Category: Pre study procedures

Title: Preparing the site team for an Investigator initiated clinical study.

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1. Table of Contents

1. Purpose:

The objective of this standard operating procedure (SOP) is to explain to the research team to prepare the site for a clinical trial.

2. Scope

This SOP is limited to describing the requirements that the research team should meet in setting up an Investigator initiated clinical study after obtaining Ethics Committee approval. This SOP concerns all departmental personnel working in clinical research and should be followed by all those working on clinical studies involving human subjects

3. Responsibilities:

The Principal investigator, Co-investigator, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for implementation of this SOP.

4. Applicable rules, regulations and guidelines

- Guidance for Industry, Good Clinical Practice: Consolidated guideline, ICH Topic E6, 1996.
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.
- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017) http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- New Drugs and Clinical Trials Rules, 2019

5. Reference to other applicable SOPs

- SOP No. D 03/05 Responsibilities of the study team
- SOP No. D 04/05 Obtaining approval from the Institutional ethics committee

6. Detailed instructions

1. The PI should ensure the following documents are in place
   - Administrative approval (to conduct research, collaborate with other partners, opening of bank account and sending biological samples out of institute)
   - Institutional Ethics Committee Approval
   - Trial Master File (Refer to SOP No.16/04 Establishing a Trial master file)
   - CTRI Registration (if applicable)
2. The PI should ensure identification of the members of the study team assigning to them their individual responsibilities. (Refer to SOP No. 03/04 Responsibilities of the study team.)
3. The PI should ensure that,
   - All staff has undergone GCP training and there is documentation of the training
   - All staff in the study are trained both in the general SOPs and study specific SOP, if relevant.
   - Delegation of responsibilities is done and submitted to the Ethics committee.
   - Two rounds of protocol readings are completed and this is documented in the training log before initiation of the study.
   - The trial is registered in www.ctri.nic.in before the first patient/participant is recruited in the study (if applicable).
   - The CTRI registration number should be immediately sent to IEC-2 or IEC-3 and a letter of acknowledgement received from them.

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