NIH head foresees ethical concerns about draft stem-cell guidelines

WASHINGTON – The acting head of the National Institutes of Health said he expects many of the public comments on the agency's new draft guidelines on embryonic stem-cell research will focus on ethical concerns about the research.

"I know many comments will have to do with ethical concerns and we will consider them," said Dr. Raynard S. Kington during an April 17 news briefing by telephone.

The NIH guidelines, which Dr. Kington said reflect "broad support in the public and in the scientific community," would 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.

Specifically banned by the draft guidelines is funding "for research using 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 have contributed to the germ line."

Dr. Kington said research on adult stem cells and induced pluripotent cells – which do not require the destruction of human embryos – will continue to receive NIH funding.

"We have a substantial investment in that area and we have been excited about the developments in recent years," he said.

The draft guidelines were issued at the direction of President Barack Obama, whose March 9 executive order overturned President George W. Bush's ban on federal funding of research that involved the destruction of human embryos. President Obama asked NIH to draw up guidelines for embryonic stem-cell research that

would be “scientifically worthy and ethically responsible.”

When President Obama’s decision was announced in March, Cardinal Justin Rigali of Philadelphia, chairman of the U.S. Conference of Catholic Bishops’ Committee on Pro-Life Activities, said it represented “a sad victory of politics over science and ethics.”

Dr. Kington said the draft guidelines would be published sometime during the week of April 20 in the Federal Register, opening a 30-period for public comment.

“At the end of the 30 days we will analyze the range of comments, consider them and ultimately have them inform our decision on the final guidelines,” which will be issued by July 7, he added.

The draft guidelines set seven requirements for informed consent in cases when embryos created for reproductive purposes are later donated for use in research:

– “All options pertaining to use of embryos no longer needed for reproductive purposes” have been explained to the potential donors.

– No inducements were offered for the donation.

– The health care facility has a policy in place to assure that quality of care is not affected by a decision to donate or not to donate.

– There is clear separation between the decision to create the embryos and the decision to donate them.

– Consent was obtained at the time of donation and donors were informed they could revoke consent at any time.

– When possible, the physician responsible for reproductive care of the donor is not the person who will perform the research.

– Written consent must include nine separate elements contained in the guidelines, including an acknowledgment that the research could have commercial potential that would not benefit the donor.