HEALTH SECTOR
NATIONAL INSTITUTE OF HEALTH

THE REPUBLIC OF PERU
[COATS OF ARMS]

No.***072*** **-2019-J-OPE/INS**

HEAD OFFICE'S DECISION

Lima, April *30th*, 2019

UPON EXAMINATION OF:

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File N^0 098-2019-OGITT/INS dated March 20th, 2019 by the General Office of Research and Technology Transfer; File N^0 321-2018-OGAT/INS dated November 26th, 2018, by the General Office of Technical Advisory; and,

WHEREAS:

Sub-paragraph XV of the Preliminary Title of Law No. 26842, General Health Law, establishes that the State promotes scientific and technological research in the field of health; likewise, in article 28 therein, it provides that experimental research with people must comply with the legislation on the subject and with the ethical principles contained in the Declaration of Helsinki and other Declarations that update the aforementioned principles;

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Article 33 of Law No. 27657, Ministry of Health Law, refers to the National Institute of Health's mission to develop and disseminate research and technology in the fields of i) Occupational health and environmental protection centered on the health of people, ii) Public health and the control of communicable diseases, iii) Food and nutrition for the health of the population, iv) Biological products related to people's health, v) Research, knowledge, and dissemination of inter-cultural aspects to improve the health of the population, and
vi) Quality control of medications, inputs, drugs, and others;

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It is necessary to reconcile sub-paragraph 2 of article 136 of Supreme Decree No. 008-2017-SA, which approves the Regulations of the Ministry of Health's Organization and Functions, which states that the National Institute of Health is a Public Body attached to the Ministry of Health; with the provisions of Legislative Decree No. 1161, Law on the Organization and Functions of the Ministry of Health, which sets forth in Articles 3 and 4 that the Ministry of Health is the Governing Body of the Health Sector and covers among several matters within the scope of its competence, Health Research and Technology, which is therefore executed through the National Institute of Health, in its capacity as a Public Body attached to the Ministry of Health;

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Supreme Decree N^0 001-2003-SA, which approves the Regulations on the Organization and Functions of the National Institute of Health, provides in its article 5, the mission to promote the development and disseminate scientific - technological research and the rendering of services in fields of public health, among others: and through article 6, it determines as one of its institutional strategic objectives, the development of research in health for risk prevention, protection from harm, health recovery, and rehabilitation of people's capabilities;

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Article 7 of the Regulations on Clinical Trials, approved by Supreme Decree No. 021-2017-SA, stipulates that the National Institute of Health is the authority responsible at the national level for ensuring compliance with the aforementioned Regulations and related rules governing the authorization and execution of clinical trials, as well as issuing the supplementary provisions required for their implementation. In addition, article 121 decrees that the supervision of clinical trials is carried out through ordinary and extraordinary inspections, with qualified multidisciplinary personnel, requiring a Guide to Inspections, approved by resolution of the National Institute of Health;

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As part of the evaluation and qualification process of the National Regulatory Authorities, the Pan American Health Organization requires compliance with Measure 5102, which states that the legal basis requires all those involved in the clinical trial to comply with Good Clinical Practices;

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By means of File No. 321-2018-OGAT/INS dated November 26th, 2018, the Director General of the General Office of Technical Advisory endorsed in all respects the content of Report No. 058-2018-OEO-OGAT/INS of the Executive Director of the Organization's Executive Office, issuing a favorable opinion to the formal revision of the Guide to Inspections of Clinical Trials, proposed by the General Office of Research and Technology Transfer;

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By means of File No. 098-2019-OGITT/INS dated March 20th, 2019, the Director General of the General Office of Research and Technology Transfer endorsed in all respects the Informative Note No. 058-2019-OGITT/INS dated March 19th, 2019, of the Executive Director of Research, in which the final version of the Guide to Inspections of Clinical Trials is attached, which has the favorable opinion to proceed with the corresponding approval process, after having assessed the observations made by the General Office of Legal Counsel, which were corrected as indicated by the Coordinator of the Inspection Department, through Information Note No. 026-2019-INSPECCIONES-OEI-OGITT-OPE/INS;

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Consequently, it is necessary to establish, by means of a Guide, the detailed description of the clinical trial inspection process within the framework of the Regulations on Clinical Trials, Standards of Good Clinical Practice, and ethical principles, and it is necessary to approve the corresponding policy document;

With the approval of the Executive Directors of the Executive Offices of Organization and Research, of the Directors General of the General Offices of Research and Technology Transfer, Technical Advisory, and Legal Counsel, and of the Deputy Chief of the National Institute of Health; and,

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In accordance with the provisions of Supreme Decree No. 021-2017-SA, Regulations on Clinical Trials in Peru; Supreme Decree No. 008-2017-SA, Regulations on the Organization and Functions of the Ministry of Health; Law No. 26842, General Health Law; Law No. 27657, Law of the Ministry of Health; and, using the powers established in Article 12(h) of the Regulations on the Organization and Functions of the National Institute of Health, approved by Supreme Decree No. 001-2013-SA,

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IT IS HEREBY DECIDED:

Article 1.- To approve the Guide to Inspections of Clinical Trials, which forms an integral part of this Head Office's Decision.

Article 2.- To send a copy of this Head Office's Decision to the General Office of Research and Technology Transfer, for information and for all relevant purposes.

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Article 3.- To entrust the Organization's Executive Office with the publication of this Head Office's Decision in the Web Portal of the National Institute of Health (www.ins.gob.pe).

To be registered and notified,

[Stamp]
NATIONAL INSTITUTE OF HEALTH
[Coat of arms of the Republic of Peru]
HEAD OFFICE

[Illegibly signed]

HANS VÁSQUEZ SOPLOPUCO
Chief
National Institute of Health

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[Logo: National Institute of Health – Ministry of Health]

GENERAL OFFICE OF RESEARCH AND TECHNOLOGY TRANSFER
OGITT [according to its Spanish acronym]

GUIDE FOR INSPECTIONS OF CLINICAL TRIALS

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Approved by	Chief's Office	Hans Demetrio Vásquez Soplopuco, MD
	Head Office's Decision N°	**-2019-J-OPE/INS**

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2019

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INTRODUCTION

The National Institute of Health (INS, according to its Spanish acronym), through the General Office of Research and Technology Transfer (OGITT), has developed the "Guide for Inspections of Clinical Trials" in compliance with the provisions of Articles 121 and 122 of the Regulations on Clinical Trials approved by Supreme Decree No. 021-2017 SA, and adhering to the principles of the Guide to Good Clinical Practice as provided by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, which is based on ethical principles, primarily substantiated by the Declaration of Helsinki.

