Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Selection

Site #: CA204
Protocol Number: FAL25
Investigator: Cunningham, Marcus

Sponsors:

Start Date : 9/10/2005
Completed Date: 9/10/2005

Location: Los Angeles Research Institute: Los Angeles, CA

Investigation Product/Test Article: Laftr
Visit Mechanism: On-site

Initially Submitted on 11/1/2009 **Final Submission By Test6 CA on 11/1/2009 7:32 AM** **Approval By student13 student13 on 11/22/2009 6:48 AM**

Attendees

Last Name	First Name	Role
Atkinson	William	Study Coordinator
Cunningham	Marcus	Principal Investigator

Checklist

Item	Question	Response	Issue	Comments
1	Were key aspects of the protocol, study-specific procedures, and requirements discussed?	Yes		
2	Was subject recruitment, including target enrollment rate and timelines discussed?	Yes		
3	Was the site's access to the study subject population and method for subject identification discussed?	Yes		PI does not forsee issues with enrollment. Site will approach potential patients who are in recovery area. Pre-procedure screening Dept will also contact Study Coordinator if potential patients are scheduled. Outpatients will been seen 14 days prior to procedure.
4	Is the Investigator currently conducting another research study that would compete for the same patient population?	No		
5	Did the Investigator express an ability to meet the enrollment requirements and timelines?	Yes		Site stated they expect to screen approximately 1-2 subjects per day, and enroll approximately 1-3 subjects per week. Based on inclusion/exclusion criteria, PI does not forsee issues with enrollment.
6	Were the roles and responsibilities of the Investigator and site staff discussed?	Yes		
7	Was the investigational status of the test article / intervention, including information from the investigator's brochure, package insert or instructions for use discussed?	Yes		
8	Were monitoring procedures and expectations (e.g., space, internet access, visit frequency, and staff availability) discussed?	Yes		The CRA informed site that Periodic Monitoring visits will occur approximately every 8 weeks. It was noted that PI and SC must be available during visits.
9	Were the data collection requirements discussed?	Yes		PI & SC were instructed on process of reviewing and signing CRFfs. They are aware that PI must sign AEs and casebooks once subjects have completed the study. Study Coordinator has experience with CRFs.
10	Were financial and contractual aspects (e.g., requirements for contract execution, financial disclosure, conflict of interest and site reimbursement) discussed?	Yes		CRA asked if PI agreed with study's reimbursement per patient. The research manager stated that PI is not privy to patient reimbursement. PI has a cap to per patient reimbursement that he receives. Research Manager works with budget. There were no contractual Issues.

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11	Were the Investigator and site staff qualifications, including relevant education and therapeutic experience assessed?			PI and Study Coordinator have worked with one other DCRI study 3 years ago. There were no performance issues. Site also has 5 years experience with other clinical studies.
12	Does the Investigator have previous experience conducting clinical trials and/or similar studies under GCP?	Yes		PI has experience conducting CABG and valve replacement studies.
13	Was the Investigator and site staff availability for conducting the study assessed?	Yes		The CRA found the site to be adequate to conduct this study. There are no conflicting studies currently at the site. PI and SC expressed no problems with availability for monitoring visits.
14	Does the Investigator give assurance that he/she has the availability to conduct and supervise the study?	Yes		
15	Can the Investigator provide adequate clinical space to accommodate this study?	Yes		CRA toured the OR, CVICU, Pharmacy & Lab. The site has adequate space to perform the study related duties.
16	Does the Investigator anticipate using satellite sites or other off-site facilities?	No		
17	Does the site have the required equipment to perform the study?	Yes		Site has 24 acc[illegible] to [illegible]79-[illegible]egree centi[illegible]rade freezer and centrifuge. Both located in the lab.
18	Were local laboratory requirements and procedures discussed?	Yes		CRA rev[illegible]ed [illegible]dule of blo[illegible]d dr[illegible]s for PK samples. Local Lab will ship samples to Core Lab. A local c[illegible]urier [illegible]ill [illegible]eliv[illegible] dry ice. Site [illegible]s participating the the extra blood draws for first 10 patients enrolled
19	Are test article dispensing and storage areas appropriate (e.g., location, temperature, environmental factors, accessibility, security and space) for the study?	Yes		to[illegible] o[illegible] the [illegible]har[illegible]acy was conducted during this visit. No issues were identified. IP will be kept in a secure l[illegible]catio[illegible]n the pharmacy at room temperature. A temperature log is maintained.
20	Is the storage area for study records/materials adequate and secure?	Yes		IP will be kept in the pharmacy at room temperature. Study Coordinator will be responsible for updating inventory.
21	Does the site have access to a properly constituted IRB/IEC/REB?			The Site plans to use a local IRB that reviews corporate compliance and the protocol. The IRB meets once a month and the turn-around time is 2 weeks. The IRB issues a letter within 24 hours if there are clarifications and/or changes requested. The Study Coordinator attends the IRB Meetings.
22	Does the site have a current OHRP Assurance?	Yes		PI provided a copy of the Assurance Number and IRB Roster
23	Will the site require translation of study documents?	No		
24	Will the site be utilizing electronic health records for this study?	No		
25	Were source documentation requirements (e.g., availability, direct access, and location) discussed?	Yes		The CRA notified the site that original medical records are required during all monitoring visits. Site uses paper medical records, which can be taken out of medical records. Site asked that medical records are requested 7 days prior to visit. Monitoring will take place in research room located in basement of the hospital. There is access to copy and fax machines.

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26	If source data will be collected and stored electronically, were the basic aspects of the site's computer system, such as security and data recovery capabilities assessed?	NA		
27	Does the site have prior experience with Electronic Data Capture (EDC)?	No		
28	Were visit findings, deficiencies, discrepancies and/or action items, including assigned responsibilities and timelines for completion discussed with the Investigator and applicable site staff?	Yes		There were no issues. The site appears to have the patient population, study personnel resources, required equipment and experience to conduct the study.

Protocol Deviation

None

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 11-22-2009 6.47.09 AM	30,611	doc	11/22/20	

Additional Observations / Comments