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Body: Ministry of Health/Brazilian Health Regulatory Agency/Collegiate Board

NORMATIVE INSTRUCTION No. 122, DATED MARCH 9th, 2022

Provides for Good Clinical Practice inspection procedures for clinical trials with drugs.

The Collegiate Board of the Brazilian Health Regulatory Agency, in the use of the attributions conferred upon it by art. 15, III and IV allied to art. 7, III and IV of Law No. 9,782, of January 26, 1999, and to article 187, VII, paragraph 1 of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 585 of December 10, 2021, in a meeting held on March 9, 2022, hereby resolves:

CHAPTER I

INITIAL PROVISIONS

Art. 1 This Normative Instruction aims to institute inspection procedures to harmonize, guide and verify compliance with Good Clinical Practices (GCP) in clinical trials with drugs, pursuant to the Collegiate Board Resolution - RDC No. 09, of February 20, 2015, and its amendments, in order to promote regulatory action in health surveillance capable of ensuring a unified standard of health efficacy and safety, considering both individuals and the community, observing the bisceptics principles of autonomy, non-maleficence, beneficence and justice.

Art. 2 The GCP inspection will be carried out by duly identified and qualified Anvisa's employees, respecting the attributions and competences inherent to the aforementioned positions.

Paragraph 1. In case of routine inspection, the site to be inspected will be notified by Anvisa, at least 15 (fifteen) days in advance.

Paragraph 2. In the event of a complaint or suspicion of irregularities, the inspection will be carried out without notice.

Paragraph 3. Both the sponsor and/or Clinical Research Organization (CRO) responsible for the study before Anvisa, as well as the Principal Investigator (PI) of the site to be inspected will be communicated, when applicable, about the inspection, through a GCP Inspection Notification Letter, sent by Anvisa.

CHAPTER II

INSPECTION PROCESS

Art. 3 The inspection process will consist of the following steps:

I - communication of inspection to sponsor/CRO and Principal Investigator;

II - opening meeting;

III - interview with the study team;

IV - visit to the facilities, if applicable;

V - document analysis; and

VI - closing meeting.

Art. 4 The Principal Investigator, when applicable, and the sponsor/CRO representative must be present at the opening and closing meetings, and one (1) team member must be available throughout the inspection period.

Sole paragraph. The presence of any other team members may be requested by Anvisa, if necessary.

Art. 5 The inspection duration will be specified in the notification letter and must take place within a maximum period of 5 (five) business days, which may exceptionally be changed, with due justification.

Art. 6 After inspection, the inspection team will prepare the Inspection Report, which must be submitted to the Principal Investigator (if applicable) and to the Sponsor/CRO of the study within 60 (sixty) calendar days.

Art. 7 The Inspection Report will list and frame the observations found, according to the classification provided for in art. 12 of this Normative Instruction.

Art. 8 Upon receipt of the Inspection Report, the Sponsor/CRO will have 120 (one hundred and twenty) calendar days for manifestation.

Art. 9 After the manifestation of the Sponsor or after the period referred to in art. 8 of this Normative Instruction, Anvisa will issue the Final Inspection Report, which will be submitted to the sponsor/CRO and Principal Investigator, if applicable

Art. 10 Observing the Inspection Report and the respective manifestation of the Sponsor/CRO, Anvisa will declare, in the Final Inspection Report, whether or not the study is being conducted in accordance with the GCP.

CHAPTER III

FINAL PROVISIONS

Art. 11. In cases of non-compliance with the GCP, Anvisa may decide for:

I - the temporary interruption of the clinical trial:

II - the definitive cancellation of the clinical trial at the site in question;

III - the definitive cancellation of the clinical trial in all sites in Brazil: or

IV - invalidation of data from sites and clinical trials that do not comply with the GCP.

Art. 12 The observations found during the inspection are defined and classified as:

1 - critical "C": findings directly related to the subject's safety, which may result in death, risk of death or unsafe conditions and, when related to the study data, may compromise its validity, as in studies conducted without authorization, tampering, lack of information or falsifications:

II - major "M": findings that may result in a risk to the subject's health or data invalidation;

III – minor "Me": findings that are not classified as critical or major observations, but that indicate deficiency and/or deviation:

IV - informative "INF": descriptive and/or complementary findings; and

V - nothing appears/not applicable "NC/NA": means that the item has not been checked or is not applicable.

Sole paragraph. In the case of item III of this article, such findings must be mentioned in the final inspection report for the purpose of implementing improvements when conducting studies.

Art. 13. Normative Instruction - IN No. 20, of October 2, 2017, published in the Official Gazette No. 190, of October 3, 2017, Section 1, page 46, is hereby revoked.

Art. 14. This Normative Instruction enters into force on April 1, 2022.

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