This Guide is a support tool for the inspectors of the General Office of Research and Technology Transfer. It has been developed within the framework of Law No. 26842, General Health Law, which in sub-paragraph XV of its Preliminary Title provides that the State promotes scientific and technological research in the field of health; likewise, in article 28 therein, it provides that experimental research with human subjects must adhere to the special legislation on the subject and the ethical principles contained in the Declaration of Helsinki and other Declarations containing the aforementioned principles.

Along the same lines, the new Law on the Organization and Functions of the Ministry of Health, approved by Legislative Decree No. 1161, article 3, in defining the scope of competence, includes, among other matters, health research and technologies, and this Institution is in charge of it. Therefore, the Regulations on the Organization and Functions of the Ministry of Health, approved by Supreme Decree No. 008-2017 SA, states in paragraph a), sub-paragraph 136.1 of article 136, that the National Institute of Health is a Public Body attached to that Sector.

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Within this framework, inspections are aimed at ensuring the quality and integrity of data or other elements related to a clinical trial, as well as protecting the rights, safety, dignity, and well-being of research subjects.

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In view of the foregoing, we submit to the consideration of the health scientific community the **"Guide for Inspections of Clinical Trials,"** with the belief that this document constitutes a useful tool for inspectors, facilitating compliance with their obligations, within the framework of the legal provisions mentioned above.

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HANS DEMETRIO VÁSQUEZ SOPLOPUCO
CHIEF
National Institute of Health

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GUIDE FOR INSPECTIONS OF CLINICAL TRIALS

1. PURPOSE

To contribute to the protection of the rights, safety, dignity, and well-being of subjects participating in a clinical trial, as well as to the reliability and soundness of clinical trial data.

2. OBJECTIVE

To standardize the conduct of the clinical trial inspection procedure carried out by a team of inspectors in order to supervise compliance with the Standards of Good Clinical Practice and the ethical principles established in the Regulations on Clinical Trials.

3. LEGAL BASIS

- Law No. 26842, General Health Law.
- Law No. 29459, Law of Pharmaceutical Products, Medical Devices, and Healthcare Products.
- Legislative Decree No. 1161, approving the Law on the Organization and Functions of the Ministry of Health.
- Supreme Decree No. 006-2017-JUS, approving the Consolidated Amended Text of Law No. 27444, General Administrative Procedure Law.
- Supreme Decree No. 021-2017 SA, approving the Regulations on Clinical Trials.
- Supreme Decree No. 039- 2015-SA, approving the Regulations of Law No. 30024, Law creating the National Register of Electronic Medical Records.

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- Supreme Decree No. 016- 2011-SA, approving the Regulations on the Registration, Control, and Health Surveillance of Pharmaceutical Products, Medical Devices, and Healthcare Products.
- Supreme Decree No. 013-2006-SA, approving the Regulations on Health Establishments and Medical Support Services.
- Supreme Decree No. 001-2003-SA, Regulations on the Organization and Functions of the National Institute of Health.

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- Ministerial Resolution No. 850-2016/MINSA, "Standards for the preparation of policy documents of the Ministry of Health."
- Ministerial Resolution No. 214-2018/MINSA, approving Technical Standard No. 139-MINSA/2018/DGAIN Technical Health Standard on Medical Record Management.
- Ministerial Resolution No. 546-2011/MINSA, approving Technical Health Standard No. 021-MINSA/DGSP-V.03 Technical Health Standard on "Categories of Health Establishments."
- Head Office's Decision No. 331-2015-J-OPE/INS, approving Directive No. 042-INS/OGAT-V.01 "Directive for the Issuance and Notification of Resolutions at the National Institute of Health."

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- Head Office's Decision No. 204-2013-J-OPE/INS, approving Directive No. 037-INS/OGAT-V.01 "Directive for the Use, Drafting, and Submission of Written Communications in the National Institute of Health."

4. SCOPE

This Guide is mandatory for use by all inspectors accredited by the General Office of Research and Technology Transfer (OGITT), to conduct inspections of clinical trials in order to monitor compliance with the Regulations on Clinical Trials. Likewise, it applies to natural or legal persons, public or private entities, of national or foreign origin, which conduct or are linked to clinical trials in the country.

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5. PROCEDURE

This Guide standardizes the INSPECTION OF CLINICAL TRIALS procedure that is carried out in compliance with the provisions of Articles 121 and 122 of the Regulations on Clinical Trials approved by Supreme Decree No. 021-2017 SA.

6. GENERAL CONSIDERATIONS

6.1. **OPERATIONAL DEFINITIONS**

For the application of the aspects contained in this Guide, the following operational definitions shall be taken into account:

a) Inspection report: It is the document prepared by the inspectors at the inspection site, which indicates the place, date, and time of the inspection, details of the findings, recommendations (where applicable), the statement of those involved, as well as of the research subjects, when appropriate. The Report must be signed by the Principal Investigator and inspectors, and may be signed by the Sponsor's representative, if present.

b) Inspected subject: Subject inspected with respect to any procedure made to the natural or legal person who indicates them as holders of rights or legitimate individual or collective interests. It is the subject that, without having initiated the procedure, possesses rights or legitimate interests that can be affected by the decision to be adopted.

c) Good Clinical Practice: Standard for the design, conduct, completion, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides a guarantee that reported data and results are credible and accurate, and that the rights, integrity, and confidentiality of research subjects are protected, as mandated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

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d) Confidentiality: Obligation on all persons and entities involved to maintain the privacy of research subjects, including their identity, personal medical information, and the information generated in the clinical trial, unless disclosure has been expressly authorized by the person concerned or, in extraordinary circumstances and with fully justified reasons, by the competent authorities.

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e) Informed consent: It is the process by which an individual voluntarily expresses acceptance to participate in a clinical trial after receiving detailed information and explanation about all aspects of the research. The decision to participate in the research has been made without coercion, undue influence, or intimidation. Informed consent is documented by means of a written, signed, and dated consent form.

f) Inspection Coordinator: The inspector in charge of coordinating the preparation and development of the inspection, as well as the activities of the inspectors.

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g) Source data: All information contained in the original records and certified copies of the original records relating to clinical findings, observations or other clinical trial activities that are necessary for the reconstruction and evaluation of the trial. The source data are contained in the source documents (original files or certified copies).

