National Cancer Institute
Central IRB Initiative

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MEMORANDUM

To: Staff from Institutions enrolled in the CIRB Initiative
Coordinating Group Staff
Various Branches, NCI Cancer Therapy Evaluation Program

From: John D. Horigan
CIRB Administrator; NCI CIRB Operations Office

Date: June 19, 2015

Subject: **FDA Inspection of CIRB**

A routine inspection of the CIRB was completed by Food and Drug Administration (FDA) representatives between February 4, 2015 and February 6, 2015.

The FDA concluded that the CIRB complied with the statutory requirements at 21 CFR 50 and 21 CFR 56. A copy of the FDA's final communication regarding the inspection is included below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Anne S. Lindblad, Ph.D.
President and CEO
EMMES Corporation
401 N. Washington Street, Suite 700
Rockville, MD 20850

Dear Dr. Lindblad:

This letter informs you of the findings of a U.S. Food and Drug Administration (FDA) inspection of the National Cancer Institute Central IRB (CIRB) conducted from February 4, 2015 to February 6, 2015. Mr. Bradley L. Maunder and Ms. Andrea B. Slavin, representing the FDA, conducted the inspection to determine if the IRB's procedures for the protection of human subjects complied with FDA regulations published in Title 21, Code of Federal Regulations (CFR), parts 50 and 56. These regulations apply to clinical investigations of products regulated by FDA.

From our review of the establishment inspection report and the documents submitted with that report, we conclude that the IRB adhered to the applicable statutory requirements and FDA regulations governing the protection of human subjects.

For helpful information on human subject protections, please visit the following FDA web page:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

We appreciate the cooperation shown to the FDA investigators during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by e-mail (Catherine.Parker@fda.hhs.gov) or by letter at the address given below.

Sincerely,

{See appended electronic signature page}

Catherine Parker, RN
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/s/

CATHERINE E PARKER
04/20/2015