Are You Sure, Your Medical Device Clinical Study Complies With GCP Principles?

SL. NO.	REQUIREMENTS	EXPECTATION	COMPLIANCE CHECK BOX
1.	***Clinical investigation***	Clinical investigations is conducted in accordance with ethical principles that have their origin in the declaration of Helsinki.	☐ Yes ☐ No ☐ N/A
2.	***Foreseeable risks***	Foreseeable risks and inconveniences are weighed against anticipated benefit before a clinical investigation is initiated and shall be continued only if anticipated benefits justify the risk.	☐ Yes ☐ No ☐ N/A
3.	***Safety and well-being of human subjects***	The rights, safety, and well-being of human subjects are most important considerations and prevail over interest of science and society.	☐ Yes ☐ No ☐ N/A
4.	***Non-clinical and clinical information***	The available non-clinical and clinical information on investigational device is adequate to support the proposed clinical investigation.	☐ Yes ☐ No ☐ N/A
5.	***Clinical investigation plan***	Clinical investigations are scientifically sound and described in a clearly detailed clinical investigation protocol (CIP).	☐ Yes ☐ No ☐ N/A
6.	***Ethics committee approval***	A clinical investigation will be conducted in compliance with the CIP that received prior ethics committee approval and non-objection of regulatory authorities (if applicable).	☐ Yes ☐ No ☐ N/A
7.	***Responsibility of a qualified healthcare professional***	The medical care given to, and medical decisions made on behalf of subjects must be the responsibility of a qualified healthcare professional.	☐ Yes ☐ No ☐ N/A
8.	***Qualified by education and training***	Each individual involved in designing, conducting, recording, and reporting a clinical investigation must be qualified by education, training, and experience to perform respective task(s).	☐ Yes ☐ No ☐ N/A
9.	***Informed consent***	Freely given informed consent shall be/was obtained from every subject prior to participation in the clinical investigation.	☐ Yes ☐ No ☐ N/A
10.	***Investigation information***	All clinical investigation information shall be/was recorded, handled, and securely stored as such, it allows accurate reporting, interpretation, monitoring, auditing, and verification.	☐ Yes ☐ No ☐ N/A
11.	***Confidentiality of records***	The confidentiality of records that could identify subjects are protected, respecting privacy rules.	☐ Yes ☐ No ☐ N/A
12.	***Investigational devices***	Investigational devices is designed, manufactured, handled, and stored in accordance with essential principles and used with the approved CIP, investigation brochure, and according to manufacturer's instructions for use.	☐ Yes ☐ No ☐ N/A
13.	***Systems and procedures***	Quality systems with procedures that ensure quality of every aspect of clinical investigation shall be implemented, monitored and evaluated.	☐ Yes ☐ No ☐ N/A

Reference:

ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice.

DISCLAIMER: This document neither creates nor confers any rights towards any person or organization and does not enforce to abide by the content. It is only intended to support organization(s) or individual(s) referring this document to understand clinical investigation of medical devices and Good clinical principles. The simple usage does not automatically imply fulfilment of any regulation. Please refer the applicable guidance for complete detail.

Doc. CQCLINICAL-016 Ver1.0, eff. October 11th, 2021