National Institutes of Health
Health Research Institute
National Bioethics Committee (NBC)
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Ref: No.4-87/Clinical trials-01/ **Date: May 19, 2023**

NBC-R Advisory for reporting of Adverse Events during clinical trials conduct in Pakistan

Adverse events (AEs) are any undesirable or unintended medical occurrences that happen to trial participants during the course of a clinical study. The proper reporting of AEs in clinical trials is of utmost importance for ensuring the safety and efficacy of investigational treatments.

It is notified that any clinical trial on human subjects must be approved by National Bioethics Committee for Research. It is mandatory that all the Adverse Events must be reported to NBC-R within 03 days. Effective and accurate reporting of AEs is crucial for assessing the potential risks and benefits of the experimental interventions being evaluated.

To ensure the integrity and reliability of clinical trial data, it is advised that the following should be complied to:

1. Clear definitions: Establish clear and consistent definitions for adverse events, including the severity and intensity grading scales. Consistency in defining and categorizing AEs must be observed
2. Comprehensive Documentation must be in place
3. Data Safety and Monitoring Board (DSMB) for trial must be notified prior to the start of study
4. Timeliness of reporting must be clear and adhered to
5. Adverse Event Reporting System must be complied to
6. Serious Adverse Events (SAEs): Prioritize the reporting of serious adverse events, *which include any untoward medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of existing hospitalization, result in persistent or significant disability or incapacity, or cause a congenital anomaly or birth defect.*
7. Investigator responsibilities: Clearly define the roles and responsibilities of investigators regarding adverse event reporting. Investigators should be knowledgeable about the reporting requirements, ensure accurate documentation, carry out Corrective and Preventive actions (CPA) and promptly communicate any significant safety concerns to the sponsor, regulatory authorities, and relevant stakeholders.
8. Transparency and Data Integrity: Maintain transparency and integrity in adverse event reporting. All reported AEs should be accurately documented, without omission or alteration, to preserve the credibility and reliability of clinical trial data. They can be asked and must be provided to NBC-R upon inquiry.
9. Regulatory Compliance: Adhere to all applicable regulations and guidelines set forth by regulatory authorities like NBC-R and DRAP
10. Minimum Information to NBC-R from Principal Investigator includes:
    1. Date of reporting:
    2. NBC Number of study:
    3. SAE Number----: (of the trial as a whole)
    4. CIOMS report form
    5. One pager summary
    6. Data Safety and Monitoring Board (DSMB) proceedings and approval
    7. IRB Notification and Actions

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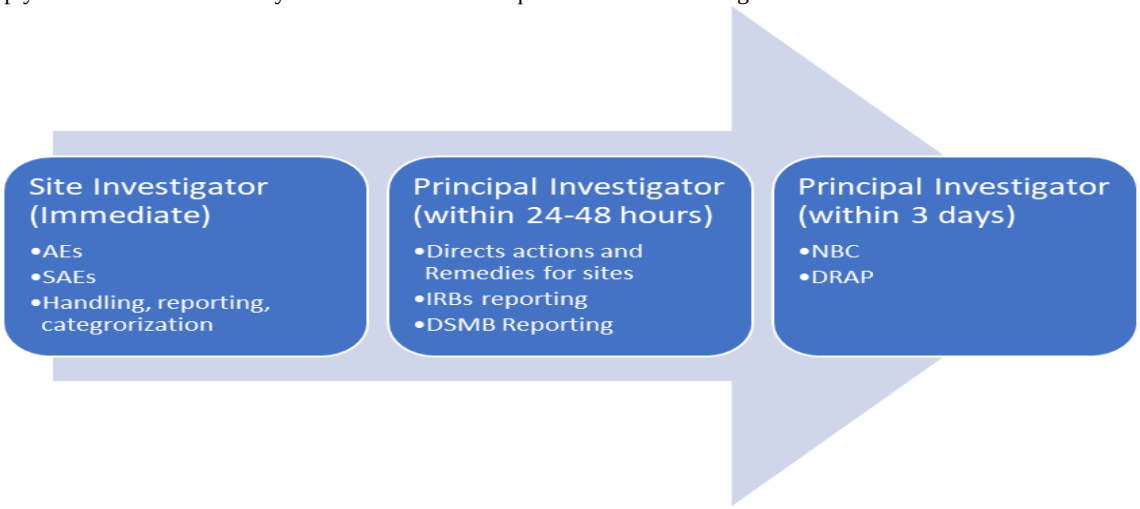
8. Reimbursement claims
9. Signatures of PI

NBC-R is committed to protecting the welfare of trial participants and promoting public trust in the clinical research process. Failure to comply with these directions may result in adverse consequences for trial investigators and facilitators like CROs and Institutions.



Adverse event reporting mechanism