Interview with IoR Script #1

Inspector: How many participants did site enrol, how many are ongoing, how many were discontinued?

Responder:160 or 150 enrolled I do not remember exact number. I believe all completed the study. (IoR must know the basic Information about the study)

Correct answerers in red: 160. All completed the study.

Inspector: What was your role as IoR?

Responder: I have oversight responsibilities related to the informed consent process, drug accountability, safety monitoring, maintaining essential study documents and delegation of responsibilities.

Inspector: What trial activities were you involved in?

Responder: I was not directly involved in any study related activities. I delegated all tasks to my team.(IoR must be able to demonstrate oversight)

I was not directly involved in any study related activities. I delegated all tasks to my team. I have oversight responsibilities.

Inspector: Please tell us about your site set up and responsibilities of the study team.

Responder: I can explain briefly, study coordinator could provide further details. Study nurses are responsible for consenting subjects; physicians are responsible for collecting medical history, physical examination, verification of subject eligibility. Study coordinator is responsible for maintenance of study files, pharmacist for Investigational Product (IP) management. (IoR must be able to demonstrate oversight)

Study nurses are responsible for consenting subjects; physicians are responsible for collecting medical history, physical examination, verification of subject eligibility. Study coordinator is responsible for maintenance of study files, pharmacist for Investigational Product (IP) management.

Inspector: How are delegated responsibilities documented?

Responder: On Delegation of Authority Log.

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Inspector: Do you check if the members of your team have all necessary training and experience to work on the study?

Responder: Study Coordinator (SC) is responsible for keeping training records updated.

(IoR must be able to demonstrate oversight)

Study Coordinator (SC) is responsible for keeping training records updated. SC must report to me in case any gaps are identified. When new team member join I check with SC if all is in place.

Inspector: Summarise any change in site personnel during the study.

Responder: Again SC will be the better person to address this question. (IoR must be able to demonstrate oversight)

I have to refer to Delegation of Authorities Log and handover documentation. I do not remember by heart.

Inspector: Who designed/provided informed consent document? Did you review it?

Responder: The form was provided by study sponsor. I did not review it. (IoR must be able to demonstrate oversight)

The form was provided by study sponsor. I did review it at the study start to make sure all elements are in place.

Inspector: Who obtained informed consent (IC)? Where? When? How much time did participant has to consider the study participation? How was process documented?

Responder: Participants were consented by staff delegated by me: study nurses, coordinator and counsellors. IC was obtained before any study procedures were initiated. The process was documented using the checklist.

Inspector: Have you or one of your physicians been involved in the consenting process?

Responder: No, we do not consider it necessary. The process is well managed by delegated staff.(only qualified Staff should answer medical questions, physician involvement is required by Declaration of Helsinki version 2004)

I will be involved or study physicians whenever participants have medical questions.

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Inspector: How were eligibility criteria assessed?

Responder: By one of the study physicians based on medical history, results of the lab tests, physical examination (this is key study activity, IoR must be able to demonstrate oversight)

By one of the study physicians based on medical history, results of the lab tests, physical examination. In case of need they will discuss with me.

Inspector: Have you been involved in the assessment of participants' eligibility?

Responder: Not directly but we discuss study enrollment during the staff meetings.

Inspector: Did you need to discuss the eligibility of any patients with the Sponsor/CRO?

Responder: For some studies, this is required I do not recall whether such process was in place for our study.

(eligibility assessment is key aspect IoR must know the process)

It was not required.

Inspector: Did all randomised patients fully meet the eligibility criteria?

Responder: I hope so (again key aspect IoR must be informed about all violation of inclusion/exclusion criteria)

Yes.

Inspector: Are there any situations the sub-investigator or any study team member had to contact you?

Responder: Whenever they feel, they need my help they can contact me. (IoR must be able to demonstrate oversight

Whenever they feel, they need my help they can contact me. Definitely I must be contacted in case of significant protocol deviations and SAEs/safety concerns. This is a part of the agenda of our staff meetings.

Inspector: Who was responsible for safety monitoring at your site?

Responder: Study physicians were responsible for collecting all safety related information and making an ongoing evaluation of participant's safety. (IoR must be able to demonstrate oversightt)

Study physicians were responsible for collecting all safety related information and making an ongoing evaluation of participant's safety. I should have been contacted in case of any concerns.

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Inspector: How was it done?

Responder: Information about potential safety issues was collected during each study visit by interviewing study participant, laboratory safety assessments were done as required by the protocol, the lab results were always reviewed by physician to check if any out of range results are present, the outcome of pelvic examination was checked and the abnormalities were managed as appropriate.

Inspector: What arrangements were in place to allow patients to make contact with the study team in an emergency?

Responder: All participants were provided with site contact details/phone numbers on the Informed Consent Form and could contact us at anytime.

Inspector: Who reported SAEs and what process was used?

Responder: This was done by study physician. I guess it was done via electronic reporting system (safety is key aspect IoR must know the SAE reporting process)

This was done by study physician via electronic reporting system.

Inspector: For AEs/SAEs, who made the assessment of causality? Were these assessments documented in the source data?

Responder: The assessments were made by study physician.

Inspector: Are you blinded or unblinded to IP?

Responder: I am blinded.

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Inspector: Please describe the unblinding process for the study.

Responder: I see no circumstances under which it is expected that unblinding will be necessary for provision of medical treatment or to otherwise protect the safety of study participants. In case of risk, I can always discontinue product use by this participant; however, knowledge of the specific product to which the participant was assigned is not necessary to guide further follow-up and/or treatment. If I feel that specific product, knowledge is necessary to protect participant safety I can contact Protocol Safety Review Team.

Inspector: How frequently were the monitoring visits (MVs) conducted?

Responder: Once per quarter. Usually I am not involved. This is coordinated by SC.

(volunteering Information and demonstrating lack of oversight)

Once per quarter.

Inspector: How you were informed about the issues identified during the monitoring visits?

Responder: I was really not involved in monitoring process. Please ask SC.

(IoR must be able to demonstrate oversight)

Follow-up letters are sent after each MV.

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Inspector: At the beginning of the interview, you explained that you were responsible for study oversight at the same time all the tasks were delegated to your staff and you were not involved in any of the critical study related tasks such as consenting, eligibility assessment, safety assessment training oversight etc. Please explain how the oversight is maintained and how do you supervise your staff.

Responder: I'm always around. We have meetings during which we discuss all problematic issues. (IoR must be able to demonstrate oversight and convince inspector that despite not being directly involved is aware of all key study aspects)

I'm always around. As I mentioned before we have meetings during which we discuss all problematic issues. My team is trained and know what kind of issues must be escalated to me.

Inspector: Are these meetings documented? How frequently do you meet with your staff?

Responder: We meet weekly, biweekly or monthly as required. As far as I know meetings are not documented. (IoR must be able to demonstrate oversight and convince inspector that despite not being directly involved is aware of all key study aspects)

It will depend on the phase of the study. We have more frequent meetings during the enrollment phase and less frequent during the maintenance phase. If important issues are discussed meetings are documented.