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Category: Pre study procedures

Title: Preparing the site team for a clinical study sponsored by a pharmaceutical company (Sponsored Study)

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1. Purpose:

The objective of this standard operating procedure (SOP) is to explain to the research team to prepare the site team for a clinical study sponsored by a pharmaceutical company.

2. Scope

This SOP is limited to describing the requirements that the research team should meet in setting up a 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 participants.

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.
- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017.
- New Drugs and Clinical Trials Rules, 2019

5. Reference to other applicable SOPs

- SOP No. D 04/05 Obtaining approval from the Institutional Ethics Committee (IEC-1 or IEC-2)
- SOP No. D 03/05 Responsibilities of the study team.
- SOP D 21/05 Contact and communication with sponsor

6. Detailed instructions

1. The PI should ensure that 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
   - Signed Clinical Trial Agreement (CTA)
   - Institutional Ethics Committee (IEC-1) approval
   - DHR and CSDCO approval
   - Trial Master File (Refer to SOP No.16/04 Establishing a Trial master file)
   - CTRI Registration (if applicable)
   - DJST/DDF/Research Society details for issue of grants
   - CDSCO vide notification: File No. CT/SAE-Misc-10/2020-Part.B

2. The PI should ensure that,
   - All staff have undergone GCP training and there is documentation of the training (to be valid throughout study)
   - 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 and the sponsors.
   - Two rounds of protocol readings are completed and are documented in the training log before site initiation.
   - The trial is registered in www.ctri.in before the first patient/participant is recruited in the study (if applicable).

- The CTRI registration number should be immediately sent to IEC and a letter of acknowledgement received from them.
- The sponsor should have registered the PI with the SUGAM portal for the study and the Login should be provided to the PI. All details of the PI should be completed on the SUGAM portal using the Login provided.

3. The PI and all research team members who are delegated responsibilities should be present during the initiation visit.

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