ALZ-NET Operations Regulatory Compliance Policy

Overview

This policy outlines the regulatory compliance requirements for Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) sites as defined by the ALZ-NET Operations and Regulatory teams at the American College of Radiology (ACR) and Advarra Institutional Review Board (IRB). Sites must respond promptly and accurately to all regulatory matters in accordance with the Policy Statement.

Policy Statement

Protocol and Informed Consent Form (ICF) Amendments

- Sites must obtain IRB approval for protocol and ICF amendments within 90 calendar days of issuance, which may include providing all necessary documents and justifications as required to the IRB.
- Failure to meet the timeline deadlines will result in a temporary enrollment hold, restricting new patient enrollment and data submission until IRB approved is granted.
- ALZ-NET operations and/or regulatory staff will notify the site in writing via email once the 90-day deadline has passed without IRB approval, confirming the enrollment hold status and outlining the steps for resolution.
- Sites must inform the ALZ-NET Operations Team via email (alz-net@acr.org) upon IRB approval to be reactivated and regain enrollment and data submission privileges. Reactivation is contingent on the site being compliant with all regulatory requirements and will occur in a reasonable business timeframe once ALZ-NET is notified.
- Sites are responsible for tracking all protocol/ICF amendment timelines to ensure compliance with this policy.

Continuing Review (CR)

- IRB approval must be obtained before CR expiration. Once the expiration date has lapsed, no ALZ-NET-related work can occur at the site until the CR is approved and received.
- If a site does not obtain IRB approval by the time the expiration date occurs, the site will be placed on a enrollment hold by the ALZ-NET Operations Team, restricting new patient enrollment and data submission until IRB approval is granted. The hold will be lifted once the site receives approval for their CR.
- Sites are responsible for tracking all CR submission and approval timelines.
- Sites are encouraged to submit for CR 30 days prior to the expiration date to ensure enough time is available in the event the IRB requires clarifications.

Protocol Deviations/Violations

- Sites are required to notify the ALZ-NET Regulatory Team (alznet-regulatory@acr.org) and submit the deviation/violation to Advarra IRB within 14 calendar days from date of discovery.
- Sites who fail to submit in a timely manner are subject to a temporary hold at the discretion of the ALZ-NET Regulatory Team, restricting new patient enrollment and data submission until the deviation/violation is resolved.
- A site enrollment hold may be issued by the ALZ-NET depending on the deviation/violation severity.
- Sites are responsible for tracking all protocol deviation/violation timelines.

Enforcement

Non-compliance may result in administrative actions (e.g. enrollment suspension, audits, possible termination).

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