DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*

ACTION: Notice of consideration of a proposed action under Section III–A–1 of the *NIH Guidelines.*

SUMMARY: The *NIH Guidelines* requires certain recombinant research to be reviewed by the NIH Recombinant DNA Advisory Committee and approved by the NIH Director (Section III–A–1). Such research involves the introduction of drug resistance into a microorganism if the introduction of that drug resistance trait can compromise the ability to treat disease caused by the microorganism in humans, animals or agriculture. In order to meet the threshold for consideration under Section III–A–1, the microorganism must be able to cause disease in humans, animals or agriculture.

A proposal to deliberately transfer a chloramphenicol resistance trait into an attenuated strain (CO92 lcr-) of *Yersinia pestis* has been submitted to the NIH Office of Biotechnology Activities (OBA) by the Institutional Biosafety Committee at Lawrence Livermore National Laboratory (LLNL). Treatment guidelines recommend streptomycin as the first-line antibiotic for treatment of disease caused by wild type *Y. pestis,* and gentamicin is recommended when streptomycin is not available. Doxycycline and chloramphenicol are also effective and ciprofloxacin is recommended as prophylaxis and has been shown to treat disease in animal models. The LLNL investigators will be using *Y. pestis* CO92 lcr- strains that have already been made resistant to ciprofloxacin or doxycycline through exposure of these attenuated strains to these antibiotics. The proposed research involves the addition of chloramphenicol resistance into these strains, thereby creating lcr- *Y. pestis* strains that are resistant to multiple antibiotics used to treat disease caused by this organism.

A fundamental question with respect to this line of proposed research is whether this specific strain (lcr-) has the ability to cause disease in humans and therefore should be subject to Section III–A–1 of the *NIH Guidelines.* While there is evidence that the strain is attenuated, this does not necessarily mean the strain is avirulent, and the RAC will review the evidence regarding the ability of this strain to cause disease. The recent death of a researcher at the University of Chicago while working with an attenuated strain of *Yersinia pestis* highlights that attenuated strains may be pathogenic in certain populations. If a determination is made that that lcr- strains do pose a potential public health risk, then these experiments will be considered at this meeting under Section III–A–1 of the *NIH Guidelines.* A recommendation will then be made as to whether this research should be allowed to proceed and, if so, under what containment conditions.

The RAC will review of this proposed work at its June 16–17, 2010 meeting, which will be held at the Hilton Washington DC/Rockville Hotel 1750 Rockville Pike, Rockville, MD and is open to the public. The public may also submit written comments.

DATES: The public is encouraged to submit written comments on this proposed action. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION CONTACT**. All comments should be submitted by June 10, 2010. All written comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892–7985, (Phone: 301–496–9838) weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Contact OBA by e-mail at *oba@od.nih.gov,* or telephone at 301–496–9838, if you have questions, or require additional information about this line of research. For additional information about the RAC meeting at which this line of research will be discussed, please visit the NIH OBA Web site at: *http://oba.od.nih.gov/oba/index.html.*

SUPPLEMENTARY INFORMATION: *Yersinia pestis* is the causative organism for plague and it regulated by the Department of Health and Human Services (HHS) as a Select Agent pursuant to the Select Agent Regulations (42 CFR part 73). There are a number of attenuated strains of *Yersinia pestis* that do not contain certain virulence factors. The strain that will be used in the proposed research, *Yersinia pestis* CO92 *lcr-,* lacks the plasmid called pCD1 or the "low calcium response-lcr" plasmid since it confers calcium dependence for growth at 37° C. Loss of the pCD1 plasmid is accompanied by a concomitant loss of virulence as indicated in studies using several animal models. This strain is excluded from the HHS list of Select Biological Agents and Toxins *http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html#hhsAgents.*

Additional background information may be obtained by contacting NIH OBA via e-mail at *oba@od.nih.gov* or by going to the OBA Web site at *http://oba.od.nih.gov/rdna/news_events_oba.html#RAC.*

Dated: May 17, 2010.

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Acting Director, Office of Biotechnology Activities, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 2282 1–29, dated April 30, 2010) is amended to establish the Human Capital Management Office, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

After the mission statement for the Office of Health and Safety (CAJP), insert the following:

Human Capital Management Office (CAJQ). (1) Develops goals and objectives and provides leadership, policy formation, oversight, and guidance in program human capital planning and development; (2) plans, directs, and manages CDC-wide training programs; (3) develops, designs, and implements a comprehensive strategic human resource leadership and career management program for all occupational series throughout CDC; (4) provides technical assistance in organizational development, career management, employee development, and training; (5) maximizes economies of scale through systematic planning