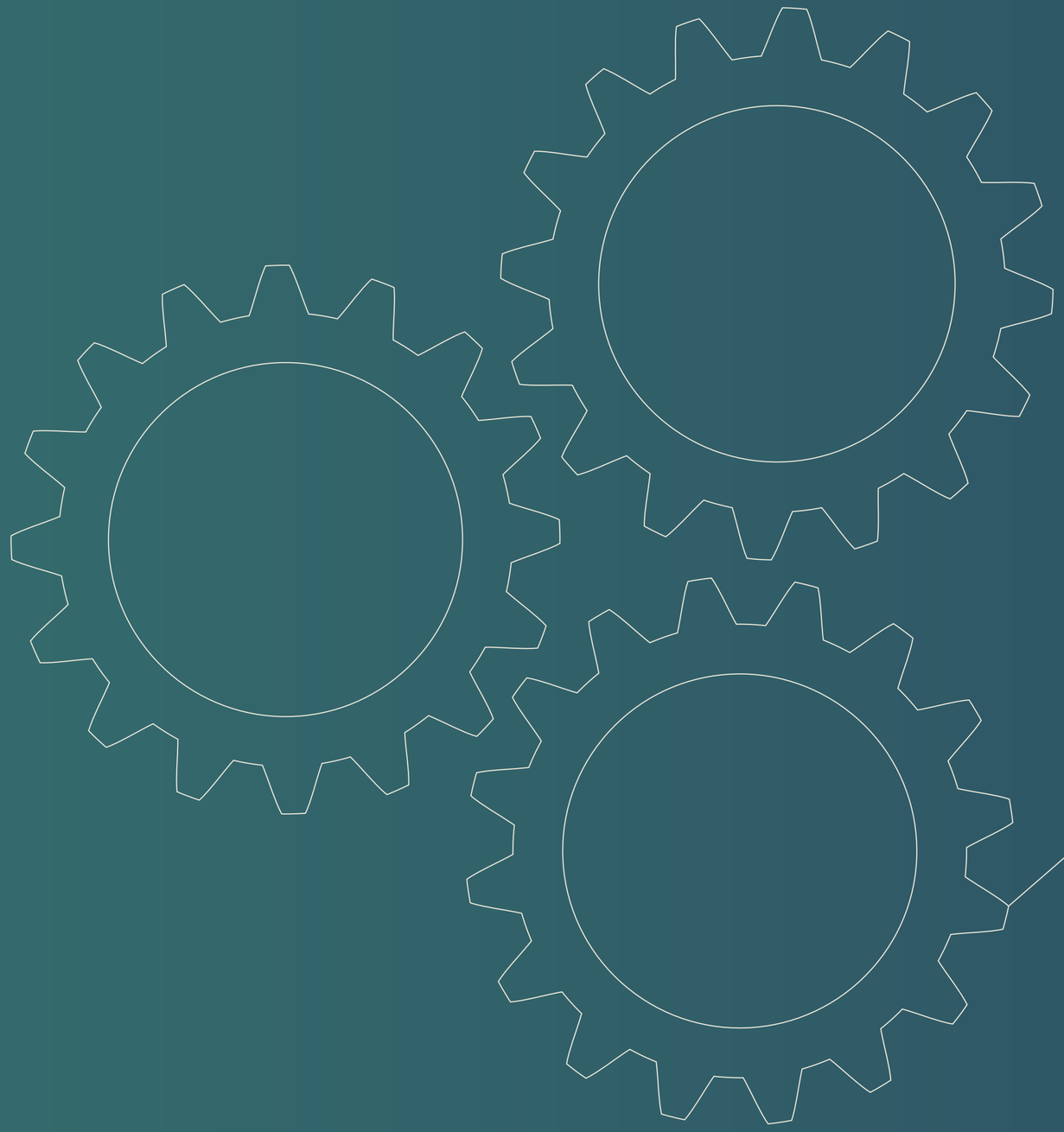

Regional Template for Clinical Trial Agreement

PAHO Pan American Health Organization

World Health Organization
Americas Region

Regional template for clinical trial agreement

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Background

Health research is an essential public health function. In addition to promoting health, research fosters economic growth *(1)*. Clinical trials – defined as research studies that prospectively assign participants to a health-related intervention – are essential for finding safe and efficacious drugs, vaccines, and other health technologies. Clinical trials involving drugs, devices, or other products or technologies for which authorization from a national regulatory authority (NRA) is sought must, in addition to adhering to international ethical standards applicable to all research involving human subjects, comply with the International Conference for Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) *(2-4)*.

