Food and Drug Administration Establishment Inspection Report

Date Assigned: 11/30/2010 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Firm Mailing Address:

FEI: 3008569813 **JD/TA:** 62 **County:** DURHAM **Est Size:** 0 - 24,999

Phone: **District:** ATL-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

Previous inspection of this Institutional Review Board (IRB) was performed on 6/28/2010 -7/1/2010. No FDA-483 was issued. The inspection was classified (b) (5)

Current inspection was initiated in response to an assignment under FACTS # 1222938 issued from HFD-45, CDRH. The assignment requested that a CDRH IRB inspection be conducted in accordance with CP 7383.809 Institutional Review Board (IRC) Program. The inspection assignment also requested a review of studies utilizing the (b) (4) device and to determine the rationale for the IRB's initial non-significant risk decision for studies using the device.

Initially, three separate assignments were issued covering three boards (IRB #4, 5 & 8) at the Duke IRB to include review of one study listed in the assignment plus two additional studies of the investigator's choice for each board. It was later determined after the start of the first inspection, that although the Duke IRB had 9 IRB boards, all operate as one entity. After discussion with staff at CDRH, two of the assignments for IRB # 5 & 8 were canceled and one inspection was conducted under IRB assignment 1222938 IRB # 4.

Current inspection revealed the firm to be operating in a state of control with no significant deficiencies noted. The following IRB files were covered: documentation of IRB initial and continuing review, presence of protocols, informed consent documents, reports of adverse events and annual reports from the clinical investigator:

Pro00004599, TOP602, Phase II Prospective Study Evaluating the Role of Personalized Chemotherapy Regimens for Chemo-Naive Select Stage IIIB and IV Non-Small Cell Lung Cancer (NSCLC) in Patients Using a Genomic Predictor of Platinum-Resistance to Guide Therapy. CI: Dr. Gordana Vlahovic

Pro00000657, TOP703, Phase II Trial Prospective Study Evaluating the Role of Directed Cisplatin based Chemo with either Vinorelabine or Pemetrexed for the Adjunct of Early Stage NSCLC in Patients Using a Genomic Expression Profiles of Chemo Sensitivity to Guide Therapy. CI: Dr. Neal E. Ready

Pro00001345, (b) (4)

CI: (b) (4)

The Institutional Review Board procedures and practices, study files and other records were reviewed and found to be well organized and to contain all necessary information. During the close out discussion, no discrepancies were found and no FDA-483 was issued. No refusals were encountered and no samples were collected during the inspection.

Initial Classification: (b) (5)
F/U: Refer to CDRH for final review/classification

Distribution: O: ATL-DO files
CC + **Exh: David Burrow,** FDA CDRH/OC Div. of Bioresearch Monitoring, 10903 New Hampshire Ave, WO66-3502, Silver Spring, MD 20993-002
CC: Compliance/FMD145
CC: Greenboro, NC RP
CS: Clinical Investigations Monitor (T. Clarida)

Endorsement Location: FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Michelle D Haamid	02/28/2011 01:45 PM ET	Thomas D Clarida	03/01/2011 03:55 PM ET
Michelle D Haamid	02/28/2011 12:13 PM ET		ET
Michelle D Haamid	02/28/2011 12:08 PM ET		ET
Michelle D Haamid	02/28/2011 10:26 AM ET		ET

Food and Drug Administration Establishment Inspection Report

FEI:3008569813 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Related Firm FEI: **Name & Address of Related Firm:**

Registration Type **Registration Dates**

There are no Registration Types

Establishment Type		Industry Code	
8	Institutional Review Committee (IRC) for Human Studies	75	Chemistry
8	Institutional Review Committee (IRC) for Human Studies	82	Immunology

District Use Code:

Food and Drug Administration Establishment Inspection Report

FEI: 3008569813 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
83809	Institutional Review Committee (IRC) for Human Studies	82 N				(b) (5)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	03/01/2011	(b) (5)	Clarida, Thomas D	ATL-IB-TC

Remarks: Referred to CDRH for final/classification.

