



## Inspection Report

HARVARD MEDICAL SCHOOL

Customer ID: 107

Certificate: 14-R-0019

Site: 002

NEW ENGLAND REGIONAL PRIMATE CENTER

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

Date: Jul-19-2011

BOSTON, MA 02115

### 2.31 (c) (7)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (c) (7) states - "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities."

1. At the end of June 2011, it was discovered during the research facility's post-approval monitoring program (PAM) that there has been more than one instance when procedures were performed on study animals that were not described in the IACUC approved proposal for animal use. The IACUC immediately formed a subcommittee to look into the issue when it was informed of the findings of the PAM and it also reported the issue to the USDA.

Per this Section of the Regulations, the IACUC must review and approve significant changes to proposals for animal use before the investigators can conduct any additional activities that were not initially described at the time of IACUC approval.

The subcommittee of the IACUC is currently in the process of investigating the extent of the non-compliant issue to determine what corrective actions are needed and to then determine an appropriate correction schedule to implement those corrective actions.

NOTE - This was a focused inspection based on the research facility's self-reporting of the non-compliant item to the USDA. The findings documented on this inspection report are undergoing further review by the Eastern Regional Office. Exit interview held 7/21/11 on-site with facility personnel. END OF REPORT.

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Jul-21-2011

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