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h) Documentation: Includes all records of any type, such as documents, magnetic records, optical records, among others, which describe the methods and conduct of the study, factors that affect it and actions taken. It also includes: the protocol, copies of the requirements submitted to the regulatory authority, authorization of the clinical trial and approval of the Institutional Research Ethics Committee (CIEI, according to its Spanish acronym), curriculum vitae of the investigators, informed consent form, monitoring reports, audit certificates, correspondence, reference parameters, case report form, periodic communications and final communication, original records

such as the medical record, laboratory tests, clinical reports, subject diaries, among others related to the clinical trial.

i) **Essential documents:** Documents that individually and collectively enable an evaluation of the conduct of a study and the quality of the general data.

j) **Source documents:** Original documents and records of clinical data used in a study, such as medical records, laboratory or pharmacy records, imaging reports and the images themselves, participant diaries, data recorded on automated instruments, magnetic media or microfilm, and photographic negatives. They include the exact certified copies of such documents.

k) **Research team:** Group made up of professionals with skills and knowledge in the execution of a clinical trial and who play a direct and significant role in such execution, including physicians, nurses, pharmaceutical chemists, among other professionals led by a principal investigator.

l) **Case Report Form (CRF):** Printed, optical, or electronic document designed to record all the information required in the protocol on each research subject to be reported to the sponsor.

m) **Medical record:** Legal medical document in which identification data and processes related to patient care are recorded in an orderly, integrated, sequential, and immediate manner that the physician or other health professionals provide to the patient and are endorsed with a handwritten or electronic signature. Medical records are managed by health establishments or medical support services.

n) **Monitoring report:** A written report from the monitor to the sponsor, according to the sponsor's procedure manuals, after each study site visit and/or any other communication related to the study.

o) **Inspection:** Official review by the National Institute of Health (INS, according to its Spanish acronym) of documents, facilities, records, quality assurance systems, and any other source considered by the INS; and, related to the clinical trial at the research site, at the facilities of the sponsor or the Contract Research Organization (OIC, according to its Spanish acronym), Institutional Research Ethics Committee, or any other involving the clinical trial.

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p) **Lead inspector:** A person accredited by the General Office of Research and Technology Transfer to inspect clinical trials with academic background, training, and experience, who is responsible for planning, development and reporting of the assigned inspection.

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q) **Secondary inspector:** A person accredited by the General Office of Research and Technology Transfer to inspect clinical trials with the academic background, training, and experience necessary to conduct and report the inspections.

r) **Research institution:** They are public or private health establishments duly authorized and categorized by the corresponding health authority, or whoever is acting on its behalf, such as hospitals, clinics, specialized health institutes, where the research sites that conduct clinical trials operate.

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s) **Investigational product:** A pharmaceutical product or medical device that is investigated or used as a comparator in a clinical trial, including products with a marketing authorization when used or combined, in formulation or packaging, in a manner different from that authorized, or when used to treat an unauthorized indication, or to obtain more information about its authorized use. For the purposes of this guide, the terms “pharmaceutical product” and “medical device” refer to the provisions of Law No. 29459, Law of Pharmaceutical Products, Medical Devices, and Healthcare Products.

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t) **Research subject:** A research subject is an individual who participates in a clinical trial and may be: a) A healthy person, b) A person (usually a patient) whose condition is relevant to the use of the investigational product.

6.2. **PROVISIONS FOR INSPECTIONS OF CLINICAL TRIALS**

a) The National Institute of Health (INS) is the authority responsible at the national level for overseeing compliance with the Regulations on Clinical Trials and related rules governing the authorization and execution of clinical trials, as well as issuing the supplementary provisions required for their implementation.

b) The General Office of Research and Technology Transfer (OGITT) of the INS inspects the conduct of clinical trials in the country, in order to ensure the quality and integrity of data or other elements related to a clinical trial and to protect the rights and well-being of research subjects.

c) Clinical trials are conducted in a public or private Health Establishment (Research Institution) duly authorized and categorized by the corresponding health authority, or whoever is acting on its behalf, such as hospitals, clinics, and specialized health institutes. One or more registered research sites may operate in the research institution.

d) Inspections will be carried out in the place where the clinical trials are conducted (Research sites of the Health Establishments of the Ministry of Health, Social Health Insurance (ESSALUD), Armed Forces, National Police, Health Services of the Private Sector), in the facilities of the Sponsor or of the Contract Research Organization, Institutional Research Ethics Committee, in facilities external to health establishments where clinical trial procedures are performed and in any other facility involving the clinical trial.

e) Supervision is carried out through ordinary and extraordinary inspections, with qualified personnel (multidisciplinary, if applicable). Inspections may be conducted at the beginning, during the execution and at the end of the clinical trial.

f) Inspectors perform ordinary inspections, according to the Annual Schedule of Ordinary Inspections, approved by the General Office of Research and Technology Transfer.

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g) Inspectors shall carry out extraordinary inspections in the event of a complaint received by means of a telephone call to 7481111, extension number 2191, written communication via e-mail: consultaensayos@ins.gob.pe or a formal document submitted through the reception desk of the National Institute of Health and in case of any relevant information received in the safety reports, notification of deviations, progress reports of a clinical trial and/or justified request of the clinical trial evaluation team, after having done an assessment and with authorization, that in the opinion of the OGITT and/or the Research Executive Office (OIE, according to its Spanish acronym) requires to be inspected.

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h) To carry out inspections of clinical trials (good clinical practices), accredited inspectors act in accordance with the powers given by Article 122 of the Regulations on Clinical Trials approved by Supreme Decree No. 021-2017 SA. Inspectors are empowered to: review the clinical trial documentation to verify compliance with the protocol and its amendments, review the informed consent of research subjects to substantiate that the safety, well-being, and rights of patients are protected, review the record of data reported and analyzed according to the protocol to verify the quality and integrity of the data, request a copy of the documentation to be inspected, take samples of the investigational product, and interview the research subjects in agreement with the provisions of this guide.

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i) If required, the OGITT coordinates with the ANM [National Medicines Authority] for the participation of ANM personnel to verify compliance with the standards of Good Manufacturing Practices, Good Storage Practices, and other related standards of the investigational product.

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j) Inspectors are under an obligation to maintain the confidentiality of the information they have access to during the inspection.

k) During the inspection, the evaluation of biological samples is carried out in accordance with the provisions of the Regulations on Clinical Trials.

l) The OGITT, where appropriate, applies security measures addressed to the sponsor, Contract Research Organization, research institution, or principal investigator in application of the standards that guarantee the safety of the research subject established by the Regulations on Clinical Trials and other related rules.

m) The OGITT when appropriate and depending on the severity of the case, applies one or more security measures before, during, or after the clinical trial.

n) When a Research site is notified by a Regulatory Agency of High Sanitary Surveillance Drugs for the conduct of an inspection visit in our country, the sponsor or Contract Research Organization, must notify to the OGITT, the date and time of this inspection visit within five (5) working days of having received the notification on the part of the Regulatory Agency of High Sanitary Surveillance Drugs. The OGITT coordinates with the Regulatory Agencies of High Sanitary Surveillance Drugs in order to participate in the inspection visit as an observer.