FEI: 3008569813 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
82 N	YI Institutional Review Committee (IRC) for Human Studies	(b) (4)	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Haamid, Michelle D	INV	ATL-DO	83809	Institutional Review Comr	82 N	80
					Total Hours:	80

FEI: 3008569813 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Inspection Result

EIR Location **Trips Num**
Turbo EIR & ATL-DO

Inspection Summary
Previous inspection of this Institutional Review Board (IRB) was performed on 6/28/2010 -7/1/2010. No FDA-483 was issued. The inspection was classified (b) (5)

Current inspection was initiated in response to an assignment under FACTS # 1222938 issued from HFD-45, CDRH. The assignment requested that a CDRH IRB inspection be conducted in accordance with CP 7383.809 Institutional Review Board (IRC) Program. The inspection assignment also requested a review of studies utilizing the (b) (4) device and to determine the rationale for the IRB's initial non-significant risk decision for studies using the device.

Initially, three separate assignments were issued covering three boards (IRB #4, 5 & 8) at the Duke IRB to include review of one study listed in the assignment plus two additional studies of the investigator's choice for each board. It was later determined after the start of the first inspection, that although the Duke IRB had 9 IRB boards all operate as one entity. After discussion with staff at CDRH, two of the assignments for IRB # 5 & 8 were canceled and one inspection was conducted under IRB assignment 1222938 IRB # 4. During the beginning of the inspections, three FDA-482, Notice of Inspections were issued to each chair for the three IRB boards for each assignment. The FDA-482's were issued to the chair's that were available and most responsible at the start of the inspection that were as follows: Sharon L. Ellison, Vice Chair IRB#4, Dr. Donna Cookmeyer, Chair IRB#5 and Nancy M. Allen LaPointe, Vice Chair IRB # 8. Others present during the opening meeting included Dr. John Falletta, Senior Chair for Duke IRB, Jody Power, IRB Executive Director, Margaret Groves, SOM Compliance.

Current inspection revealed the firm to be operating in a state of control with no significant deficiencies noted. The following IRB files were covered: documentation of IRB initial and continuing review, presence of protocols, informed consent documents, reports of adverse events and annual reports from the clinical investigator:

Pro00004599, TOP602, (b) (4)
CI: (b) (4)

Pro00000657, TOP703, (b) (4)
CI: (b) (4)

Pro00001345, (b) (4)
CI: (b) (4)

The Institutional Review Board procedures and practices, study files and other records were reviewed and found to be well organized and to contain all necessary information. During the close out discussion, no discrepancies were found and no FDA-483 was issued. No refusals were encountered and no samples were collected during the inspection.

IB Suggested Actions

Action **Remarks**

Referrals

FEI: 3008569813 **Inspection Start Date:** 01/31/2011 **Inspection End Date:** 02/04/2011

Firm Name & Address: Duke University Health System Irb , 2424 Erwin Rd , Ste 405 Durham, NC 27705-3824 US

Org Name	Mail Code	Remarks

Refusals

Inspection Refusals:

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

SUMMARY

Previous inspection of this Institutional Review Board (IRB) was performed on 6/28/2010 -7/1/2010. No FDA-483 was issued. The inspection was classified (b) (5)

Current inspection was initiated in response to an assignment under FACTS # 1222938 issued from HFD-45, CDRH. The assignment requested that a CDRH IRB inspection be conducted in accordance with CP 7383.809 Institutional Review Board (IRC) Program. The inspection assignment also requested a review of studies utilizing the (b) (4) device and to determine the rationale for the IRB's initial non-significant risk decision for studies using the device.

Initially, three separate assignments were issued covering three boards (IRB #4, 5 & 8) at the Duke IRB to include review of one study listed in the assignment plus two additional studies of the investigator's choice for each board. It was later determined after the start of the first inspection, that although the Duke IRB had 9 IRB boards all operate as one entity. After discussion with staff at CDRH, two of the assignments for IRB # 5 & 8 were canceled and one inspection was conducted under IRB assignment 1222938 IRB # 4. During the beginning of the inspections, three FDA-482, Notice of Inspections were issued to each chair for the three IRB boards for each assignment. The FDA-482's were issued to the chair's that were available and most responsible at the start of the inspection that were as follows: Sharon L. Ellison, Vice Chair IRB#4, Dr. Donna Cookmeyer, Chair IRB#5 and Nancy M. Allen LaPointe, Vice Chair IRB # 8. Others present during the opening meeting included Dr. John Falletta, Senior Chair for Duke IRB, Jody Power, IRB Executive Director, Margaret Groves, SOM Compliance.

