ICH GCP E6(R3): Principles

THE GLOBAL HEALTH NETWORK
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1. "Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants."

2. "Informed consent is an integral feature of the ethical conduct of a trial. Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed."

3. "Clinical trials should be subject to an independent review by an institutional review board/independent ethics committee (IRB/IEC)."

4. "Clinical trials should be scientifically sound for their intended purpose and based on robust and current scientific knowledge and approaches."

5. "Clinical trials should be designed and conducted by qualified individuals."

6. "Quality should be built into the scientific and operational design and conduct of clinical trials."

7. "Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected and that avoids unnecessary burden on participants and investigators."

8. "Clinical trials should be described in a clear, concise, scientifically sound and operationally feasible protocol."

9. "Clinical trials should generate reliable results."

10. "Roles and responsibilities in clinical trials should be clear and documented appropriately."

11. "Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be managed in accordance with the product specifications and the trial protocol."