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Safety Monitoring In Clinical Trials

□ Safety Monitoring in clinical trials:

- Defination:

- Can be defined as a planned, ongoing process of reviewing data collected in a clinical trial with the primary purpose of protecting the safety of trial participants, the credibility of the trial, and the validity of trial results.

- As appropriate, monitoring might be conducted by the investigator the sponsor (e.g, medical monitor) or by an independent monitoring board.

- Persons affected:

1. Principal investigators
2. Institutional Review Board
3. Other oversight committees charged with evaluating the integrity and safety of data collected during human subjects research.

- Data and safety monitoring is required for all types of clinical trials, including physiologic,

toxicity and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness, and comparative trials (phase III).

- Monitoring should be commensurate (متناسب) with risks and a variety of types of monitoring may be anticipated (پیش بینی کردن).

- Depending on the nature, size and complexity of the clinical trial in many cases, the principal investigator would be expected to perform the monitoring function.

- It is recommended that all clinical trials, even those that pose little likelihood of harm, should consider an external monitoring body.

Purpose:

To establish guidelines for protecting the safety of participants in human subjects research and ensuring validity, integrity of

data collected by appropriate DSM.

□ Policy:

This policy is to ensure that human subjects research includes provisions for monitoring data to ensure the safety of participants and that the IRB has criteria by which to evaluate whether research submitted for review adequately protects human subjects.

The level and formality of monitoring should increase as the level of risk increases.

Data and Safety Monitoring Board (DSMB):

- A DSMB is an independent group of individuals with pertinent (=skill) expertise that reviews on a regular basis.
- Unblinded data from protocols involving human subjects research to assure the continuing safety of research subjects, relevance of the study question, appropriateness of the study, and integrity of the accumulating data.

- The DSMB reviews data independently from the investigator(s) and IRB to:

i: Determine whether the accumulating data support continuing the trial, whether

ii - Study procedures should be changed, or whether the trial should be halted for reasons relating to the safety of the subjects, the efficacy of the treatment under study, or adequate study performance (e.g. poor recruitment of subjects).

- Human subjects research that require a Data Safety Monitoring Board include:

1. Procedures that involve Blinding
2. Research that involves multiple sites, research that targets vulnerable subjects, or
3. Employs high-risk interventions
4. The data and safety monitoring functions and oversight of such activities are distinct from the requirement of study review and approval by the IRB.

Responsibilities:

1. Principal Investigators: MR. PES

i- Ensuring the IRB is provided sufficient information to evaluate the appropriateness of a data and safety plan to ensure participants are appropriately protected.

ii- And responsible for developing and presenting to the IRB a plan to monitor the data to ensure participant's welfare and safety are adequately protected.

iii - Setting intervals at which the data will be evaluated are timely and effective.

iv- Identifying a mechanism for reporting the finding (including DSMB reports) in a timely fashion to the IRB, the sponsor and as appropriate federal agencies.

v. Reporting findings to the participants, if applicable to allow them opportunity to re-affirm their willingness to continue participation.

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2. Data and Safety Monitoring Board:

i- All investigators involved in the research, is responsible for providing impartial (بی طرفانہ) evaluation of the data at pre-determined intervals and reporting in a timely fashion the outcome of those evaluations to:

. Sponsors

◦ Institutional Review Board (IRB)

ii- Review the research protocol and plans for data and safety monitoring.

iii- Evaluate the progress (ترقی) of interventional trials), including periodic assessments of data quality and timeliness, participant recruitment (بھرتی), accrual and retention.

◦ Participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome.

iv. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact (اثر) on the safety of the participants or the ethics of the study.

v. Make recommendations to the IRBs and investigators concerning continuation or conclusion (بايان) of the trial (s).

3- Sponsors:

i- Reporting to the IRB any findings that could affect the safety of participants which could influence the conduct of the study within the time frame outlined in the clinical trial agreement with the institution.

ii- Reporting to the IRB any findings that could impact subject safety with two years of study closure.

4. The IRB:

i. Modifications to that plan.

-Is responsible for reviewing the plan to ensure Subject safety.

ii. Require a third party to implement data and Safety monitoring

iii. Approve these plan.

iv. They can have the authority to stop a research Study in progress, remove individual subjects from a Study, and take what ever steps are necessary to protect the safety and well-being of research Subjects.