CT 303 _____

EFFECTIVE DATE: February 2024

To encourage authenticity and the production of quality data. Good documentation efforts support the completion of all regulation requirements, such as ALCOA-C, accurate communication and action planning, human subjects protections, and effective corrective and preventive actions for any clinical trial.

Policy

All documentation practices are held to standards as defined in ICH-GCP. GCP training is required for all staff documenting clinical trial data, as outlined in SOP 101.

Principal Investigators (PIs) are required to provide adequate oversight of all clinical research activities at the site, whether the activity is conducted by the PI, by study team members, or by applicable third parties. Adequate oversight encompasses many activities and obligations, such as ensuring regulatory compliance, staff training, and subject medical care. Oversight must be clearly documented in the subject's chart.

Procedure

1. PI oversight of site documentation practices include:
   1.1. Signing of inclusion/exclusion source to indicate review and veriivi icd(a)-4 (t)2 ahtac evactg15ryi i-4 (
   1.1. 1.1.

1.1. 1.1.

1.1. s9ID 5 BD-1 (ncc)-3 (um)5 (i)ord1ourh.1Rnd vumeonTa-3 (nt)2 (a)[s) -3 (nt)2 (a)-ho3 (g)-2c r1 Tc -0. (g)-2d b3 (cid(g)-1 ( )]TJ

- Available: Data record is available for review, audit, or inspection, over its lifetime.
- Traceable: Data should be traceable throughout the data life cycle. Original data entry and all changes must be signed or initialed at the time of entry.
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4. All data should be recorded in uneditable black or blue ink. Do not use pencil.

5. All activities must be recorded. Examples include:
    - Telephone logs, including communications with subject, monitor or Sponsor.
    - Records of research team meetings.
    - All study visits as outlined in the protocol
    - Return and dispensation of investigational product or devices.

6. Corrections shall not alter or obscure an earlier entry. Original entry must remain legible.
    - Do not make erasures.
    - Do not use correction fluids (“white-out”).
    - Do not over-sD/TT3 1 j EMC /Lbl5ou4 Tw ( )Tj EMC /LBody <</MCI5 0/b2 0 0 12 <</MCI

9.2. Data that is collected for the sole purpose of the sponsored research is property of the sponsor unless otherwise stated in the Clinical Trial Agreement (CTA).

CT 101 Good Clinical Practice
CT 104 Protecting Confidential Information

N/A

February 2027

Director, Clinical Trials Office