



Homeland
Security

OCT 15 2019

MEMORANDUM FOR:

(b)(6)

Assistant Professor
Department of Bioengineering
Northeastern University

FROM:

(b)(6)

Regulatory Compliance Program Manager
U.S. Department of Homeland Security

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SUBJECT:

Site Visit to Northeastern University to Assess the Animal Care and Use Program

The Department of Homeland Security (DHS) Compliance Assurance Program Office (CAPO) conducted a site visit to Northeastern University on September 10-11, 2019. During the visit, DHS CAPO personnel conducted a review of Northeastern University's animal care and use program and its implementation in the conduct of a project funded by DHS, titled "Health Consequences Following Acute and Chronic Firefighter Exposures to Wildland Fire Smoke."

To support this review, DHS CAPO personnel evaluated Northeastern University's animal care and use program. DHS CAPO personnel met with Northeastern University officials and program staff to discuss institutional policies and procedures, review compliance-related documents, and assess laboratory facilities where DHS-funded research is conducted. The DHS CAPO's observations for the reviewed project and referenced programs at Northeastern University are summarized in the following sections.

Site Visit Summary

During the initial session of the visit, Northeastern University staff provided DHS CAPO personnel with an overview of the facilities and institutional programs. Subsequent sessions included discussions on relevant laboratory and institutional procedures, documentation reviews, interviews, and walkthroughs of the laboratory and animal holding spaces assigned to the DHS funded project. Regulatory animal care and use, and safety compliance elements were evaluated during the site visit.

During the site visit, DHS CAPO identified areas for potential enhancement of the laboratory and institutional programs. Recommendations regarding these areas were discussed during the exit briefing and are provided in Enclosure (1). Northeastern University staff were accommodating, professional, and knowledgeable, and have worked diligently to establish a culture of safety and best practices within the organization.

Animal Care and Use Program

Enclosure (1) to this memorandum provides a list of DHS CAPO recommendations for additional enhancements to the animal care and use program as discussed with the officials during the site visit and Close-Out Meeting.



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Enclosure (2) provides information regarding the submission of documentation required for ongoing regulatory compliance.

General Comments

The DHS CAPO appreciates the support and assistance provided by all Northeastern University officials and program staff involved in the site visit. The DHS CAPO recognizes the time and resource commitments made by Northeastern University personnel during the visit in providing program overviews, assembling materials for review, facilitating the facility walkthroughs, and otherwise coordinating with DHS CAPO personnel.

The requirements and recommendations in the enclosures to this memorandum are communicated both to help ensure ongoing compliance and to encourage the implementation of "best practices."

Reporting Requirements

The DHS CAPO requests a written response within 30 calendar days of receipt of this memorandum indicating your review of the recommendations presented in Enclosure (1), and your plans to incorporate each of them, as appropriate. This response should be submitted via e-mail to STRegulatoryCompliance@hq.dhs.gov.

If there are any questions or concerns regarding the recommendations or the site visit process, please contact me at (b)(6). Please see Enclosure (2) for requirements for ongoing documentation submission to the DHS CAPO.

Encl:

- (1) Recommendations for Northeastern University's Animal Care and Use Program
- (2) Requirements for Ongoing Documentation Submission to the DHS CAPO

cc:

(b)(6) Assistant Professor, Northeastern University
(b)(6) Grants & Contracts, Northeastern University

Based upon the site visit to Northeastern University facilities, the DHS Compliance Assurance Program Office (CAPO) provides the following recommendations to further enhance Northeastern University's program for compliance with regulations policies, and guidance pertaining to laboratory safety and the care and use of animals in research.

Recommendations for Laboratory work at Northeastern University

(b)(5)



**Requirements for Ongoing Documentation Submission to
the DHS Compliance Assurance Program Office**

Regulatory Compliance Requirements

Documentation pertaining to the following must be provided to the Compliance Assurance Program Office (CAPO) as they occur:

- The addition of any animals to the program;
- Any changes in the use of animals (modifications to existing protocols, or new protocols);
- Any changes in the status of ongoing projects (e.g., suspension, cancellation); and
- Occupational exposures and other safety incidents (within 72 hours).

All questions and documentation submissions should be directed to the Regulatory Compliance Group at STRegulatoryCompliance@hq.dhs.gov.