DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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July 21, 2006

Eric C. Hartman
President
customKYnetics, Inc.
304 Crossfield Drive, Suite A
Versailles, KY 40383

Laban D. Miller, Ph.D.
Vice President of Corporate Systems
Cardinal Hill Healthcare System
2050 Versailles Road
Lexington, KY 40504

Wendy Baldwin, Ph.D.
Executive Vice President for Research
University of Kentucky
311h Main Building
Lexington, KY 40506-0032

RE: Human Research Subject Protections Under Federalwide Assurances FWA 1829, FWA 5232, and FWA 5295

Research Project:	**Adaptive Stimulator for Exercise and Rehabilitation**
Principal Investigator:	**Eric Hartman**
HHS Project Number:	**R44HD041820-02**
Research Project:	**Customized Electrical Stimulation for SCI Rehabilitation**
Principal Investigator:	**Eric Hartman**
HHS Project Number:	**5R44HD039013-03**
UK IRB Number:	**03-0428-FIV**

Dear Mr. Hartman, Dr. Miller, and Dr. Baldwin:

The Office for Human Research Protections (OHRP) has reviewed the reports submitted by customKYnetics, Inc., Cardinal Hill Healthcare System, and the University of Kentucky dated July 8, 2005, July 11, 2005 and July 13, 2005, respectively, in response to OHRP's June 2, 2005 letter regarding the above-referenced research.

Based on the review of your reports, OHRP makes the following determinations regarding the above-referenced research:

(1) OHRP notes that no human subjects research has been conducted under Department of Health and Human Services (HHS) project number R44HD041820-02 and that the allegations related solely to HHS project number 5R44HD039013-03 (UK Protocol # 03-0428-FIV).

(2) HHS regulations at 45 CFR 46.111(a)(1) state that, in order to approve research an institutional review board (IRB) must determine that risks to subjects are minimized. It was alleged that no meaningful mechanical testing was conducted on the neuromuscular stimulation device used in Protocol # 03-0428-FIV. OHRP notes that your reports provide evidence of mechanical testing of the device used in Protocol # 03-0428-FIV. OHRP finds that this allegation could not be substantiated.

(3) HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5) require that unanticipated problems involving risks to subjects or others be promptly reported to the IRB, appropriate institutional officials, OHRP, and the heads of the sponsoring federal department or agency. It was alleged that a subject was exposed to the device's maximal stimulation due to a malfunction in the electrical and software design and that this was not appropriately reported. OHRP notes that on at least one occasion a subject was exposed to the device's maximal stimulation. This incident was promptly reported via e-mail to the IRB and it was determined that the incident did not represent an unanticipated problem involving risk to subjects because the risk was identified in the protocol and informed consent document and thus further reporting was not necessary. OHRP finds that this allegation could not be substantiated.

As a result of the above determinations, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter these determinations.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Michael Lynch, Chair, Research Committee, Carinal Hill Healthcare System
Dr. Thomas Foster, Chair, IRB #1-3, UK
Dr. Sam Shekar, NIH
Dr. Valery Gordon. OER, NIH
Dr. Duane Alexander, Director, NICHD, NIH
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borror, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Patricia El-Hinnawy, OHRP
Ms. Carla Brown, OHRP