



May 22, 2009

**Association of
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National Institutes of Health Guidelines
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Darrell G. Kirch, M.D.
President and Chief Executive Officer

Dear Sir/Madam:

The Association of American Medical Colleges (AAMC) offers the following comments on the April 23rd notice, titled, "Draft National Institute of Health Guidelines for Human Stem Cell Research" (74 FR 18578-18580). The Association was very pleased with President Barack Obama's March 9 Executive Order 13505 "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." We congratulate the NIH for expeditiously releasing draft Guidelines implementing the Executive Order and for offering the opportunity for public comment.

AAMC is a not-for-profit association representing all 130 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. The AAMC member medical schools and teaching hospitals collectively perform about 60 percent of all extramural research sponsored by the NIH, and a significant portion of the life sciences research supported by other agencies.

We recognize the significant ethical issues that are raised by human embryonic stem cell research and we respect the views of those who oppose such research, including some in our own medical school and teaching hospital community. However, we are persuaded by countervailing ethical consideration: that it would be tragic to waste the unique potential afforded by embryonic stem cells, especially those derived from embryos destined to be discarded in any case, to alleviate human suffering and enhance the quality of human life.

The AAMC generally supports the proposed NIH Guidelines. We believe that the proposed assurance system is appropriate, consistent, and workable. For stem cell lines created after the effective date of the final NIH Guidelines, we believe the processes and consent requirements are workable and reasonable. However, we are concerned about some of the limitations contained in the policy and are particularly troubled by the lack of an effective process for assuring that on-going research using stem cell lines created before the effective date of the final NIH Guidelines will be eligible for Federal funding.

Below we outline two major concerns with the proposed Guidelines and then offer a number of additional comments, concerns, and requests for clarification.

Major Concerns:

The proposed Guidelines limit federal funding to those stem cell lines derived from IVF embryos in excess of clinical need. The Guidelines specifically make ineligible for funding research using lines derived by three other methods, somatic cell nuclear transfer (SCNT), parthenogenesis, or from IVF embryos created for research purposes. AAMC believes that it is ethical to conduct research on stem cell lines derived from embryos produced through somatic cell nuclear transfer, parthenogenesis, and –in rare and special cases – from embryos generated for research purposes. We urge NIH to allow research using lines from these sources to be eligible for federal funding. At a minimum, we hope NIH will explicitly commit the agency to review the final guidelines on an annual basis and in light of scientific developments and the tools needed to advance the research agenda.

The most vexing issue unresolved by the proposed Guidelines is the status of the hundreds of stem cell lines in existence, but derived before the Guidelines become effective. For nearly eight years, the Federal government's standard for lines eligible for funding has been based on the derivation occurring before the announcement of the policy and meeting a very broad four prong test:

- The stem cells must have been derived from an embryo that was created for reproductive purposes;
- The embryo was no longer needed for these purposes;
- Informed consent must have been obtained for the donation of the embryo; and
- No financial inducements were provided for donation of the embryo.

We urge that NIH allow federal funding for all human embryonic stem cell lines in existence before the effective date of the final Guidelines, based on an institutional assurance that the above criteria were met. We also urge that the same treatment be afforded to excess IVF embryos whose donation to stem cell research has been completed prior to the issuance of the Guidelines but which have not yet been used to derive stem cell lines.

The method that an institution uses to provide such an assurance should not be limited by the Guidelines. Some institutions may wish to use an Embryonic Stem Cell Research Oversight Committee (ESCRO) or other process to make such a determination. In addition, we do not believe the informed consent criteria outlined in the Guidelines should be applied *de novo* to existing lines. We suggest that the criteria used by NIH since 2001 as a basis for “grandfathering” existing lines is rational and consistent.

We believe that an NIH Registry of eligible stem cell lines would give our community some compliance certainty. However, we understand NIH's reluctance to manage a registry that may grow exponentially over time. Alternatively, we suggest NIH consider maintaining a registry of

stem cell lines that are ineligible for funding, based on the NIH Intramural Program's review of a line's derivation process or from verified institutional concerns.

Additional Comments, Concerns, and Requests for Clarification:

The proposed Guidelines are titled, "Draft National Institute of Health Guidelines for Human Stem Cell Research." That title is misleading as the Guidelines apply only to the NIH funding of human embryonic stem cell research. We suggest that the title be changed to reflect this limitation.

While we understand that these Guidelines necessarily are restricted to NIH extramural grant funding, we believe the NIH and the Office of Science and Technology Policy (OSTP) should work to ensure that all grant funding agencies adopt these guidelines. Uniform agency policies are wise public policy and will assist in ensuring compliance.

It is important to recognize that the proposed Guidelines are placing new requirements on IVF clinics, many of which are not involved in research. As such, some of the policies that NIH is requiring are unlikely to be in place or appropriate. For example, the proposed Guidelines require that IVF clinics have in place a policy stating that treatment for potential donors to stem cell research would not be affected by the donor's decision to donate an embryo for research. While this concept is appropriate and uniformly accepted, clinics that do not themselves do research are unlikely to have such a written policy in place. It is clearly reasonable, however, to expect IVF clinics that are engaged in research to have such a policy in place. IVF clinics that do not perform research should not be required to have such a written policy in order for donations to occur.

Given the stated eligibility criteria, we generally support the informed consent criteria established in the notice. Some areas would benefit from clarification, however. Section II (B)(1) states that IVF clinics would need to document that, "All options pertaining to the use of embryos no longer needed for reproductive purposes were explained to the potential donor(s)." (emphasis added) Not all IVF clinics offer "all options" to donors. This is an imprecise phrase in any case. We suggest that the phrase be changed to "available options".

An additional concern focuses on the withdrawal of consent. Section II (B)(5) correctly mandates that donors be informed that they retain the right to withdraw consent until the embryos are actually used in research. In some cases, however, embryos are stripped of all personal identifiers before research begins. As such, we believe the language should be modified to make it clear that donors retain the right to withdraw consent until the embryos are actually used in research or personal identifiers are removed.

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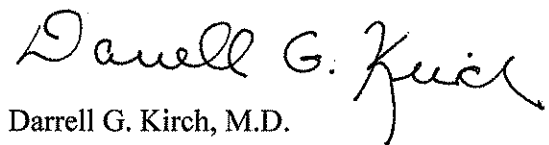
In addition, we suggest an additional provision be included making it explicit that consent withdrawal after the research has begun will have no effect and that the use and distribution of any derived stem cell line will be unaffected. We raise this concern because media reports

indicated that one stem cell line on the NIH Registry was withdrawn after donor consent was withdrawn post-derivation.

The proposed Guidelines specify that although a stem cell line may come from allowable sources, certain uses are nevertheless ineligible for Federal funding. Section III (B) lists research involving the breeding of animals where introduction of stem cells "may have contributed to the germ line." (emphasis added) This is an impossible compliance standard. We suggest that it be rewritten to prohibit funding for research "intended or likely to contribute stem cells to the germ line."

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the draft NIH Guidelines related to the Federal funding of human embryonic stem cell research. Should you have questions about AAMC's position or if we can be of further assistance, contact Tony Mazzaschi at 202-828-0059 or tmazzaschi@aamc.org.

Sincerely,

A handwritten signature in cursive script that reads "Darrell G. Kirch".

Darrell G. Kirch, M.D.