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	01/22/2013 - 02/07/2013* FEI NUMBER 1000220451

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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

FIRM NAME	STREET ADDRESS
BRI-IRB	9432 Katy Freeway # 370
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 WE OBSERVED:

OBSERVATION 1

The IRB used an expedited review procedure for research which did not appear in an FDA list of categories eligible for expedited review, and which had not previously been approved by the IRB.

Specifically, your IRB routinely provided expedited approvals for new subjects to enroll under Single Patient Protocols. For Example:

(A) Subject (b) (4) (pediatric) was given IRB Approval via Expedited Review to enroll in a Single Patient Protocol on March 28, 2012 and was approved by the full IRB meeting on August 3, 2012.

(B) Subject (b) (4) (pediatric) was given IRB Approval via Expedited Review to enroll in a Single Patient Protocol on May 2, 2012 and was approved by the full IRB meeting on August 3, 2012.

(C) Subject (b) (4) (pediatric) was given IRB Approval via Expedited Review to enroll in a Single Patient Protocol on May 3, 2012 and was approved by the full IRB meeting on August 3, 2012.

(D) Subject (b) (4) (adult) was given IRB Approval via Expedited Review to enroll in a Single Patient Protocol on June 21, 2012 and was re-approved via an expedited mechanism after FDA requested changes to the informed consent document on July 19, 2012.

(E) Subject (b) (4) (adult) was given IRB Approval via Expedited Review to enroll in a Single Patient Protocol on two separate occasions; On June 21, 2012 and again on July 20th, 2012 after FDA requested changes to the informed consent. The Single Patient Protocol was approved by the full IRB meeting on October 19, 2012.

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	Andrea A. Branche, Investigator Patrick J. Mcneilly, Investigator	02/07/2013

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OBSERVATION 2

The IRB approved the conduct of research, but did not determine that the risks to subjects were reasonable in relation to the anticipated benefits (if any) to subjects, and to the importance of the knowledge that might be expected to result.

Specifically, Your IRB gave Expedited Approval for several Single Patient Protocols (SPP) without all the clinical information necessary to determine that the risk to subjects are minimized. For Example:

(A) Subject #(b) (4) was given IRB Approval via Expedited Review on June 21, 2012, by the IRB Vice-Chairman. The information provided by the Investigator only included the Informed Consent document. No additional clinical and/or health history information was provided prior to provisional and subsequent full board approval.

(B) Subject #(b) (4) was given IRB Approval via Expedited Review on June 21, 2012, by the IRB Vice-Chairman. The information provided by the Investigator only included the Informed Consent document. No additional clinical and/or health history information was provided prior to provisional and subsequent full board approval.

(C) Subject #(b) (4) was given IRB Approval via Expedited Review on June 21, 2012, by the IRB Vice-Chairman. The information provided by the Investigator only included the Informed Consent document. No additional clinical and/or health history information was provided prior to provisional and subsequent full board approval.

(D) Subject #(b) (4) was given IRB Approval via Expedited Review on July 28th, 2011 by the IRB Chairman. The Expedited Review approval included a request stating, "Please clarify history and physical for assigning (b) (4) - not evident at present." This information was needed to ensure risks were reasonable in relation to benefits.

OBSERVATION 3

The IRB did not determine at the time of initial review that a study was in compliance with 21 CFR Part 50 Subpart D, "Additional Safeguards for Children in Clinical Investigations."

Specifically, An IRB that reviews and approves research involving children is required to make a

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finding at the time of approval that the study is in compliance with 21 CFR 50, Subpart D" Additional Safeguards for Children in Clinical Investigations." Your IRB approved research involving children without documentation of the IRBs finding that the clinical investigation satisfied the criteria under Subpart D. For Example:

(A) The IRB approved a Single Patient Protocol (SPP) for pediatric subject #(b) (4) on May 2, 2012. There is no documentation of the IRBs determination under 21 CFR 50 Subpart D for this subject.
(B) The IRB approved SPP for pediatric subject #(b) (4) on May 3, 2012. There is no documentation of the IRBs determination under 21 CFR 50 Subpart D for this subject.
(C) The IRB approved SPP for pediatric subject #(b) (4) on March 29, 2012. There is no documentation of the IRBs determination under 21 CFR 50 Subpart D for this subject.

This is a repeat observation from the 10/2010 FDA Inspection.

OBSERVATION 4

The IRB did not follow its written procedure for conducting its initial review of research.

Specifically, The IRB is required to follow its written procedures for conducting initial and continuing review. Your IRB did not follow your procedures for conducting initial and continuing review because these subjects received IRB initial approval via an expedited review procedure not described in your Standard Operating Procedures. If your IRB would have followed your own SOP for initial and continuing review, the following subjects would have received review and approval from the full board rather than through expedited review. For Example:

(A) Subject (b) (4) (pediatric) was given Expedited Review approval for a Single Patient Protocol (SPP) on March 28, 2012 and was approved by the full IRB on August 3, 2012.

(B) Subject (b) (4) (pediatric) was given Expedited Review approval for a SPP on May 2, 2012 and was approved by the full IRB meeting on August 3, 2012.

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(C) Subject (b) (4) (pediatric) was given Expedited Review approval for a SPP on May 3, 2012 and was approved by the full IRB meeting on August 3, 2012.

(D) Subject (b) (4) (adult) was given Expedited Review approval on two occasions for a SPE on June 21, 2012 and after FDA requested changes to the informed consent document on July 19, 2012. The SPP was approved by the full IRB meeting on October 19, 2012.

(E) Subject (b) (4) (adult) was given Expedited Review approval on two occasions for an SPP on June 21, 2012 and after FDA requested changes to the informed consent document on July 20, 2012. The SPP was approved by the full IRB meeting on October 19, 2012 .

OBSERVATION 5

The IRB has no written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any unanticipated problems involving risks to human subjects or others.

Specifically, Your current SOP -2012 v2-draft doc does not describe the requirements of Investigators on how unanticipated problems are reported to the IRB, Institutional Official, and the FDA, such as time intervals and the mode of reporting, or otherwise address how the prompt reporting of such instances will be ensured.

OBSERVATION 6

The IRB has no written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any instance of serious or continuing noncompliance with theses regulations or the requirements or determinations of the IRB.

Specifically, Your current SOP - 2012 v2-draft doc does not address how the IRB will report issues of serious or continuing noncompliance to [appropriate institutional officials and/or FDA], or otherwise address how the prompt reporting of such instances will be ensured.

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OBSERVATION 7

A list of IRB members has not been prepared and maintained, identifying members by name, earned degrees, representative capacity, and any employment or other relationship between each member and the institution.

Specifically, The IRB Roster does not include the member employment or other affiliation between the member and the IRB.

*** DATES OF INSPECTION:**
01/22/2013(Tue), 01/23/2013(Wed), 01/24/2013(Thu), 01/25/2013(Fri), 01/28/2013(Mon), 01/29/2013(Tue), 01/30/2013(Wed), 01/31/2013(Thu), 02/01/2013(Fri), 02/05/2013(Tue), 02/06/2013(Wed), 02/07/2013(Thu)

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