CHICKEN SOUP FOR THE BUSY COORDINATOR

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What Should Be Done If Subject Recruitment Was Not Done According to IRB Approved Protocol?

Scenario

Protocol amendment for research study X was submitted to the IRB and received approval on 1 Feb 2024. The Co-Investigator (Co-I) recruited a new research participant and carried out the screening visit on 2 Feb 2024 based on the previous protocol.

One week later, it was found out by the research study's monitor during a routine monitoring visit that the research participant was not enrolled according to the latest approved amended protocol and the recruited participant met 1 of the exclusion criteria and should have been a "screen failed".

How should this situation be managed by the PI & Study Team / CRC?

1. The Study Team / CRC should inform the PI and department managers immediately.
2. The PI and Study Team should check to ensure subject's well-being.
3. Withdraw the research participant according to the PI's instructions and protocol
4. Document (e.g., source documents) and explain the incident in detail.
5. Submit a non-compliance report to the IRB as soon as possible but not later than 14 calendar days after first knowledge by the PI.
6. Report to institutional research office.
7. Provide Corrective Action Preventive Action (CAPA) for post monitoring visit follow-up actions.

How to prevent such prospective issue from occurring?

What Can The PI Do?	What Can The CRC do?
✓ Ensure that all study team members are informed and updated on the latest approved protocol version.	✓ Ensure that the Investigator File is updated with the latest approved protocol version and supersede the previous protocol versions.
✓ Ensure re-training of all study team members on the latest approved protocol version and thoroughly understand the requirements of the amended protocol (e.g., adhere to the amended protocol's recruitment requirements)	✓ Document the re-training of all study team members on the amended protocol in the training record and file it in the Investigator File
✓ Ensure that research participants are screened and verified eligible for the study participation, in accordance with the latest approved protocol.	

REMINDER:

- Do not implement any protocol deviation or changes without agreement by the sponsor (if applicable) and prior review and approval by the IRB (except to eliminate immediate hazards to the participant or the change involves only logistical or administrative changes to the research study).
- Readers are required to ensure that clinical trials are conducted in compliance with the protocol, SOP, GCP and applicable regulatory requirements.

Reference: NHG Investigator Manual
Additional Resources: NHG Proper Conduct of Research SOP 501-A02 Responsibilities of Study Team & 501-C01 Subject Screening and Recruitment, ICH GCP E6(R2)

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