7. SPECIFIC CONSIDERATIONS

7.1. SUPERVISION

Supervision is the technical-administrative diligence mandated by the National Institute of Health's OGITT, with the aim of verifying that the conduct of a clinical trial complies with the provisions of the Regulations on Clinical Trials. Supervision is carried out through ordinary and extraordinary inspections.

7.2. INSPECTION OF CLINICAL TRIALS

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The inspection of clinical trials is a process that requires the development of activities prior, during, and after the conduct of the inspection. That is the reason why it is carried out in three (03) phases:

1. Planning of Inspections
    a. Annual Inspection Schedule
    b. Selection of Inspectors
    c. Inspection Preparation
    d. Inspection Notification

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2. Clinical Trial Inspection
    a. Inspection kick-off meeting
    b. Execution of the Inspection
    c. Interview of research subjects
    d. Closing Meeting
3. Post-Inspection Activities

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7.3. PLANNING OF INSPECTIONS

Planning of Ordinary Inspections

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Planning is the first phase of the ordinary inspections and consists of four (4) activities: Annual Inspection Schedule, Selection of Inspectors, Inspection Preparation, and Inspection Notification.

a) Annual Inspection Schedule

The OGITT's team of Inspectors, during the previous year, prepares the Annual Ordinary Inspection Schedule. This Schedule is presented by the inspection team coordinator, during the second half of each year, to the Executive Management of the Research Executive Office.

The clinical trial selection for ordinary inspections is made on the basis of the following criteria:

l. By research protocol:
    - Vulnerable population

- Investigation phase
- Impact of the study on public health
- Safety criteria of the investigational product
- Investigational product type (recombinant product, monoclonal antibody, cell therapy, gene therapy, new chemical entities, blood product, orphan product, others)
- Therapeutic indication (new clinical indication of an investigational product, evaluation of an investigational product in a population not comprehensively studied in previous phases, others)
- At the reasoned request of the clinical trial evaluation team

II. By research site:

- High recruitment
- Investigator's background
- High number of clinical trials
- Relevant information received in the safety reports and/or in the progress reports at the discretion of the National Institute of Health
- Inspection history (never inspected, long time since last inspection, previous inspection with findings)

The coordinator of the inspection team coordinates with the aforementioned Executive Management every month for the execution of the ordinary inspections, according to the Annual Ordinary Inspection Schedule and the Institutional Operational Plan.

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b) Selection of Inspectors

The inspection coordinator appoints at least two (02) inspectors in rotation: lead inspector and secondary inspector for each inspection. The inspectors should be suitable to conduct the inspection, free from situations affecting their impartiality and from potential conflicts of interest.

Designated inspectors should have access to all information they require to conduct the inspection, including information from previous inspections, as appropriate.

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c) Inspection Preparation

Before the inspection, the designated inspectors review the OGITT-authorized Research Protocol and Amendments, the Investigator's Brochure and its updates, and all clinical trial information submitted to the OGITT by the Sponsor or Contract Research Organization.

The designated inspectors prepare a Pre-Inspection report based on the review and analysis of the clinical trial documentation, as appropriate, and will include the list of data records and source documents specific to the clinical trial, among other documentation that will be reviewed during the official proceeding.

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The Pre-Inspection Report is a work document of the inspectors, prior to the inspection.

d) Inspection Notification to the inspected subject

The notification of inspections before they are carried out is an important condition that must be met in accordance with the following considerations:

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- The development of the inspection is notified in writing to the sponsor or Contract Research Organization and to the establishment or service to be inspected (research institution) indicating the date and time in which the inspection will be carried out.

- In addition, the sponsor or Contract Research Organization notifies the principal investigator responsible for conducting the clinical trial at a specific research site of the development of the inspection.
- Notification of the inspection is made no less than two (02) working days prior to the start date of the inspection in order to ensure the presence of the principal investigator and his or her research team, and/or sponsor or legal representative of the Contract Research Organization, as appropriate, and access to clinical trial records.
- Inspections will be notified by the OGITT, by way of an Official Letter. The list of Essential Documents should be made available in the files, as applicable to the research site of the research institution (health establishment), sponsor's or Contract Research Organization's facility (Annex 1).
- Inspections are notified by way of an Official Letter, by the OGITT, to the National Medicines Authority, when required.
- Inspections are notified by way of an Official Letter, by the OGITT, to the corresponding Research Ethics Committee, when required.
- The rescheduling of the inspection's start date is requested in writing, in a timely manner, which will proceed for reasons of force majeure that make it impossible to have one of the parties present, provided that this is duly justified.

Planning of Extraordinary Inspections

The planning of the extraordinary inspections is carried out by way of two (02) activities: Selection of the inspectors and inspection preparation, which have the same characteristics as for the ordinary inspections.

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There is no annual schedule for extraordinary inspections since a prior selection of the clinical trial is not required; likewise, it is performed without the requirement of prior notification, due to the fact that by their nature they are performed at any time for the purpose of anticipating or correcting any circumstance that risks the health of the research subject, or in the event of a complaint.

7.4. **CONDUCT OF CLINICAL TRIAL INSPECTIONS**

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During the inspection, the review of documentation, facilities, records, and any other source of information related to the clinical trial is conducted at the research site, and/or at the sponsor's or Contract Research Organization's facilities and facility(ies) external to the research institution where the clinical trial-related procedures and activities are performed, and at any other facility that the National Institute of Health deems necessary to inspect.

a) Kick-off meeting

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Inspectors report to the facilities of the research institution's research site or to the sponsor's or Contract Research Organization's facilities, as appropriate, at the start date and time set out in the official letter notifying the ordinary inspection.

The kick-off meeting is held before the beginning of the ordinary or extraordinary inspection, with the participation of the OGITT inspectors and the principal investigator responsible for conducting the clinical trial (and ANM personnel, as appropriate). The sponsor or legal representative of the Contract Research Organization may be present during the inspection, on an optional and voluntary basis, as an observer and to support to the research team.

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During the kick-off meeting, the lead inspector of the OGITT:

- ✓ Explains the scope and purpose of the inspection.
- ✓ Explains the inspection methodology: by means of interviews, document review, and verification of the facilities required for the development of the clinical trial.

