DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	10/12/2010 - 10/28/2010* FEI NUMBER 1000220451

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Carlton F. Hazlewood, Ph.D., Chairman

FIRM NAME	STREET ADDRESS
Burzynski Research Institute / IRB	9432 Katy Freeway #105
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77055-6349	Institutional Review Board

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The IRB has no written procedure for conducting its initial and continuing review of research.

Specifically,

A). The Continuing review for studies under IND (b) (4) # (b) (4) was approved for continuation during the March 26, 2010 meeting. The IRB did not have, nor request any copies of the current Informed Consent in use from the Investigator. The Investigator provided the date of approval of the current cosent form in use. The approval date of the IC provided by the Investigator for Protocols # (b) (4) and (b) (4) is 12/05/02. There was no available consent form approved for this date for thes two studies. The consent forms found in the IRB records for studies (b) (4) and (b) (4) were dated 12/11/2001 and 10/22/2002 respectively.

B). the BRI IRB Standard Operating Procedures (Both Approved Version - Rev H, and Draft) do not include any procedures for conducting reviews of device studies to determine whether they involve a significant risk device per 21 CFR 812.66.

OBSERVATION 2

The IRB has no written procedure for determining which projects require review more often than annually .

Specifically, your SOPs do not provide any evaluation of studies based on risk/harm to the subject for continuing review.

OBSERVATION 3

Copies have not been maintained of all approved sample consent documents and progress reports submitted by investigators.

Specifically, The IRB has accepted (b) (4) study closure notices during the 01/22/2010 meeting for Protocols # (b) (4) and (b) (4) from the Investigator. There is no final study report available for these studies. Additionally, the IRB records for Study Protocol (b) (4) do not indicate when the last version of the IC was approved, and what is the actual date of this Infomed Consent.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrea A. Branche, Investigator	10/28/2010

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OBSERVATION 4

The IRB did not determine at the time of initial review and at the time of continuing review for an on-going study which was started on/before April 30, 2001 that a study was in compliance with 21 CFR Part 50 Subpart D, "Additional Safeguards for Children in Clinical Investigations."

Specifically, this IRB approved Protocol b) (4) and b) (4). These protocols were approved to include children from b) (4 months to b) (4 year of age. This IRB has no procedures for safeguarding children, the assent of children in clinical trials, and determining the need for both parents to sign the informed consent as required by the state.

*** DATES OF INSPECTION:**
10/12/2010(Tue), 10/13/2010(Wed), 10/14/2010(Thu), 10/15/2010(Fri), 10/18/2010(Mon), 10/19/2010(Tue), 10/20/2010(Wed), 10/28/2010(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrea A. Branche, Investigator	10/28/2010