published in July.

"In accordance with the guidelines, these stem-cell lines were derived from embryos that were donated under ethically sound informed consent processes," said Collins. "More lines are under review now, and we anticipate continuing to expand this list of responsibly derived lines eligible for NIH funding."

When the final guidelines were published July 7, Cardinal Justin Rigali of Philadelphia, then chairman of the bishops' Committee on Pro-Life Activities, said they ignored the comments of tens of thousands of Americans who expressed opposition to embryonic stem-cell research during the public comment period and failed to respect "existing federal law against funding research in which human embryos are harmed or destroyed."

Collins said 20 more stem-cell lines could be recommended for approval as early as Dec. 4, when the Advisory Committee to the Director meets. Along with the external

Working Group for Human Embryonic Stem-Cell Eligibility Review, the advisory committee is charged with deciding whether certain cell lines created before the guidelines were developed meet the core principles of voluntary informed consent.

The guidelines allow the use of federal funds for embryonic stem-cell research only on embryos created for reproductive purposes at in vitro fertilization clinics and no longer needed for that purpose. They specifically ban funding for "research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis and/or IVF embryos created for research purposes."

Also prohibited is funding of research in which stem cells "are introduced into nonhuman primate blastocysts" or research "involving the breeding of animals where the introduction of human embryonic stem cells or human-induced pluripotent stem cells may contribute to the germ line."

Among the requirements for informed consent set by the guidelines are:

– No payments for donated embryos.

– "All options available in the health care facility where treatment was sought pertaining to the embryos" have been explained to the donor or donors.

– The researcher must not influence donors' decisions and should not be the same person as the attending physician "unless separation was not practicable."

– Donors must be told that the embryos will be used for stem-cell research, that the donors will receive no commercial or direct medical benefit from the donation, that the embryos may be kept for many years and that they can withdraw consent at any time until the embryos are used.

When he announced the final NIH guidelines in July, Dr. Raynard S. Kington, then NIH acting director, said 30,000 of the approximately 49,000 comments received by NIH during a monthlong period of public comment opposed any federal funding of human embryonic stem-cell research.

But those responses were "deemed not responsive to the question put forth" and

were therefore not considered, Kington said. “We did not ask them whether” to fund such research, he said, “but how it should be funded.”