- ✓ Explains that if deemed necessary, interviews will be conducted with the research subjects participating in the clinical trial.
- ✓ Requests all information considered relevant during the inspection.
- ✓ Explains that copies of documents and records considered relevant will be requested. These documents will only be identified by the code assigned to the research subject during his/her participation in the clinical trial, and his/her identity will be protected by crossing out/unlinking the information that identifies the subject.
- ✓ Informs that photographs may be taken of the labels of investigational products and supplementary products, as well as labels attached to equipment and instruments used in the clinical trial and of any other source of objective information required as evidence of the observations found during the inspection.

b) Execution of the Inspection

General Verifications

During the execution of the inspection, the inspectors review and verify that the safety, dignity, and well-being of the research subjects participating in the clinical trial are protected, that the clinical trial data are reliable and robust, that it is conducted in accordance with the approved research protocol, Good Clinical Practices, Regulations on Clinical Trials, and related rules. The following considerations will be taken into account:

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- ✓ Inspectors shall identify and review source documents and other essential clinical trial documents using the List of Essential Documents (See Annex 01). These documents must be the original documents or a certified copy thereof.

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- ✓ For the selection of medical records, priority is given to those of research subjects who suffered a fatal adverse event, serious adverse event, prompted an extraordinary inspection and/or withdrew from the study. Likewise, the study files, Case Report Form (CRF), Informed Consent Form (ICF), diaries, and questionnaires, among others, of the selected medical records are reviewed. Access to electronic CRFs will be carried out with the coordination of the principal investigator or study monitor.
- ✓ The written or electronic notes taken by the inspectors during the inspection are kept in the file at the OGITT and constitute a means of proof regarding the inspection findings.

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- ✓ Inspectors may request to take with them copies of study records if they deem it necessary. These documents will only be identified by the code assigned to the research subject during his or her participation in the clinical trial, his or her identity being protected by crossing out/unlinking the information that identifies the subject.
- ✓ Inspectors verify the free nature of the investigational products for the research subjects, the free nature of the study procedures, and the financial compensation for expenses (payments, benefits and/or compensations) according to the approved Informed Consent Form and current local regulations.

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- ✓ The Trial Master File is reviewed and must contain the essential documents according to Annex 1, except for those that form an integral part of the Medical Record.
- ✓ Inspectors must compare the protocol and amendments approved by the Institutional Research Ethics Committee and those submitted to the OGITT, with the protocol found in the investigator's file regarding inclusion and exclusion criteria, types, dose, frequency, and route of administration of treatments, randomization and blinding procedures. In addition, they should verify that the agreement of the principal investigator with the protocol of the study (in English and Spanish), and its amendments, are signed respectively.

Informed Consent Verification

Inspectors review the forms and the collection of the informed consent, verifying the following:

- ✓ The informed consent form that was used matches the updated version and is approved by the corresponding Institutional Research Ethics Committee and National Institute of Health.
- ✓ The Standard Operating Procedure applied in obtaining the informed consents must have been followed with regard to the research subject. The informed consent must have been freely expressed, the confidentiality of the data of the subject participating in the clinical trial must be guaranteed, and the conditions established in Article 33 of the Regulations on Clinical Trials must have been met.
- ✓ The informed consent form has been filled out and signed with the date and time indicated by the research subject or his or her legal representative and by the investigator who conducted the process, as appropriate. Likewise, in the event that the subject does not know how to read or write, he/she has placed his/her fingerprint as a sign of conformity and, in addition, another person designated by him/her who does not belong to the research team has signed as a witness.

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Interviews with the Principal Investigator and members of the research team

The inspection team conducts an interview with the principal investigator of the study in which questions will be addressed in relation to generalities on regulatory aspects, composition of his or her research team, assignment of responsibilities, recruitment mechanism, protocol procedures (inclusion/exclusion criteria, research subject visits, adverse event management), investigational product management, data management and collection, knowledge of the regulations on clinical trials, among others.

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The inspection team may conduct interviews with members of the research team, addressing questions related to the duties they perform in the conduct of the clinical trial.

Medical Record Verification

The following should be verified in the medical record of each research subject enrolled:

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- ✓ Compliance with the Technical Health Standard for medical record management with special emphasis on data recording and processes related to the care of the research subject in an orderly, integrated, sequential, and immediate manner regarding the care that the physician or other professionals provide. Medical records should be under custody and kept in the research institution's medical records file.
- ✓ The recruitment mechanism of each research subject and the absence of coercion.
- ✓ The documented consent process, including the start date and time, as well as verifying that the research subject was told about the risks/benefits of participating, was given time to reflect on his or her decision to participate in the clinical trial and to ask questions and clarify information, and that the investigator verified the understanding of the information provided in the Informed Consent Form.

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- ✓ That the signature of the research subjects is required in two informed consent forms and that one of them was given to the research subject or his or her legal representative.
- ✓ Origin of the research subject, if he or she is referred from another institution or is the patient of the principal investigator or sub-investigator, describing how he or she came to participate in the study.
- ✓ Research subject's visits. They must contain the date and time of the visit, reason for the visit, most important symptoms and signs, treatment received, compliance, and outcome

thereof (if any), vital functions, general physical examination, diagnosis, and concomitant treatment. Likewise, the visit forms that are part of the medical record must include the full name and surnames of the research subject and the medical record number, located in a consistent and easily visible place.

- ✓ The identity of the subject, duly accredited by means of a photocopy of the National Identity Document (DNI), alien's card (resident), passport, or foreign identity document (foreigner in transit), as regulated by Legislative Decree No. 1306 and as appropriate.
- ✓ Evidence that each inclusion and exclusion criterion was reviewed and analyzed by the principal investigator or his/her designee, in such a way that the document or written note supporting the compliance thereof is indicated.
- ✓ Procedures for confirming fertility of female participants and administration of contraceptive methods.
- ✓ The medication or kit number administered to the research subject specifying the dose, route of administration, and frequency; if applicable.
- ✓ The activities performed by the research subject at each visit to the research site and his or her compliance with the time and procedures outlined in the study protocol.
- ✓ Telephone calls made to the research subject, if applicable.
- ✓ The detail of the adverse events occurred, indicating the causality assessment and relationship with the investigational product. As well as all the documentation that supplements the assessment thereof.
- ✓ Medical examinations results −original or certified copy− (laboratory, radiological, EKGs, etc.) that are signed and dated by the principal investigator or sub-investigator.
- ✓ Review and analysis of medical examinations prior to the administration of clinical trial products during the treatment period.

