		EALTH AND HUMAN	
DISTRICT ADDRESS AND	ISTRICT ADDRESS AND PHONE NUMBER FOOD AND DRUG ADMINIST		DATE(S) OF INSPECTION
4040 North	Central Expressway, Suite 30	00	12/03/2008 - 12/10/2008
Dallas, TX	75204		PEI NUMBER
	5200 Fax: (214) 253-5314	- al 4 a	1000220451
NAME AND TITLE OF INDI	nformation: www.fda.gov/oc/ir vDUALTOWHOW REPORT ISSUED	idustry	
	on F. Hazlewood, Ph.D., IRB	Chairman	
FIRM NAME	D	STREET ADDRESS	
CITY, STATE, ZIP CODE, C	Research Institute / IRB	TYPE ESTABLISHMENT IN	Freeway # 370
Houston, T	x 77055-6349	IRB	
observation, or he action with the Fl questions, please	do not represent a final Agency determination ave implemented, or plan to implement, correct DA representative(s) during the inspection or succentact FDA at the phone number and address PECTION OF YOUR FIRM I OBSERVED:	ive action in response to abmit this information	to an observation, you may discuss the objection o
DURING AN INSI	PECTION OF YOUR FIRM TOBSERVED:		
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OBSERVATIO	ר אע		
A clinical inves	tigation requiring prior submission to the I	DA was initiated wi	ithout IRB approval.
			- -
1		(4)	th study protocol (2) entitled
(b) (4) Hazelwood, I reports between number. On	by (b) (4) M.D. Ph.D., Co-P.I. Fifteen human subjected January and February 2007 with February 15, 2008 the BRI IRB app	(4) ., Principal Investors' were entered an effective?	th study protocol (D) (4) entitled stigator (P.I.) and Carlton F. into protocol #(b) (4) under pilot case FDA Investigational New Drug
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(8) OF INSPECTION			
4040 North Central Expressway, Suite 300- Dallas, TX 75204	12/03/2008 - 12/10/2008 FEI NUMBER			
(214) 253-5200 Fax: (214) 253-5314	1000220451			
Industry Information: www.fda.gov/oc/indu	ustry			
TO: Carlton F. Hazlewood, Ph.D., IRB Chairman				
FIRM NAME	STREET ADDRESS			
Burzynski Research Institute / IRB	9432 Katy Freeway # 370			
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Houston, TX 77055-6349	IRB			

OBSERVATION 3

Copies have not been maintained of all research proposals reviewed.

Specifically,;

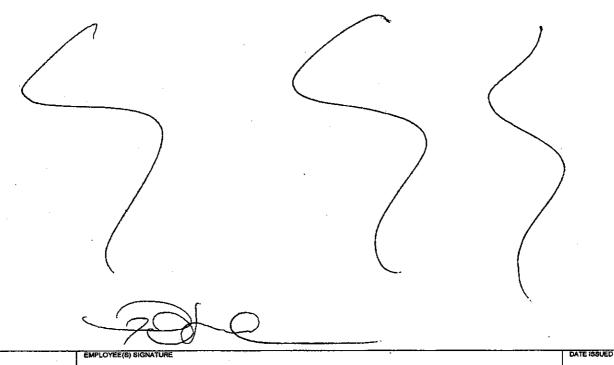
A) The Investigators Brochure for study protocol #(b) (4) was not found in the BRI IRB study records.

(b) (4) device (Protocol #(b) (4) was not found in the BRI IRB study records.

OBSERVATION 4

Documentation has not been maintained of written procedures for the IRB, as required by 21 CFR 56.108(a) and (b).

Specifically, The BRI IRB written procedures section 4.2.2.1 states that "These policies and Procedures (SOPs) will be reviewed annually". The SOPs were not reviewed from 2003 through 2008.



SEE REVERSE OF THIS PAGE Patrick D Stone, Investigator

12/10/2008

FORM FDA 483 (04/03)

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

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