GCP requires that, before any activity begins in clinical trials involving drugs, devices, or other products or technologies, agreements must be in place setting out the financial aspects of such studies and establishing the roles and responsibilities of the parties involved in conducting the trials. These responsibilities address key considerations for the ethical conduct of this type of research, such as those related to potential harm to participants. However, neither GCP nor national regulations specify the particular provisions that should be included in these agreements. Despite this, NRAs in the Region often require, as part of the clinical trial authorization process, the submission of a duly signed copy of the clinical trial agreement, in addition to an insurance policy that covers damages for possible adverse events related to the intervention under study and the procedures established in the research protocol.

The need to address the logistical and legal challenges posed by multicenter clinical trials was one of the lessons learned from the COVID-19 pandemic in the Region *(5)*. Participants at a regional workshop held as part of the implementation of WHO resolution WHA75.8, aimed at improving the efficiency and impact of clinical trials, noted that one of the challenges in conducting multicenter clinical trials is the heterogeneity of contractual clauses and the delays that the drafting, negotiation, and signing of clinical trial agreements cause for the parties involved in the research. It was also noted that such agreements require specialized legal expertise that is often limited in the Region. In particular, they require lawyers who are experts on legal issues related to health research and its governance, ethical standards, and regulatory standards for clinical trials. For this reason, a recommendation was made to harmonize the legal aspects involved in conducting clinical

trials, including the core content of clinical trial agreements and provisions related to insurance policies *(6)*.

This document proposes a regional template for clinical trial agreements that sets out the basic clauses that should be included and harmonizes their essential content. It is intended to guide research institutions, sponsors, and investigators on key legal aspects of drafting and negotiating these agreements – including aspects related to clinical trial insurance policies – in order to streamline the processes required for initiating clinical trials and to help ensure that they are conducted in line with current international ethical and regulatory standards. This template also seeks to strengthen governance and legal certainty in the conduct of clinical trials.

What are clinical trial agreements?

These agreements are legally binding contracts that establish the rights and obligations of the parties involved in a clinical trial and set out the administrative and financial provisions related to its conduct. Generally, the parties involved are the sponsor, the institution hosting the clinical trial, and the principal investigator, although a contract research organization (**CRO**) may also be a party to the agreement if the sponsor has delegated functions to it. Signing these agreements before conducting a clinical trial is not a mere formality; the agreement specifies the legal responsibilities of the parties in order to protect their interests and those of the participants, clearly sets out the financial aspects, and fosters trust and transparency between the parties. The legal certainty that such agreements provide is a catalyst for responsible investment in research and for the conduct of high-quality clinical trials consistent with international ethical and regulatory standards.

Normative framework for clinical trial agreements

- International Ethical Guidelines for Health-related Research Involving Humans of the Council for International Organizations of Medical Sciences (CIOMS).
- Guideline for Good Clinical Practice (GCP) of the International Council for Harmonisation (ICH).
- Applicable national law (including rules on health-related research and clinical trials, as well as the general regime of contracts, rights and obligations, and other applicable public policy rules).
- Applicable foreign law (depending on the specific case, the parties may agree on the complementary or supplementary application of the law of a foreign jurisdiction).

Scope of the clinical trial agreement template

This document proposes a template for a tripartite agreement between the sponsor, the institution where the clinical trial is conducted, and the principal investigator. Although this structure may not comprehensively cover other ways of partnering or collaborating to conduct clinical trials (for example, if the intellectual output is the principal investigator's and the sponsorship is only financial – i.e., the sponsor merely provides funding for the study but neither participates in the scientific design nor assumes control over data generation or analysis), it reflects the most common scenario for clinical trials conducted in Latin America and the Caribbean: those that study interventions for authorization and marketing where the sponsor is a private entity responsible for the trial's financing, organization, and supervision (e.g., a trial sponsored by the pharmaceutical industry). Nevertheless, the clauses proposed in this document can also serve as a reference for other forms of collaboration or partnership between the parties to conduct clinical trials.