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Verification of Investigational Products

It consists of verifying the labeling of investigational products, according to the requirements of national regulations, which were received at the site by authorized personnel, and which are stored and kept (temperature, humidity, light), in agreement with the provisions of the authorized research protocol and the requirements of the Regulations on Clinical Trials and related rules.

The product distribution cycle is also verified based on the dates of receipt, delivery, and return; product ID, batch numbers, expiration dates, and quantities, administration to the research subjects according to the assignment provided for in the protocol (dose, frequency, administration route, and duration) and agreement between the accountability sheets, source documents, and clinical data registration forms.

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Facility Verification

It consists of verifying the conditions of the facilities of the research site or external institutions where procedures related to the study are performed, such as the hospitalization department, clinics, nursing department, file area, investigational product dispensing unit, sampling area, sample storage and/or processing area, laboratory, and emergency department, among others. Likewise, the adequate protection and confidentiality of the data may be verified, as well as the source data recorded in automated instruments (hemoglucotest, Hemocue, electrocardiogram, etc.).

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c) Interview of Research Subjects

The interview with the research subjects is carried out in specific cases that are previously justified in the Pre-Inspection report.

In justified cases, if during the course of the inspection it is considered necessary to interview a research subject(s), it should be detailed in the Post-Inspection report.

- ✓ The reasons for conducting the interview with the research subject may be the presence of serious adverse events, deviations reported during the trial, or complaint by the research subject.
- ✓ The interview with the research subject(s) of the study meets the high standards of ethics and subject protection. Therefore, it is carried out with an adequate informed consent process, the objective of which is documented in the Post-Inspection Report. The questions asked and the transcript of the answers given by the research subjects will be documented.
- ✓ In case the research subject accepts the audio recording of the interview, this will be documented by means of the "Verbal informed consent form for recording the interview of the research subjects of a clinical trial" (Annex 2). For the recording, the official recorder of the OGITT is used, which is provided to the lead inspector for this purpose.
- ✓ The interview with the research subject is carried out in a private environment in the research site's facilities, after coordination with the principal investigator. The inspectors (lead and secondary) and the research subject will participate in the interview. In addition, a representative of the sponsor may participate as an observer with the research subject's consent.

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- ✓ The data obtained from the recording of the interview will be used only as part of the clinical trial supervision responsibilities of the National Institute of Health in strict compliance with Law No. 29733 - Personal Data Protection Law, and its regulations. In this sense, the information provided will not be made public and the full confidentiality of the data obtained will be guaranteed.

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- ✓ Inspectors identify themselves and explain to the research subject the reasons for the inspection and the interview, and then ask questions pertinent to their participation in the study. During the course of the interview, the research subject is identified only by way of the code given to him or her in his or her participation in the clinical trial. The informed consent process, the objective of the interview, the questions asked, and answers given by the research subject will be documented in the Post-Inspection Report.

  The information gathered from the interview must be attached in a CD with the recording as evidence, transcribed, and analyzed in order to make recommendations.

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- ✓ In case the recording is requested by the principal investigator or the legal representative of the sponsor, it will be provided upon justified request, with express authorization of OGITT and after the final outcome of the inspection. In case the research subject requests the recording of the interview, the transcript of the interview in PDF format will be provided after the final outcome of the inspection.
- ✓ Expenses incurred by the research subject/research subject's family member for transportation from home/work place to the research site, and vice versa, will be covered by the clinical trial sponsor.

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- ✓ If the research subject is a minor, the interview will be conducted with the parents/guardians of the research subject of the clinical trial. In the event that informed consent for participation in the study has been provided by the research subject's legal representative, the interview and consent for the recording of the interview will be provided by the same person.

d) Closing Meeting

The Inspection Team in charge (EIR, according to its Spanish acronym) − in closed session − discusses the findings and proceeds to prepare the Inspection Report, a primary document containing the findings and recommendations made during the inspection, which is written in a clear and objective manner.

- ✓ The closing meeting will be attended by the inspectors, research team and sponsor's representative (if present). The main objective of this meeting is to read the Inspection Report, explain each of the findings and recommendations.
- ✓ Two (02) original documents of the inspection report must be signed by the principal investigator, by the inspectors, and by the sponsor's representative (if present). One original document is given to the investigator, and one original document remains in the possession of the inspectors and will be part of the archive of the Inspection file in the Research Executive Office.
- ✓ The inspectors inform that they will analyze all the information resulting from the inspection according to the Manual of Clinical Trials Procedures - Version 03 approved by Head Office's Decision No. 279-2017-J-OPE/INS, with the participation of the Research Executive Office and the General Office of Research and Technology Transfer, with the purpose of formalizing the observations made during the inspection visit and other observations, classifying the findings, and taking the pertinent actions based on the established regulatory conditions.

7.5. **POST-INSPECTION ACTIONS**

a) Preparation of the Post-Inspection Report

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The Inspection Team in charge will prepare the Post-Inspection Report addressed to the Research Executive Office in which there will be a clear and objective description of the findings, arguments, and recommendation(s) made on the basis of the Inspection Report as well as all the information resulting from the visit.

New evidence could be added to the observations made in the inspection report, based on the concrete case and facts noted after the inspection, as well as particularities by clinical trial inspected on the grounds of the inspection's preparatory actions, that were duly addressed, especially after the post-inspection analysis and the subsequent review of the documentation copies obtained during the inspection of the corresponding site.

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b) Categorization of severity of findings

According to the nature of the observations found during the conduct of the inspection and after the corresponding subsequent analysis, findings will be classified as: "minor, major, or critical", in order to later determine the actions to be executed to redirect inappropriate actions or practices, by way of the application of security measures mainly, and if appropriate, sanctions.

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Minor findings are conditions, practices, or processes that are not expected to adversely affect the rights, safety, or well-being of subjects and/or the quality and integrity of data. Minor findings indicate the need to improve procedures, conditions, or practices; for example:

- ✓ Making modifications to clinical trial authorization conditions or amendments to the research protocol without prior authorization by the regulatory authority, provided that these modifications do not adversely affect the rights, safety, or well-being of subjects and/or the quality and integrity of data.
- ✓ Conducting the clinical trial without conforming to the contents of the protocols on the basis of which the authorization was granted, provided that these deviations do not adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of the data.

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- ✓ Clinical trial information not recorded, or managed and stored in a manner that does not enable accurate reporting, interpretation, and verification, provided that this information does not adversely affect the rights, safety, or well-being of subjects and/or the quality and integrity of data.
- ✓ The presence of several minor findings may indicate poor quality and the sum of them may equal a major finding.