Current inspection revealed the firm to be operating in a state of control with no significant deficiencies noted. The following IRB studies were covered:

Pro00004599, TOP602, (b) (4)
CI: (b) (4)

Pro00000657, TOP703, (b) (4)
CI: (b) (4)

Pro00001345, (b) (4)

CI: (b) (4)

The Institutional Review Board procedures and practices, study files and other records were reviewed and found to be well organized and to contain all necessary information. During the close out discussion, no discrepancies were found and no FDA-483 was issued. No refusals were encountered and no samples were collected during the inspection.

ADMINISTRATIVE DATA

Inspected firm:	Duke University Health System IRB
Location:	2424 Erwin Rd Ste 405 Durham, NC 27705-3824
Phone:	919-668-5114
FAX:	
Mailing address:	2424 Erwin Rd Ste 405 Durham, NC 27705-3824
Dates of inspection:	1/31/2011, 2/1/2011, 2/2/2011, 2/3/2011, 2/4/2011
Days in the facility:	5
Participants:	Michelle D Haamid, Investigator

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

During the opening meeting on 1/18/11 with Drs. Vlahovic and Ready, Dr. Falletta and Ms. Groves were present. I informed them both at that time that I would be conducting an inspection of the Duke IRB. I scheduled the inspection for 1/31/11. On 1/31/11, I met with Dr. Falletta, Senior Chair, Dr. Donna Cookmeyer, IRB# 5 Chair, Dr. Sharon Ellison, IRB# 4, Vice Chair and Dr. Nancy LaPointe, IRB#8, Vice Chair. Credentials were presented and a FDA-482, Notice of Inspection, was issued to Drs Cookmeyer, Ellison and LaPointe. Others present included Ms. Jody Power, IRB Executive Director for the IRB and Ms. Margaret Groves, SOM Compliance. The chairperson's were the most responsible for their IRB at the time of the inspection. They serve as the head of their boards and are responsible for overseeing the meetings and review of research.

Ms. Power provided relevant information and paper and CD copies of records during the course of the inspection. Dr. John Falletta is the Senior Chair for all IRB boards of the Duke IRB and he has the overall responsibility for Duke IRB Administration. Dr. Falletta also provided information regarding the IRB review of studies.

Any FDA correspondences should be addressed to Jody Power, the Executive Director for the IRB. Correspondences should be mailed to the following address: Duke University Health System IRB, 2424 Erwin Rd. Ste 405 Hock Plaza Durham, NC 27710.

IRB OPERATIONS

According to Dr. Falletta, the Duke IRB as a whole reviews approximately 4500 – 5000 protocols per year and receives over 11,000 submissions per year. Per the assignment, this inspection focused on studies utilizing the (b)(4) device. A list of all active ongoing non-significant risk (NSR) and significant risk (SR) device studies within the past year was requested and a copy is included as **Exhibit# 2**. There (b)(4) chairpersons and there are (b)(4) full time staff that triage submissions as studies are received for review. Reviews are handled either by full board or by an expedited process. There are approximately (b)(4) of reviewed studies conducted by a convened full board and (b)(4) of the reviews by expedited procedures.

The IRB currently has registered each board separately within the FDA/HHS database. After the opening meeting and start of tracking of the three studies requested for review, it was determined that the IRB boards review studies as one entity. According to Ms. Power, one study may have its initial review by one board but a different board may review the continuing review or amendments during future reviews. As a result of this, I recommended that the IRB should change their registration to one registration. This suggestion was given because it is difficult to track any one study based on the IRB board. All boards under the Duke IRB follow the same SOP's and policies.

Although any board under the IRB can review studies during the progress of a study, if a board approves a study with the condition of modifications, the same board would review the study modifications upon subsequent resubmission for approval. A copy of the printouts listing each board registration is included as **Exhibit#3.** Other boards afterward can review future progress.

In order to be considered for review, each proposed study submission will consist of all the documents as required by the IRB. According to the IRB procedures and Ms. Power, each proposed study is reviewed in depth by a primary reviewer. At least (b)(4) days prior, each member of the IRB has access electronically to the study information related to the upcoming meeting. The study information consist of a submission form, progress report (if a renewal), protocol summary, protocol, consent documents, advertisements, recruitment material, waiver requests, notice of review preparatory to research, list of problems or events requiring reporting, investigators assessment for adverse events and any other required documents.

