



**Association of
American Medical Colleges**
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May 3, 2009

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 700, MSC 7985
Bethesda, MD 20892-7985

Subject: Response to Proposed Revisions in the NIH Guidelines for Research Involving
Recombinant DNA Molecules, 74 FR 9411

Dear Sir/Madam:

The Association of American Medical Colleges (AAMC) is pleased to submit the following comments on the proposed revisions to the NIH Guidelines for Research Involving Recombinant DNA Molecules, published in the March 4, 2009 Federal Register.

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 share the concerns of the American Society for Microbiology (ASM) on the proposed revision to Section III-A-1 Major Actions Under the NIH Guidelines. The proposed revised section states that all experiments involving “the deliberate transfer of a drug resistance trait to a microorganism, if such acquisition could compromise the ability to treat or manage disease agents in human and veterinary medicine or agriculture,” must receive RAC review and require NIH Director approval. The current NIH Guidelines state that if the microorganism is known to acquire the trait naturally, then transfer of the drug resistance may not need RAC review. The NIH is now proposing to delete the phrase “that are not known to acquire the trait naturally” in Section III-A-1.

We have heard from a number of institutions and faculty members concerned that the proposed revision will have a detrimental impact on research protocols where introduction of antibiotic resistance markers into bacteria is currently permitted and routinely used. This appears to be the case in a very large number of molecular and genetic studies. There is no evidence that any NIH

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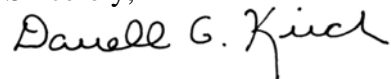
harm has resulted from the use of antibiotic resistance markers in compliance with current NIH Guidelines and there is no evidence that such use poses an actual risk in the future.

We strongly urge that this proposed revision be withdrawn and that the Recombinant DNA Advisory Committee hold a new public in-depth review of the scientific, safety, and ethical dimensions of this proposed change. This will allow the Committee to better understand the implications of the change and why the affected research community views this proposal with such alarm.

We have no objection to the other changes to the guidelines proposed in the March 4 notice.

We appreciate the opportunity to comment on this matter. Any questions should be directed to Tony Mazzaschi, 202-828-0059 or tmazzaschi@aamc.org.

Sincerely,

A handwritten signature in cursive script that reads "Darrell G. Kirch". The signature is written in black ink and is positioned below the word "Sincerely,".

Darrell G. Kirch, M.D.