[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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 action under the NIH Guidelines.

SUMMARY: The National Institutes of Health (NIH) considered 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 was discussed at the December 4, 2015, RAC meeting. The proposal was published in the Federal Register on December 29, 2015, (80 FR 81346) with a request for public comment; one comment was received. This notice announces the final NIH action regarding this proposal.

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

SUPPLEMENTARY INFORMATION: This final action does not allow an investigator at the University of Chicago to transfer chloramphenicol resistance to three different Rickettsia species: Rickettsia typhi, rickettsii, and felis. The investigator also proposed to transfer chloramphenicol resistance to a fourth Rickettsia species, R. conorii. Transfer of chloramphenicol resistance to R. conorii was previously approved by the NIH Director as a Major Action (see 73 FR 32719) and therefore did not need to be reviewed and approved under Section III-A-1-a of the NIH Guidelines. Thus, the University of Chicago investigator was allowed to proceed with the transfer of chloramphenicol resistance to R. conorii under Section III-B-2 of the NIH Guidelines.

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 presented to and discussed with the RAC at its December 4, 2015, meeting. At the March 8, 2016, meeting, the RAC continued the discussion which included consideration of the one comment received to the December 29, 2015, notice and unanimously recommended (by a vote of 11 in favor, none opposed, and no abstentions) that the transfer of chloramphenicol resistance to R. typhi, rickettsii, and felis should not be allowed to proceed. On August

23, 2016, the NIH Director disapproved the proposal to transfer chloramphenicol resistance to R. typhi, rickettsii, and felis.

Dated: January 6, 2017

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Francis S. Collins,

Director

National Institutes of Health

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