This template is also intended to help strengthen leadership and institutional capacities in the field of research. This means that institutions conducting

clinical trials assume key responsibilities that go beyond simply providing infrastructure or human resources for research. Consequently, this template assigns institutions an active role in the comprehensive management of processes related to clinical trials from their initial phases; this role includes providing investigators with the necessary technical and operational support throughout the studies. The timely, responsible, and sustained involvement of institutions is crucial to consolidating a culture of research and advancing toward the professionalization of clinical trials in the region. The inclusion of the principal investigator (PI) as a party to the agreement is equally important, as the PI's signature confirms that he or she understands and agrees to the terms of the agreement as the leader and the person responsible for conducting the clinical trial and protecting the participants.

Lastly, it is important to note that this template proposes a minimum set of clauses. The matters covered encompass the essential considerations for putting in place a legally valid, balanced, and transparent contractual relationship that provides for the appropriate allocation of responsibilities among the parties conducting the clinical trials and ensures adherence to international ethical and regulatory standards. This template is not intended to duplicate the provisions contained in international ethical or regulatory standards or in national laws and regulations on research. However, the content of the agreement will need to be considered and, if necessary, adapted to the specific requirements of the applicable legal system and institutional regulations (e.g., by incorporating anti-corruption or anti-money-laundering clauses).

Subject matter included in the clinical trial agreement template

1. General provisions of the agreement: purpose and identification of the parties involved in the conduct of the clinical trial
2. International standards and applicable laws and regulations
3. Authorization and institutional capacity to conduct the clinical trial
4. Requirements for and responsibilities of the principal investigator and the research team
5. Investigational product management
6. Informed consent process
7. Responsibilities of the sponsor
8. Clinical trial monitoring
9. Ethical oversight of the clinical trial
10. Clinical trial oversight by the NRA
11. Requirements of other competent authorities related to the clinical trial

12. Confidential information on the sponsor and the institution and obligation of confidentiality
13. Personal data protection
14. Collection, storage, and use of biological materials and related data
15. Management and retention of clinical trial documentation
16. Compensation for damages to participants and insurance policy
17. Publication of the clinical trial
18. Access to beneficial interventions
19. Responsible conduct of research
20. Transfer of the parties' responsibilities and obligations
21. Sponsor's intellectual property rights
22. Authorization for the use of names, logos, symbols, trademarks, or distinctive signs
23. Final provisions of the agreement: relationship between the parties, breaches, amendment, termination of the agreement, term of the agreement, and applicable law

How to use this clinical trial agreement template?

Below is a template for drafting the minimum clauses to be included in a clinical trial agreement. The template provides the essential content of each clause and may be freely used. In some cases, instructions are included regarding the information that should be added, depending on the specific context. Throughout the document, explanatory notes provide definitions, examples, or other relevant information to aid in understanding the clauses and the adjustments that may be necessary in certain contexts.

Download the agreement template in Word here.

Clause 1. Purpose of the agreement

This Clinical Trial Agreement is a legally binding contract that determines the responsibilities and obligations of the parties involved in the conduct of the *(name of the clinical trial, identification code, or other relevant information)*, hereinafter referred to as the **CLINICAL TRIAL**.

Clause 2. Parties

The parties to this Agreement are:

A. *(Sponsor's legal name and other relevant identification data)*, hereinafter referred to as the **SPONSOR**.

B. *(Contract research organization's legal name and other relevant identification data)*, hereinafter **CRO** (if applicable).

C. *(Principal investigator's name, identity document, and other relevant identification data)*, hereinafter referred to as the **PRINCIPAL INVESTIGATOR**.

D. *(Legal name and other relevant identification data of the institution where the clinical trial is to be conducted)*, hereinafter referred to as the **INSTITUTION**.

The parties declare that they have the legal capacity to enter into this Agreement and to comply with all obligations set forth herein.

The sponsor may engage a **CRO** to perform one or more of its functions related to the trial. However, the sponsor remains responsible for the implementation of the research protocol, the results, and the clinical trial as a whole.

