



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Action under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH)

ACTION: Notice of proposed actions under the NIH Guidelines.

SUMMARY: The NIH is considering a proposal to conduct research involving the deliberate transfer of a chloramphenicol resistance trait to Rickettsia typhi, conorii, rickettsii, and felis. The acquisition of this antibiotic resistance trait could possibly compromise the use of a class of antibiotics for the treatment of Rickettsia infections in humans. Under the NIH Guidelines (http://www.osp.od.nih.gov/sites/default/files/NIH_Guidelines.html), these experiments can proceed only after they are reviewed by the NIH Recombinant DNA Advisory Committee (RAC) and specifically approved by the NIH Director as Major Actions. This proposal will be discussed at the March 8-10, 2016 RAC meeting. The public is encouraged to provide comments on this proposed action.

DATES: To ensure consideration, comments must be submitted in writing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments may be submitted by e-mail at SciencePolicy@od.nih.gov, by fax at 301-496-9839, or by mail to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985. All written comments received in response to this notice will be available for public inspection at the NIH Office of Science Policy (OSP), 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted to the NIH OSP website (<http://osp.od.nih.gov/>). In addition, an opportunity for public comment will be provided at the RAC meeting, to be held March 8-10, 2016. The meeting location will be announced on the NIH OSP website at a later date.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about this proposed action, please contact the NIH and by e-mail at SciencePolicy@od.nih.gov, or by telephone at 301-496-9838 and reference this notice.

SUPPLEMENTARY INFORMATION: The NIH has received a request to consider experiments that involve the deliberate transfer of a drug resistance trait to a microorganism such that the acquisition could compromise the use of the drug to control disease in humans, veterinary medicine, or agriculture. This type of research falls under Section III-A-1-a of the NIH Guidelines, requiring NIH Director approval for the

experiment to proceed and is thus considered to be a Major Action (http://www.osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc351276270).

An investigator at the University of Chicago has proposed to transfer chloramphenicol resistance to four different *Rickettsia* species: *Rickettsia typhi*, *conorii*, *rickettsii*, and *felis*. The transfer of chloramphenicol resistance to *R. conorii* was previously approved by the NIH Director as a Major Action (see 73 FR 32719) and therefore does not need to be reviewed and approved under Section III-A-1-a.

The proposed experiment entails transferring chloramphenicol resistance to *R. rickettsii* and *R. typhi* via vectors that are based upon *Escherichia coli* pET or pUC plasmids. These plasmids confer resistance to chloramphenicol since they contain transposons that express chloramphenicol acetyl transferase (CAT). In addition, the investigator proposes to transfer chloramphenicol resistance to *R. felis* via a shuttle vector that is designed to replicate in both *E. coli* and *Rickettsia*. This shuttle vector will be generated by fusion of an *R. felis* plasmid to an *E. coli* plasmid that expresses CAT. In addition, the *R. felis* plasmid also contains DNA sequences that are homologous to those necessary for bacterial conjugation. A goal of this work is to discover whether the shuttle vector (and chloramphenicol resistance) may be transmitted from *R. felis* to other *Rickettsia* via conjugation.

The proposal to transfer chloramphenicol resistance to *R. typhi*, *rickettsii*, and *felis* was discussed with a working group of the RAC via a teleconference call on October 22, 2015. The recommendations of this group were initially presented to and discussed with the RAC at its December 4, 2015, meeting. As indicated above, the RAC will continue to consider this proposal and make recommendations to the NIH Director at

its upcoming meeting on March 8-10, 2016. An agenda will be available on the NIH OSP website (<http://osp.od.nih.gov/>) in advance of this meeting. The public is encouraged to submit written comments on this proposed action.

Dated: December 21, 2015

Lawrence A. Tabak, D.D.S., Ph.D.

Deputy Director

National Institutes of Health

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