The IRB procedures address how initial and continuing reviews are conducted. The IRB requires clinical investigators to provide continuing review reports at intervals appropriate to the level of risk and complexity of the protocol but not less frequently than once per year.

The IRB's written procedures for the waiver of consent under emergent conditions are described within the procedures. The IRB's written procedures do address determinations of significant vs. non-significant risk devices.

During meetings per IRB policy, there must be a (b)(4) or (b)(4), 1 (b)(4) and 1 (b)(4) present to conduct an IRB meeting. IRB meetings are held (b)(4) with (b)(4) boards meeting each (b)(4) of the (b)(4) For example, board (b)(4) will meet during the (b)(4) on (b)(4) and board (b)(4) will meet during the (b)(4) on (b)(4) and so on until all 8 boards have meet (b)(4). Exceptions are made to the schedule during holidays. A schedule is listed within the IRB's SOP's indicating when each board meets during a particular month. The minutes from IRB meetings indicate that the following issues are covered at IRB meetings: new protocols and informed consent forms; request for continuing review; protocol revisions; study terminations; items approved through expedited review and adverse events.

The IRB does require investigators to abstain from voting on matters in which the member has a conflicting interest. Members may not vote in a decision/action in which they have a vested interest in the project. They may present information to the board on the study but are not allowed to vote on the study. Review of IRB meeting minutes revealed that the IRB does review proposed and continuing studies at convened meetings. In order to obtain IRB approval, a proposal must receive majority vote of the members present. A majority is defined as (b)(4) of the members plus (b)(4) The IRB does not have audit functions and utilizes outside entities to conduct audits of research that require further investigation.

The IRB's written procedures include a section for informed consent. Review of three study files (listed in the Summary of Findings section) disclosed no instances where an abbreviated informed consent procedure was used or an oral presentation of informed consent was given by the investigator to the subject.

The informed consent documents for the three studies reviewed were submitted to the FDA in an attachment prior to this inspection. Copies were found to be electronically maintained in the IRB's files and revealed to be the same as the consent documents already submitted to FDA. No additional copies were collected. No problems were found with the consent documentation.

A detail description of the IRB operations can be found within the IRB's policies listed on the CD provided from the IRB labeled "IRB SOP's" which are included with this report as **Exhibit#1**

AUTHORITY

The IRB has the authority to approve, disapprove or require modification to research studies. This authority is documented within the IRB's procedures. In addition, the IRB has the authority to suspend or discontinue research if the IRB believes the study is not being conducted according to

requirements, unexpected adverse events have occurred, the rights of human subjects are questioned or protocol compliance is an issue . Review of the IRB minutes for the studies covered revealed that the IRB exercised its authority to approve, disapprove and modify studies.

MEMBERSHIP

According to the chairman and IRB procedures, members are selected from a variety of backgrounds, qualified through experience and expertise, diversity (consideration of gender, race, and cultural background) and sensitivity to community attitudes. The review of the 2011current IRB membership rosters for boards 4, 5 and 8 found that each board includes at least one voting member whose primary concerns are in scientific areas; at least one member whose primary concerns are in non-scientific areas; and at least one member who represents the community. A copy of a current listing (2/2011) of all IRB rosters for all 9 boards can be found on the CD provided under the policies and rosters tab. The CD is included as **Exhibit#1.**

Members can serve as alternates for any board but are assigned a permanent board to serve. The IRB is comprised of nine individual IRB's, eight of which meet (b)(4) and the ninth that functions as a (b)(4) IRB.

Dr. John Falletta is the senior chair of all boards for the IRB and there (b)(4) chairman for each of the (b)(4) boards that review research. All chairman and committee members have their titles and affiliation with the Duke University Health System listed on the IRB Membership Rosters.

There are two sets of membership rosters. One is a roster that is updated and printed monthly and the second is one that is printed prior to convened meetings to show the most up-to-date members. The second rosters help assist with documentation of the members in attendance and documentation of the number of members voting for or against during studies. Members present are highlighted in green. Copies of IRB rosters **(Exhibits # 4, 5 & 6)** for boards that reviewed the three studies for the specific time periods were collected.

