CHICKEN SOUP FOR THE BUSY COORDINATOR

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How to conduct and document E-SIV

Scenario

Principal Investigator (PI) was supposed to conduct an onsite Site Initiation Visit (SIV) for an Investigator Initiated Trial (IIT). However due to Covid-19 heightened measures, PI decided to conduct the SIV online and sought the Clinical Research Coordinator (CRC), Crystal's advice and support for the online SIV conduct.

What is an E-Site Initiation Visit (E-SIV)?

All study staff should be qualified, trained and updated about the protocol and delegated by the PI. SIV is conducted to ensure all study team members have an adequate understanding of the details of the protocol relevant to the tasks they will be performing and to clarify doubts. PI and study team members may refer to NHG PCR SOP 501-B03 to obtain guidance on how to conduct a SIV. Due to the safety management measures taken during the pandemic, the SIV can be done online, thus naming it E-SIV.

What do we need to prepare before an E-SIV?

The PI and study team members will need to source for a secure platform to conduct the E-SIV. The CRC will communicate with the PI and study team to get a mutually convenient date and time to conduct the E-SIV. To facilitate the smooth running of the E-SIV, CRC will send the meeting agenda, details and meeting link to the study team members before the meeting. If there is a need, study documents used during the E-SIV may also be emailed to the study team members through password protected files via a secured file transfer like eDOC.

What happens during an E-SIV?

Once all the study team members have entered the virtual meeting room, the host will commence the E-SIV via the online platform. The host may start off by covering the details of the protocol via a presentation. After the presentation, the host may suggest to the study team members to share and clarify any queries they may have. As required by DSRB/IRB, a monitoring plan should be in place prior to study initiation. Hence, it is recommended for the study team to come out with a monitoring plan and workflow during the E-SIV. Study team members may refer to NHG Investigator's manual to get more information on the monitoring plan.

What to be done and documented after an E-SIV?

Attendance at the E-SIV can be recorded using Study Initiation Meeting Attendance Log. Study team members who have attended the E-SIV may insert e-signatures on the attendance list. Templates for the logs can be found on NHG research website. After all the signatures have been obtained, a copy of the Study Initiation Meeting Attendance Log should be kept in the Investigator Site File. The PI must ensure that trainings conducted are documented. The study team may use the PCR 505-001: Training Record Form to record the trainings completed. The Study Delegation Log should also be completed and signed off by the PI for any task delegated to Study Team members prior to the start of their involvement/conduct of the Study.

Suggested platforms to use for the E-SIV?

CRCs are recommended to check with their research institution on the recommended platform to use for E-SIV. Examples of recommended platforms are, Zoom or Microsoft teams.

References:

1. PCR SOP 501-B03: Study Initiation
2. Investigator's Manual Addendum Version 1 December 2018

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