REPORT SUMMARY NEW ENGLAND PRIMATE RESEARCH CENTER INDEPENDENT REVIEW PANEL August 13, 2012

In March 2012, the Dean of the Faculty of Medicine at Harvard University (HU) convened and charged an Independent Review Panel to "assess the current veterinary and animal husbandry operations, logistics, and management" at the New England Primate Research Center (NEPRC or the "Center"). Established by Congress in 1962 and formally dedicated in 1966, the NEPRC is one of eight NIH-funded national primate research centers in the US. These centers play vital roles in advancing our understanding of human and animal diseases including AIDS, cancer, neuropsychiatric disorders, drug addiction and neurodegenerative disease. It is in these specific areas that the NEPRC has historically excelled.

Evaluation of process improvements and long-term strategy to deliver humane and effective animal care and assure safe and productive research at the Center were the Panel's priorities. Information about recent primate deaths and United States Department of Agriculture (USDA)-documented non-compliant activity provided valuable context for the Panel, but the specifics of these past events were not the focus of the Panel's review. Scientific programs at the Center were also not a specific focus.

The Panel acknowledges the dedication and concern of the NEPRC, Harvard Medical School (HMS) and HU personnel, their clear desire to assure animal and human welfare and their commitment to returning the Center to its previous position of excellence. Personnel at all levels supported and encouraged the Panel's work, and their assistance was essential to obtaining information and developing perspective throughout the review period. We were grateful for the transparency, openness and efficiency with which requests for documents, interviews or other resources were met.

The Panel gathered and analyzed information and data from more than 150 written documents, numerous phone interviews, bi-weekly Panel conference calls and a site visit to the NEPRC. We reviewed multiple aspects of the NEPRC, including elements of organizational structure, key personnel (husbandry, technical and professional staff, investigators), animal husbandry, veterinary support, facility operations, infrastructure in support of animal care and equipment installation and maintenance.

It was not the intent of the Panel to provide a comprehensive list of every risk or concern identified from previous reports or our own review. The Panel chose to highlight major themes and processes that, if appropriately addressed, will help assure animal and human well-being at the Center. The Panel's observations and recommendations were grouped into three categories focused on the NEPRC, HMS and the Harvard Medical Area Institutional Animal Care and Use Committee (IACUC), which is the internal committee that reviews and oversees proposed uses of animals in research at the NEPRC, as mandated by federal regulations and accreditation standards.

Recommendations included:

- Appoint an Attending Veterinarian and a biosafety officer dedicated to the NEPRC as part of
 a general move towards permanent, stable NEPRC leadership by individuals with the
 knowledge, experience and communication skills necessary to build a cooperative, collegial
 team.
- Create a comprehensive multi-level training and career development program, including a team-based work model to enhance organizational development and increase optimal staff interactions and cross-disciplinary accountability.
- Assess critically the structure, charge, scope and composition of existing NEPRC committees and consider the need for new approaches to internal oversight and governance.
- Encourage broad-based identification of and open communication about problems, and active involvement in problem solving. This should be accomplished through review and revision of existing policies as well as employee education and training.
- Establish a NEPRC-specific IACUC subcommittee as part of a general move towards improving the interface between the IACUC and the NEPRC.
- Ensure the continued involvement of the IACUC in the review and approval of NEPRC animal care standard operating procedures prior to implementation.
- Define the IACUC's responsibilities to reflect clearly its oversight, as opposed to management, responsibilities.
- Identify and empower an experienced advocate for NEPRC within the senior leadership of HMS to ensure consistent HMS support for NEPRC.

To return to its leadership position in the field of nonhuman primate research, the NEPRC must uphold the highest standards in animal care, health and well-being while conducting exemplary biomedical research. Dedication to this mission is essential to sustain the distinctive contributions to human and animal health delivered by such research.

The Panel believes that the NEPRC is making meaningful progress and positioning itself to continue to make valuable contributions to Harvard and to the larger biomedical research community. Ongoing implementation of recommendations from this and other reviews supports resuming the consideration of new research protocols at the NEPRC.

Submitted on behalf of the Panel,

Deboral J. Lochevar

Deborah Kochevar, Chair

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