Informed Consent Process (IC) Script #2

Inspector: Who could obtain consent?

Responder: Any team research member delegated by Principal Investigator (PI) may conduct informed consent process. Usually the process is conducted by study nurse (SN), counsellors or study coordinator (SC).(do not use word usually if the site has defined process this process must be always followed)

Correct answers in red: Any team research member delegated by Principal Investigator (PI) may conduct informed consent process. The process is conducted by study nurse (SN), counsellors or study coordinator (SC).

Inspector: How do I find out who is delegated to obtain consent?

Responder: This will be documented on the Delegation of Authorities Log.

Inspector: What requirements must the individual met to be delegated to conduct IC process?

Responder: The person must speak and understand the language in which participant/legal guardian chooses to take informed consent and must be trained on IC process.

Inspector: Tell me more about the training you received.

Responder: I was trained on ICH GCP and the procedure (SOP) related to consenting process.

Inspector: Will physician be involved in the IC process?

Responder: No (medical questions should be addressed by qualified physician)

Yes in case of need

.

Informed Consent Process (IC) Script #2

Inspector: What happens in the case medical questions are raised by the participant?

Responder: Participants usually do not have that kind of questions.(never say never and be able to demonstrate that you have good process in place)

Medical questions will be always addressed by Investigator of Record or study physician.

Inspector: Is physician involvement required by the SOP?

Responder: I do not know. It is not required. I am not sure.(person involved in consenting must know answer, it is highly recommended to have such requirement in the SOP)

Yes. SOP states that IC proces is conducted by SN, SC, or counselor and this is followed by the contact with IoR/study physician.

Inspector: Is physician involvement required by the country regulations?

Responder: I do not know. I have never been trained on country regulations. Nobody told me that I should be trained on local regulations (person involved in consenting should know, in addition volunteering Information and blaming the others for not providing clear instruction)

The regulations state that the Investigator, or designated person delegated by the Investigator.

Or

I do not remember. I will check and will come back with an answer.

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

Responder: I was not involved in this process but I guess the form was provided by the study Sponsor.(guessing, not being able to demonstrate the knowledge of the process)

I was not involved in this process. I was provided with the ICF by IoR.

Informed Consent Process (IC) Script #2

Inspector: Did you consent any illiterate participants? Please describe the IC process for this group of patients.

Responder: The impartial witness must be present during the entire IC discussion. The participant may come with her own witness or another clinic-affiliated person will be asked to be present during the process. The ICF must be read to the participant in a language she understands. Should the participant be able to write her name she will complete the signature page. If participant is unable to write she will make her mark (thumb print) on each page of consent form. The form will be signed and dated by the witness and the person who consented the participant.

Inspector: Who could act as impartial witness?

Responder: Anybody selected by the participant or by the site.(incorrect definition of impartial witness)

Witness must be always independent of the trial and cannot be influenced by people involved with the trial.

Inspector: How is the consent process documented?

Responder: The process is usually documented using IC checklist (do not use the word usually)

The process is documented using IC checklist.

Informed Consent Process (IC) Script #2

Inspector: How do you know if correct version of ICF is used?

Responder: I always pick-up the form available in the Regulatory Binder. (good process must be in place to avoid the risk of providing participants with incorrect version and the process must be described)

We are informed by SC whenever revised ICF is issued and approved and patients have to be re-consented. The training session is organised to discuss the changes. The revised forms are available in Regulatory Binder. Expired forms are marked as such.

Inspector What process did you follow when revised consent document became available?

Responder: Same process will be followed for initial IC and all revisions.

Inspector: Did you consent any minors?

Responder: No.

Inspector: Do you have procedure for consenting minors?

Responder: Yes, the process is covered by the SOP.

Inspector: Is consent of one or two parents required in case minor is enrolled in the study?

Responder: I have to check. Minors are not enrolled in the study under inspection.