RECORD KEEPING REQUIREMENTS

The IRB does retain electronically copies of approved versions of consent forms and protocols; as well as, communications between the IRB and the investigator.

Minutes from all three studies listed in the summary of findings section were reviewed at random and no deficiencies were noted. Examples of IRB minutes have been included and referenced below by study reviewed. These meeting minutes were selected in relation to the three studies selected for review.

During the course of the current inspection a total of three studies were reviewed. Each study file contained a copy of the protocol, informed consent documents, protocol revision summaries and correspondences between the IRB and the investigator.

Verification of documentation of current IRB performance with regards to the three tracked studies was completed by viewing the documents on the IRB's online database. Records related to the three referenced studies covered during this inspection were collected to illustrate current IRB practices.

Study# Pro00000657, Pro00004599, and Pro00001345 were all initially reviewed by the IRB during 2007. A copy of the IRB approval letters were reviewed on the IRB's database for each study and were previously voluntarily submitted to FDA by the IRB via email attachment. The electronic approval letters matched the letters that had been previously submitted and no additional copies were requested. The IRB meeting minutes from 2007 -2011 showing continuing review of the studies were reviewed and have been attached via a CD prepared by the IRB and are included as **Exhibit #1**. The meeting minutes are listed under the section listed IRB minutes that also contain the corresponding voting member's log. The voting log shows the members present and number voting.

An agenda and meeting minutes document studies to be reviewed and are stored by year in binders. The agenda, voting logs and meeting minutes are organized by category and each study is assigned a number on the agenda. This indicates which study is reviewed first and the category. The number and category is listed with the title of the study above the description of the IRB review and action. For example, a new initial review will be listed as "1N" with the study title. The "1N" indicates it as a new study review and the first new study on the agenda. A description of the categories by letters is listed on the minutes and agenda. In addition, the agenda and voting log list the study using the similar number and category naming system. No problems were found with the review of the meeting minutes, agendas or attached logs.

In addition, amendments for the studies were reviewed and verified. The IRB documents the amendments by review type, review date, approval date and status and uses a business item report to document the title, principal investigator, date and description of the amendments. Every amendment was verified to ensure that a description was documented and available for review by the IRB boards. **Exhibits#7, 8 & 9** are copies of the amendments with the amendment listing and business item report with the amendment descriptions identified with the study number. The below chart list the study approvals reviewed by date.

Study#	**IRB# Approval Date**	**Date Approval Type**
Pro00000657	IRB # 5, 7/18/07	Initial
Pro00000657	IRB# 1, 7/2/08	Continuing Review
Pro00000657	IRB# 8, 6/25/09	Continuing Review

Pro00000657	IRB# 8, 6/24/10	Continuing Review
Pro00004599	IRB # 4, 2/8/07	Initial
Pro00004599	IRB # 5, 1/16/08	Continuing Review
Pro00004599	IRB# 8, 1/29/09	Continuing Review
Pro00004599	IRB# 4, 1/14/10	Continuing Review
Pro00001345	IRB# 8, 7/26/07	Initial
Pro00001345	IRB# 7, 7/23/08	Continuing Review
Pro00001345	IRB# 2, 7/2/09	Continuing Review
Pro00001345	IRB# 2, 7/8/10	Continuing Review

No problems were found with any of the tracked studies reviewed by the IRB.

IRB RATIONALE FOR NSR DETERMINATON FOR STUDIES Pro00000657, Pro00004599 & Pro00001345

During an opening meeting and an additional meeting, I asked Dr. Falletta what was the IRB's rationale for the Non-Significant risk (NSR) determination for the studies being tracked in this inspection. Dr. Falletta said that his explanation was Duke IRB's rationale prior to FDA involvement. Dr. Falletta told me that the (b)(4) was not considered by the IRB to be a device initially. They looked at it as a tool that could (b)(4) and not whether (b)(4) They focused on whether safety and effectiveness was being studied of the device and determined if it was not then it did not pose a significant risk (SR). Dr. Falletta explained that the IRB felt the devices posed no significant risk because approved drugs would be used that were considered standard of care for (b)(4) patients.