Clause 3. International standards and applicable laws and regulations

The parties undertake to conduct the **CLINICAL TRIAL** in accordance with the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH), the Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants of the World Medical Association, and the International Ethical Guidelines for Health-related Research of the Council for International Organizations of Medical Sciences (CIOMS), as well as the following applicable laws and regulations: *(specify)*.

Clause 4. Institutional authorization to conduct the clinical trial

The **INSTITUTION** authorizes the conduct of the **CLINICAL TRIAL** at: *(legal name, identifiers of the research centers or units where the clinical trial will be conducted, registration or accreditation, if any)*, in accordance with this Agreement, the applicable laws and regulations, and relevant international standards.

Clause 5. Capacity of the institution to host the clinical trial (resources, infrastructure, services, and personnel)

The **INSTITUTION** has the necessary infrastructure, resources, and services to enable the **PRINCIPAL INVESTIGATOR**, the research team, and the study personnel to adequately perform their duties in a timely manner. The **INSTITUTION** warrants that *(name of the research center or unit)* is authorized to operate and has the capacity to conduct the **CLINICAL TRIAL** in accordance with the research protocol, the terms of this Agreement, and applicable laws and regulations.

If the institution lacks the necessary infrastructure or services, it may contract with third parties with the sponsor's authorization. It is important for the institution to assess and acknowledge any limitations in its ability to meet the requirements of the research protocol for the proper conduct of the clinical trial, including participant safety.

The sponsor may transfer resources and infrastructure to the institution, either permanently or temporarily, for the proper conduct of the clinical trial. The sponsor and the institution may agree on the final disposition of such resources and infrastructure (e.g., donation or return).

Study personnel are not limited to the research team, but also include other individuals with assigned tasks related to the clinical trial (e.g., administrative tasks).

The **SPONSOR** has had the opportunity to inspect the **INSTITUTION** and the research center or unit, and has verified that they meet the necessary requirements for the proper conduct of the **CLINICAL TRIAL** in accordance with the research protocol, GCP, ethical standards, and applicable national laws and regulations.

Clause 6. Responsibilities of the institution with respect to study personnel

The **INSTITUTION** warrants that the **PRINCIPAL INVESTIGATOR** and study personnel:

a. are adequately trained to perform their duties with respect to the **CLINICAL TRIAL**, including training for the research team in GCP, research ethics, and responsible conduct of research;

b. are not involved in other clinical trials whose conduct might compromise the proper conduct of this **CLINICAL TRIAL** at any stage during the term of this Agreement; and

c. are not barred by law, ethical or regulatory sanctions, or any other relevant reason from participating in the **CLINICAL TRIAL**.

This provision is not intended to require the principal investigator or study personnel to work exclusively on the clinical trial that is the subject of this Agreement. Its purpose is to ensure that the principal investigator and study personnel have the necessary time available to fulfill the responsibilities set forth in this agreement and to avoid conflicts of interest.

Clause 7. Requirements for the principal investigator

The **PRINCIPAL INVESTIGATOR** must:

a. be affiliated or have a contractual relationship with the **INSTITUTION**;

b. have the requisite training, experience, and time and availability to perform the **CLINICAL TRIAL**;

c. be thoroughly familiar with the research protocol and comply with the obligations arising from this Agreement and from the national legal framework and the relevant international ethical and regulatory standards; and

d. lead the research team and study personnel and be responsible for their performance, in accordance with the research protocol, the obligations arising from this Agreement, the relevant ethical standards, and GCP.

Clause 8. Conflicts of interest of the principal investigator and the research team

The **PRINCIPAL INVESTIGATOR** and the research team shall declare any conflict of interest to the **INSTITUTION** and the **SPONSOR** before beginning any activity related to the **CLINICAL TRIAL**. The declarations shall be kept up to date during the term of this Agreement.

A conflict of interest is the possibility that other interests of the investigators and research team (e.g., scientific recognition or financial gain) may unduly affect the proper conduct of the clinical trial.

