



July 2, 2009

Ara Tahmassian, Ph.D.
Associate Vice President, Research Compliance
Boston University and Boston Medical Center

Dear Dr. Tahmassian,

I am happy to forward you the recommendations of the *ad hoc* Advisory Committee on Dual Use Research of Concern (DURC). We have reviewed the Report of the National Science Advisory Board for Biosecurity (NSABB) Working Group on Oversight Framework Development (NSAAB Report, which is attached), and we recommend that Boston University (BU) and Boston Medical Center (BMC) carry out a two-stage plan in anticipation of Federal regulations.

The first stage involves the initiation of education and training for faculty and staff combined with review and decision-making by an *ad hoc* committee and the Provost or Provost, Medical Campus as the need arises.

The second stage involves the development of a formal policy and process in compliance with Federal regulations after such regulations have been officially proposed. We anticipate that the formal policy and process will establish a more fully developed program of education and training; review and decision-making involving a Dual Use Research Review Committee; and related institutional action. Development of this policy should involve input from the various stakeholders at BU/BMC. These include: 1) faculty/principal investigators; 2) senior administrators (presidents, vice-presidents, provosts, Associate Vice President for Research Compliance); 3) research compliance committees (e.g., Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Laboratory Safety Committees (LSC); 4) administrative offices (e.g., Office of Research Administration (ORA), Office of Sponsored Research (OSP); 5) legal counsel (BU and BMC); and 6) corporate communications (BU and BMC). We think it is essential that this policy be developed with the full involvement of the faculty.

We also believe it is essential that the research reviews and decisions at each stage be consistent with our fundamental commitment to the pursuit of knowledge and openness in research.

Education and Training

The NSABB report emphasizes that Principal Investigators (PIs) are in the best position to determine whether their ongoing or planned research might be considered DURC. We agree and believe that PIs

should be primarily responsible for reviewing their research for dual use potential. In order to enable PIs to effectively evaluate their research, we recommend that BU/BMC develop a program to educate researchers to identify research with dual use potential. Education should provide investigators with an understanding of what types of research could be considered DURC. The education and training should include a discussion of the seven types of “experiments of concern” that are described in the NSABB Report.

This training program should be developed under the leadership of the Director of Research Safety. Given that some non-biological research might fall under the definition of DURC, training should be required for all scientific research personnel at BU/BMC. Training should be a requirement for final IBC, IACUC, IRB, or LSC approval of research studies.

We recommend that BU/BMC begin to develop an education and training program immediately. The education and training program should be part of the annual lab safety training that is given on both the Charles River and Medical Campuses. However, initially a Department-by-Department education program should be implemented. This will bring all faculty “up-to-speed” without having to wait for them to attend safety training that will be staggered over the next year.

We recommend that, as part of this education program, faculty should be provided a questionnaire that asks whether they are currently carrying out or are planning to carry out research that can be considered one of the “seven experiments of concern” as defined by the National Research Council. We recommend that this questionnaire be incorporated into the Research Information Management System once that system has been implemented.

Review and Decision-Making

We recommend that the Office of the Director of Research Safety be available to assist PIs, if necessary, in determining whether their research meets the definition of DURC. In the event that, during this initial determination, a research project is identified as possibly meeting the definition of one of the “seven experiments of concern”, it should be reviewed by an *ad hoc* Dual Use Research Review Committee pending the adoption of a more formal policy and process. The *ad hoc* committee should be guided by the recommendations and principles set forth in the NSABB Report.

In the event that a research project is identified as DURC, the *ad hoc* committee should conduct a risk assessment and benefit analysis regarding the conduct and communication of the research study, in consultation with the PI and the various institutional stakeholders, including administrators (BU and BMC) and legal counsel. The determinations of the *ad hoc* committee should be reviewed by the University Provost or Provost, Medical Campus (for the applicable campus) in consultation with the Associate Vice President for Research Compliance.

We also recommend that the Office of the Associate Vice President for Research Compliance be the repository for the questionnaire forms by PIs, the recommendations of the *ad hoc* committee, and final decisions by the Provost and Provost, Medical Campus.

Respectfully submitted,

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