During the course of the study, one of the clinical sites utilized Western IRB (WIRB) to review the study and determined the study device to be a significant risk. In addition, WIRB stated that an IDE would be required and no IND was required. After the Duke IRB learned of WIRB's determination, the Duke IRB did another review of the study.

The Duke IRB initiated an investigation via use of a third party and letters were sent to FDA to inquire about whether an IDE and/IND would be required to use the device. After the Duke IRB heard from FDA that an IDE would be needed, there were some changes made to the protocol of the studies and another inquiry letter during the end of 12/09 was sent to FDA to see if an IDE would still be required. At the same time, the studies had been placed on hold sometime around 8/09 and no new patients were allowed to be enrolled. Meanwhile, the Duke Cancer Center committee had reviewed the study issues, and determined that subjects already enrolled in the studies should

continue to receive treatment. See the dean's letter that was submitted to FDA **(Exhibit# 10)** discussing the allowance of continued treatment to existing patients. According to Dr. Falletta after a couple of months, there was no response from the FDA regarding the changes made or whether an IDE should be filed. The IRB assumed that no news meant good news and decided to allow continued enrollment around 2/10 or 3/10 of the studies. Dr. Falletta said that the IRB now realizes that it was probably wrong to assume everything was ok to proceed. The IRB realizes now that the device does pose significant risk and that an IDE should have been filed. Currently, all three studies have been closed, and the clinical sites do not plan to file an IDE.

Specific questions were asked per the CDRH assignment in regards to review of medical device studies and requested the following information: Does the IRB consider device description and confirm the device regulatory status, require regulatory status documentation, verify the qualifications of principal investigators, select members based on their knowledge and experience with similar protocols and devices and review the scientific merits of the proposed research?

These questions were asked and documentation was reviewed to determine how the IRB addresses the concerns. The current IRB SOP's addresses how studies are reviewed. A primary reviewer with expertise in the area of the product being studied is assigned to review the protocol and documentation in depth prior to review by the full board. In addition, experts are also called in to assist with the review to gain a better understanding of the study and to determine the scientific soundness of the study. The IRB requires all documentation to be submitted from the principal investigator to the IRB which should include all associated risk involved with the study. If the sponsor has already determined an IDE is required then the IRB requires principal investigators to either list the IDE number on the protocol or provide the IDE document from the sponsor. If the principal investigator is a sponsor investigator, then the IRB requires documentation from the FDA to be submitted.

According to the IRB polices, only cancer center faculty can be principal investigators on cancer studies. Cancer studies also are required to go through Cancer Center Protocol Committee for evaluation of the scientific soundness to ensure proper conduct of research. Verification of qualifications of staff is verified by the Duke University Health System human resources department and not the IRB. In regards to the (b)(4) studies, the methodology that had been preformed already for the (b)(4) device would not have been reviewed by the cancer protocol committee or the physicians conducting the studies. According to Dr. Falletta, the cancer protocol committee or the physicians did not have the staff or resources to verify the methodology. Although the cancer center did not review the science behind the methodology, a separate review was conducted by a third party of the methodology. A review of previous records submitted from the IRB, found that a detail description of this review and findings was provided via an attachment to the FDA prior to the inspection.

DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a final discussion was held with Dr. Falletta IRB Senior Chairman, IRB about the areas covered during the inspection. No FDA-483 was issued and no samples were collected. This final closeout was conducted immediately after a closeout meeting that was held with principal investigators Dr. Neal E. Ready and Dr. Gordana Vlahovic. Others present at both meetings were Aledi Marten, SOM Compliance, Margaret Groves, SOM Compliance, Nancy Allen LaPointe, IRB Chair, Dr. Wesley Byerly, Dean's Office, SOM, Tina Tyson, Chief Compliance Officer, Bruce Burnett, Regulatory, Debra Shoemaker, Clinical Coordinator, Traci Foster, Clinical Trials Manager, Jody Power, IRB Executive Director and Donna Cookmeyer , IRB Chair.

REFUSALS

There were no refusals encountered during the inspection.