Major findings relate to serious faults and direct violations of GCP principles that could adversely affect the rights, safety, or well-being of research subjects and/or the quality and integrity of the data; for example:

- ✓ Making modifications to clinical trial authorization conditions or amendments to the research protocol without prior authorization by the regulatory authority.
- ✓ Failure to comply with the obligation to report serious adverse events to the OGITT.
- ✓ Communicating to the OGITT the serious adverse events, serious adverse reactions, and suspected serious and unexpected adverse reactions occurred in the country after the deadline of seven (7) calendar days after the event took place or as soon as the event is known.
- ✓ Promoting, giving information, or advertising the product in the research phase.
- ✓ Conducting the clinical trial without conforming to the contents of the protocols and/or Informed Consent Forms on the basis of which the authorization was granted is a major finding provided that these deviations could adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of the data.
- ✓ Conducting a trial without the qualification, training, and/or experience to perform the corresponding tasks.
- ✓ The presence of several major findings may equal a critical finding.

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Critical findings relate to events that adversely affect the rights, safety, or well-being of the research subjects and/or the quality and integrity of the data; for example:

- ✓ Using any investigational product on subjects without the authorization of the regulatory authority.
- ✓ Conducting clinical trials without prior authorization of the regulatory authority.
- ✓ Failure of persons and entities participating in the clinical trial to guarantee the confidentiality and privacy of the research subject.
- ✓ Non-compliance with the security measures established by the OGITT.
- ✓ Conducting the clinical trial without the informed consent of the research subject or the person legally entitled to consent, or not having informed the person about the clinical trial in which he or she participates as a research subject.
- ✓ Conducting the clinical trial without conforming to the contents of the protocols and/or Informed Consent Forms, on the basis of which the authorization was granted, adversely affecting the rights, safety, or well-being of the research subjects and/or the quality and integrity of the data.
- ✓ Fabricating or falsifying the information required by the Regulations on Clinical Trials, or data related to the trial.
- ✓ Preventing the actions of clinical trial inspectors.

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If, during the execution of the inspection, *critical findings are identified, an immediate security measure may be applied.* In this case, the post-inspection report must be submitted, within one (01) working day after signing the inspection report, to the Inspection Coordinator who will review the report and forward the file to the Research Executive Office.

The OGITT, in coordination with the Research Executive Office and having the respective legal recommendation, ratifies, modifies, or suspends the adopted measure, which will be communicated by way of an Official Letter to the sponsor or Contract Research Organization (addressed to the principal investigator), Research Institution, and to the corresponding Institutional Research Ethics Committee within one (02) working days [sic].

In case a minor or major finding is determined, the report and the corresponding draft of the Inspection Official Letter must be submitted, within a maximum term of three (3) working days after the inspection report is signed, to the Inspection Coordinator, who will review the report and send the file to the Executive Management of the Research Executive Office, which will coordinate with the OGITT's General Management to communicate the findings and recommendations, by way of an Official Letter, to the sponsor or Contract Research Organization (addressed to the principal investigator), Research Institution, and to the corresponding Institutional Research Ethics Committee within three (3) working days.

c) Response of the Inspected Subject / Re-evaluation of Observations

In order to respond to the findings, the inspected subject must present his or her case no later than ten (10) working days after receipt of the Official Letter of Observations. It is the responsibility of the inspection coordinator to verify that the inspected subject's responses are submitted within the allotted time.

The Inspection Team in charge evaluates whether the observations have been corrected according to the new facts or information presented, which are supported by evidence. If the inspected subject corrects the observations, an Official Letter of Conformity for the clearing of observations will be sent within 15 working days.

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If there is no correction and the inspected subject is required to submit administrative documentation (in addition to technical support when applicable) to clear an observation, the request for the clearing of observations is repeated for a second time, granting a new term and urging the compliance with or response regarding the actions that are being taken to consider the subsisting observation(s) as withdrawn. If the inspected subject submits the clearing of observations, conformity shall be given, by means of the corresponding Official Letter, within fifteen (15) working days.

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If, after the evaluation and analysis of the inspected subject's responses, observations are not corrected, the Inspection Team in charge prepares a Final Report for the Inspection Team Coordinator, indicating which observations were not cleared, the conclusions derived from them and the recommendations that should be adopted as Security Measures. The Inspection Coordinator forwards the Final Report and draft Official Letters to the Research Executive Office.

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d) Security Measures

In view of a final inspection report recommending the application of security measures, the General Management of OGITT, in coordination with the Executive Management of the Research Executive Office, will apply the security measure(s) to the inspected subject.

The OGITT will notify the security measure(s) to the inspected subject, without limiting the foregoing to any civil or criminal actions and/or communication to the Public Prosecutor's Office, if applicable.

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e) Publication of the inspections results on the National Institute of Health web portal

The National Institute of Health will make the results of inspections available to citizens through the REPEC [Peruvian Clinical Trials Registry] web portal (number of inspections carried out according to whether they are ordinary or extraordinary, cities where inspections were conducted,

number of inspections with minor, major, and/or critical findings, relevant findings). This information will be updated on an annual basis.

8. RECOMMENDATIONS

For the proper application of and compliance with the provisions of this Guide, the following recommendations are established:

8.1. The National Institute of Health, through the OGITT, must implement the necessary adjustments to enable it to comply with and enforce the provisions of this Guide. The National Institute of Health must ensure its dissemination to the inspected subject.

8.2. Research institutions, sponsors, or their legal representative or Contract Research Organization, chairs of the Institutional Research Ethics Committee and Principal Investigators, should be aware of the contents of this guide and facilitate compliance, as appropriate, so that clinical trial inspections are conducted as prescribed.

9. ANNEXES

ANNEX 1: Clinical Trial Essential Documents List

ANNEX 2: Verbal informed consent form for recording the interview of the research subjects of a clinical trial

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ANEXOS

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ANNEX 1: Clinical Trial Essential Documents List

