Clinical Trip Report

Duke Clinical Research Institute

FALCON : Site Initiation

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

Sponsors:

Start Date : 10/20/2005
Completed Date: 10/20/2005

Location: Los Angeles Research Institute: Los Angeles, CA

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

Initially Submitted on 11/22/2009 **Final Submission By Test6 CA on 11/22/2009 6:58 AM** **Approval By student13 student13 on 11/22/2009 7:00 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		Key aspects were reviewed with PI and SC. We discussed Inclusion/Exclusion criteria, drug administration, schedule of events, study procedures, ICF process, documentation, and event reporting. PI & SC reviewed study drug administration & regulatory binder before initiation visit. Appropriate questions were asked by SC and related staff.
2	Was subject recruitment, including target enrollment rate and timelines discussed?	Yes		Study Coordinator has access to medical records for patients and will obtain IRB approval to review them. Once patient is found to meet inclusion/exclusion criteria, the PI or Sub-I will speak with patient to solicit interest and then have SC to come in and consent subject. Site will also approach potential patients in post-cath recovery area. The patients who are in the hospital will be seen the day before their procedure. Outpatients will be seen 1-5 days prior to their procedures. There will be no advertisement created or posted regarding the study.
3	Was the site's access to the study subject population and method for subject identification discussed?	Yes		See answer to question # 2
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?	No		The site is confident they will enroll sufficient subjects with protocol timelines. Subjects will be recruited from his practice and hospital referrals.
6	Were the roles and responsibilities of the Investigator and site staff discussed?	Yes		The PI and site staff's responsibilities were thoroughly reviewed during the visit. Site Signature Delegation Log ws submitted to DCRI and updated. PI is aware that the delegation log is updated as needed.
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		Accountability, randomization, dispensing, and administration were discussed with study coordinator. SC has previous experience with ALMAC randomization process. The Pharmacy does not require and order to dispense IP. The SC will remain in OR until study drug is dispensed.
8	Were monitoring procedures and expectations (e.g., space, internet access, visit frequency, and staff availability) discussed?	Yes		Site was informed that monitoring visits will be approximately ever 8 weeks and first visit will be 2 weeks after first subject is enrolled. Site is aware that all source docs will be reviewed for the 1st subject, and all ICF and critical variables will be reviewed for subsequent subjects.

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				Site is aware not to discard drug labels until CRA verifies drug accountability. Site has the appropriate amount of staff and space for conduct the study and
9	Were the data collection requirements discussed?	Yes		The PI was instructed on the process of reviewing and signing CRFs, AEs and the casebook once the subjects have completed the study. The PI understood that should electronic signature become necessary, his electronic signature is legally binding. There are no potential issues at this time.
10	Were financial and contractual aspects (e.g., requirements for contract execution, financial disclosure, conflict of interest and site reimbursement) discussed?	Yes		The site anticipates contract executiion by the end of this month
11	Were the Investigator and site staff qualifications, including relevant education and therapeutic experience assessed?			
12	Does the Investigator have previous experience conducting clinical trials and/or similar studies under GCP?	Yes		PI has 5 years experience as a PI and sub-investigator. PI has experience conducitn CABG and valve replacement/repair studies.
13	Was the Investigator and site staff availability for conducting the study assessed?	Yes		PI will allot approximately 2[illegible]% of his ti[illegible] this study. SC will allot at least 50 % of her time to this study. Both will be a[illegible]able fo[illegible]all [illegible]onitoring v[illegible]its.
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?	Y[illegible]		[illegible]e s[illegible]e has [illegible]dequate space to accommodate the study. CRA confirmed this at the Site Initiation Visit by c[illegible]nduc[illegible]g a tour of the OR, CVICU, pharmacy and lab.
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		
18	Were local laboratory requirements and procedures discussed?	Yes		The PI is aware that he is responosible for reviewing all lab results and that his signature on CRF indicates he has reviewed them and verifies they are accurate.
19	Are test article dispensing and storage areas appropriate (e.g., location, temperature, environmental factors, accessibility, security and space) for the study?	Yes		Study medication will be sotred in locked file cabinets inside the pharmacy at room temperature. The code to the main pharmacy changes intermittently. The SC is responsible for maintaining drug accountability log and and ensuring study medication shipments are received and secured.
20	Is the storage area for study records/materials adequate and secure?	Yes		The sorage area for study records will be located in a locked file cabinet in a locked room. The room code changes intermittently and is known only to the personnel working on this study
21	Does the site have access to a properly constituted IRB/IEC/REB?	Yes		Site uses local IRB - Covenant - The site plans to submit for the next IRB meeting (next month). Turn around time for approval is 2 weeks. IRB issues letter within 24 hours if further clarification and/or changes are requested. The SC attends IRB Meetings.

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22	Does the site have a current OHRP Assurance?	Yes		Site provided OHRP 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 site uses a combination of electronic and paper medical records. Site will use paper source documents to capture any data not captured by medical record. Site maintains a folder for each subject containing any study specific documentation.
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		

Follow Up

Activity Type	Visit Date	Description	Status	Assigned To	Resolution	Completed Date
Regulatory Documentation	10/20/2005	Regulatory Binder was not completely reviewed during SIV. CRA will complete review at first PMV.	Open	Test6 CA		
Study Med Prep/Admin	10/20/2005	The site would like to have an additional shipment of IP because they expect to be a high enroller.	Open	Test6 CA	Site will receive 1 extra shipment of study drug and a re-supply rate will be determined based on enrollment.	

Protocol Deviation

None

Attachments

Attachment Name	Size (Bytes)	Type	Modified	Comments
Confirmation Letter 11-22-2009 6.52.52	36,900	doc	11/22/2009	

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AM				

Additional Observations / Comments