EXHIBITS COLLECTED

1. CD with SOP's, Meeting minutes, agenda and voting logs
2. List of currently open studies medical device studies from past year.
3. IRB Registration listing
4. Study Pro00000657, Membership Rosters
5. Study Pro00004599, Membership Rosters
6. Study Pro00001345, Membership Rosters
7. Study Pro00000657, amendment listing and business item report
8. Study Pro00004599, amendment listing and business item report
9. Study Pro00001345, amendment listing and business item report
10. Dean's Letter to FDA

ATTACHMENTS

1. FDA-482, Notice of Inspection each for three IRB Chairpersons
2. CDRH, Assignment memo and background information
3. FACTS Assignment sheet
4. FACTS coversheet

Michelle D Haamid

Michelle D Haamid, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

TO

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. FIRM NAME

5. HOUR a.m. / p.m.

6. NUMBER AND STREET

7. CITY AND STATE & ZIP CODE

8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance form the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments form small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data

(Continued on Reverse)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

TO

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. FIRM NAME

5. HOUR a.m. / p.m.

6. NUMBER AND STREET

7. CITY AND STATE & ZIP CODE

8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance form the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments form small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities), bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data

(Continued on Reverse)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

TO

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. FIRM NAME

5. HOUR a.m. / p.m.

6. NUMBER AND STREET

7. CITY AND STATE & ZIP CODE

8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance form the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments form small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data

(Continued on Reverse)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful--

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Memorandum of Institutional Review Board Inspection Assignment

Date: October 8, 2010

From: Pharmacist
Division of Bioresearch Monitoring
Center for Devices and Radiological Health

Subject: Directed Institutional Review Board (IRB) Inspection Assignment

To: Dawn Todd-Murrell Director, Investigations Branch
Atlanta District Office (HFR-SE150)

Reference:

CP:	7348.809 (IRB)
PAC:	83809
Op:	12 (domestic)
Priority:	**High**
EIR Due Date:	Jan 30, 2011
FACTS #:	1222938
FEI Number	*to be assigned by field*

This assignment is a covered activity under MDUFMA.

Institutional Review Board	**Protocol** (b) (4)
IRB 4 Duke University Health System Institutional Review Board (IRB) 2424 Erwin Rd., Ste. 405 Hock Plaza Durham, NC 27710 John Harrelson, M.D., Chair, Duke University Health System IRB Telephone Number: (919) 668-5111	(b) (4)

BACKGROUND INFORMATION

In the past, all the IRBs under Duke University Health System were covered under one FEI number, and had been inspected as a single entity. However, because the IRBs are now registered individually, we consider each IRB an individual entity for purposes of inspection. This inspection should cover IRB 4 specifically. This appears to be the first inspection of IRB 4.

GENERAL INSTRUCTIONS

In your review, please include the above device research protocol (**Attachment 1**) as well as two other medical device studies of your choosing. Please perform an IRB inspection in accordance with the current Compliance Program 7348.809. Major program elements include: IRB membership; written procedures for initial and continuing review and approval of research projects; documentation of continuing review of research; IRB reporting requirements; expedited review process; emergency review; and informed consent.

SPECIAL INSTRUCTIONS

Please collect (b) (5)

Please also obtain (b) (5) (b) (5)

studies. For each study selected, please obtain:

(b) (5)

In addition to the information requested above, please obtain a (b) (5) If no SR device studies

(b) (5) [redacted]

Please also determine (b) (5) [redacted], for example:

1 (b) (5) [redacted]

2

3

4

5

In addition, does the IRB consider (b) (5) [redacted]

Please also obtain (b) (5) [redacted]

REPORTING INSTRUCTIONS

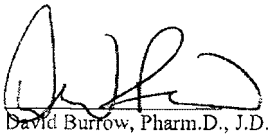
(b) (5) [redacted]

As soon as possible, after the inspection is complete, send an e-mail to me at David.Burrow@fda.hhs.gov with any inspectional findings. If a Form FDA 483 is issued, fax it to my attention at (301) 847-8136. Forward the EIR, with exhibits, to:

David Burrow
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
WO66-3502
Silver Spring, MD 20993-0002

Important: After the inspection, forward immediately any IRB written response. We must review it prior to our issuing post-inspection correspondence to the IRB.

If you have any questions with respect to this assignment, you may call David Burrow at (301) 796-5632.



David Burrow, Pharm.D., J.D.

ATTACHMENTS:

Attachment 1. Study Protocol 04599
Attachment 2. Related Correspondence