REFERENCE	DOCUMENTS	AVAILABLE IN THE FILES OF THE:	
		RESEARCH SITE	SPONSOR
DOCUMENTS BEFORE THE START OF THE CLINICAL TRIAL			
Art. 67 g) of the Regulations on Clinical Trials	Sworn statement signed by the principal investigator indicating compliance with the obligations and requirements established in Supreme Decree 0.21-2017-SA	X	X
GCP 8.2.1	Investigator's Brochure	X	X
GCP 8.2.2	Research Protocol	X	
GCP 8.2.3	Informed consent form	X	X
Art. 67 c) of the Regulations on Clinical Trials	Approval by the highest authority of the Research Institution	X	X
GCP 8.2.9	OGITT's authorization resolution	X	X
GCP 8.2.9	OGITT's authorization resolution for the expansion of the Research Site	X	X
GCP 8.2.7	Approval of the research protocol by the Institutional Research Ethics Committee	X	X
GCP 8.2.7	Approval of the informed consent by the Institutional Research Ethics Committee	X	X
GCP 8.2.3	Draft recruitment notices approved by the Institutional Research Ethics Committee	X	X
GCP 8.2.8	List of members and titles of the Institutional Research Ethics Committee	X	X
GCP 8.2.2	Case report form (CRF)	X	X
GCP 4.2.5	Delegation of responsibility log	X	X
GCP 8.2.10	Research team training log	X	X
Art. 67 p) of the Regulations on Clinical Trials and GCP 8.2.10	Documented curriculum vitae of the research team	X	X
Art. 67 p) of the Regulations on Clinical Trials and GCP 8.2.10	Certificate of Good Clinical Practice and Research Ethics of all the research team	X	X
GCP 8.2.11	Normal laboratory values to be used in the clinical trial	X	X
GCP 8.2.12	Laboratory quality certification/accreditation	X	X
GCP 2.13	Laboratory Procedures Manual	X	X
GCP 8.2.12	Calibration of medical and laboratory equipment	X	X
GCP 8.2.13	Example of investigational product labeling	[redacted]	X
GCP 8.2.14	Instructions for handling and storage of the investigational product (if not detailed in the protocol or Investigator's Brochure)	X	X
GCP 8.2.15	Import authorization of the investigational and supplementary product	X	X
GCP 8.2.15	Import registration of the investigational and supplementary product	X	X
GCP 8.2.16	Certificate of analysis of the investigational product	[redacted]	X
GCP 8.2.17	Unblinding procedures	X	X
GCP 8.2.18	Randomization master list	[redacted]	X
GCP 5.18.2	Documented curriculum vitae of the monitor	X	X
GCP 5.18.3	Site monitoring plan	X	X
GCP 8.2.19	Pre-trial monitoring report (feasibility)	[redacted]	X
GCP 8.2.20	Monitoring start visit report	X	X
GCP 8.2.4	Contract signed by the investigator with the Sponsor/Contract Research Organization	X	X
GCP 8.2.5	Insurance policy	X	X
GCP 8.2.5	Sworn statement of the sponsor stating that they have financial funds	X	X
DOCUMENTS DURING THE CLINICAL TRIAL			
GCP 8.3.1	Investigator's Brochure Updates	X	X

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	GCP 8.3.2	Amendments to the Research Protocol approved / authorized by the Institutional Research Ethics Committee/OGITT, respectively	X	X
	GCP 8.3.2	Amendments to the Informed Consent Form approved / authorized by the Institutional Research Ethics Committee/OGITT, respectively	X	X
	GCP 8.3.4	Time Extension Resolution	X	X
	GCP 8.3.5	Curriculum vitae of new members of the research team	X	X
	GCP 4.2.5	Updates to the Delegation of Responsibility Log	X	X
	GCP 8.3.6	Updates of normal laboratory values	X	X
	GCP 8.2.12	Medical and laboratory equipment calibration update	X	X
	GCP 8.3.11	Relevant communications (letters, meeting notes, communications with the Institutional Research Ethics Committee and Sponsor)		X
	GCP 8.3.12	Signed and dated Informed Consent Forms	X	X
	GCP 8.3.14	Signed, dated, and completed CRFs	X	X
	GCP 8.3.13	Source documents: medical records, laboratory, etc.	X	X
	GCP 8.3.20	Record of screened subjects	X	[redacted]
	GCP 8.3.22	Record of enrolled subjects	X	
	GCP 8.3.21	List of research subjects' identification codes	X	
	GCP 8.3.13	National Identity Document / passport number of research subjects	X	
	GCP 8.3.8	Import registration of the investigational and supplementary product	X	X
	GCP 8.3.23	Investigational product accountability at the site	X	X
	GCP 8.3.10	List of monitoring visits	X	X
	GCP 8.3.10	Monitoring reports, follow-up letters	X	X
[Illegible stamp and initials]	GCP 8.3.17	Serious Adverse Event Reporting to the National Institute of Health	X	X
	GCP 8.3.17	Serious Adverse Event Reporting to the Institutional Research Ethics Committee	X	X
	GCP 8.3.16	Serious Adverse Event Reporting to the Sponsor	X	X
	GCP 8.3.18	Safety information reporting from the Sponsor to the Principal Investigator	X	X
[Illegible stamp and initials]	GCP 8.3.11	Progress reports to the National Institute of Health	X	X
	GCP 8.3.11	Progress reports to the Institutional Research Ethics Committee	X	X
	GCP 8.3.11	Notification of deviations	X	X
	DOCUMENENTATION AT THE END OF THE CLINICAL TRIAL			
	GCP 8.4.1	Accountability of the investigational product	X	X
	GCP 8.4.2	Documents of destruction of the investigational product	X	X
	GCP 8.4.3	Coded list of research subject identification	X	[redacted]
[Illegible stamp and initials]	GCP 8.4.7	Final Report submitted to the Institutional Research Ethics Committee and the OGITT	X	X
	GCP 8.4.5	Closure monitoring report	X	X

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ANNEX 2

VERBAL INFORMED CONSENT FORM FOR RECORDING THE INTERVIEW OF THE RESEARCH SUBJECTS OF A CLINICAL TRIAL

Verbal Informed Consent for recording the interview of the research subjects of a clinical trial.
Clinical Trial Inspection Team – Version 1.0 / March 28, 2017

Dear Sir/Madam/Miss:

My name is …… and I am a medical inspector of clinical trials of the National Institute of Health, on this date …… we request your consent to record the audio of the interview that we are going to carry out, since you or your son/daughter is participating in the study …… (*insert name of the study here*). The purpose of recording the audio is to analyze the information that we will collect during the interview.

Let me tell you that the decision to agree to have your interview recorded is voluntary. If you do not agree, this will not affect the medical care quality or your participation in the study.

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If you choose to participate, you will answer a series of questions about your participation in the study. You will be able to answer the questions in about 30 minutes.

At the end of the interview, if you have any doubts or questions, I will gladly answer them.

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Your answers will be kept confidential, as will your identity, as you will not be identified by your name. The data obtained from the interview recording will be used only by the National Institute of Health clinical trial inspection team, and the information provided will always be kept in a safe place for ten years and then eliminated.

You will not receive any direct benefit, beyond the satisfaction of having contributed to this interview.

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Do I have your consent, Mr./Mrs./Ms.?

Yes/No Dr. ……., you have/you do not have my consent.

[Illegible stamp and initials]