Clause 9. Change of principal investigator

In the event that the **PRINCIPAL INVESTIGATOR** is unable to continue in his or her role, the **INSTITUTION** shall notify the **SPONSOR** within *(number)* days of becoming aware of the situation. This includes cases in which the **PRINCIPAL INVESTIGATOR** resigns voluntarily from the position, or when he or she has been reprimanded or sanctioned under applicable national laws or regulations or institutional policies, or his or her professional license has been revoked or suspended, or if there is any reason that would render him or her unfit to continue serving as the **PRINCIPAL INVESTIGATOR**.

The **INSTITUTION** shall act expeditiously and in good faith to find a replacement for the **PRINCIPAL INVESTIGATOR** in the shortest possible time and shall ensure that neither the conduct of the **CLINICAL TRIAL** nor the participants are affected. If a suitable replacement for the **PRINCIPAL INVESTIGATOR** cannot be found, this Agreement may be terminated by either party.

Clause 10. Responsibilities of the principal investigator

The **PRINCIPAL INVESTIGATOR** shall:

a. commit to conducting the **CLINICAL TRIAL** for the agreed time, ensuring adequate availability to fulfill the responsibilities and obligations set forth in this Agreement and in the research protocol;

b. prior to initiation of the **CLINICAL TRIAL**, request the review and obtain ethics approval of the **CLINICAL TRIAL** protocol, including informed consent documents and other documentation requiring ethics approval under the applicable laws and regulations, from *(name of the relevant research ethics committee)*, in accordance with the applicable laws and regulations in force;

c. initiate the **CLINICAL TRIAL** once the authorization of *(name of the NRA)* has been obtained;

d. promptly address any comments or observations made by the research ethics committee (REC) and submit all information required during the initial review process or the subsequent ethical monitoring of the **CLINICAL TRIAL** in accordance with the committee's standard operating procedures;

e. implement any substantive amendments authorized by the REC and *(name of the NRA)*, under the terms established by the **SPONSOR**, except in the case of non-substantive amendments or modifications to the protocol that might jeopardize the lives, well-being, and safety of participants, according to the research protocol and applicable laws and regulations; such modifications and non-substantive amendments shall be reported to the REC and the NRA in a timely manner;

f. make reasonable efforts to achieve the participant recruitment target in accordance with the established procedures within the timeframes set out in the research protocol and comply with instructions regarding participant recruitment (e.g., expansion or suspension) as soon as they have been amended;

g. ensure the accuracy, completeness, legibility, and consistency of the data derived from source documents that are included in the case report form (CRF);

The principal investigator must have sufficient time to carry out the clinical trial. Adequate availability will vary according to each protocol.

h. communicate to the **SPONSOR** all information related to the conduct of the **CLINICAL TRIAL**, including serious adverse events and safety measures taken to protect research participants;

i. maintain the confidentiality of commercial and intellectual data and information owned by the **SPONSOR**; and

j. cooperate with the **SPONSOR** in preparing a final report on the **CLINICAL TRIAL** that includes relevant information on the research protocol, results, and analysis, and the conclusions, once the study is completed.

Clause 11. Delegation of duties

The delegation of duties by the **PRINCIPAL INVESTIGATOR** to members of the research team and study personnel shall be recorded in a delegation of duties log. The **PRINCIPAL INVESTIGATOR** shall ensure that the delegated persons have sufficient experience and training to perform the assigned tasks. The **PRINCIPAL INVESTIGATOR** shall also supervise the performance of delegated duties in accordance with the research protocol, GCP, and applicable laws and regulations. The **PRINCIPAL INVESTIGATOR** bears ultimate responsibility for the proper performance of the delegated functions.

Clause 12. Participation in scientific or academic activities

The **PRINCIPAL INVESTIGATOR** and the respective research team shall participate in meetings, workshops, or other scientific activities related to the conduct of the **CLINICAL TRIAL**, which will be convened by the **SPONSOR** with reasonable advance notice.

The costs for the participation of the **PRINCIPAL INVESTIGATOR** and the research team in the activities described will be included in the **CLINICAL TRIAL** budget. Any additional compensation must be agreed upon in advance with the **SPONSOR**, on a case-by-case basis. Information about payments or reimbursements made by the **SPONSOR** may be publicly disclosed.

Clause 13. Investigational product management

The **SPONSOR** shall ensure the timely provision, in the required quantities, of the investigational product and all necessary materials, packaged and labeled in accordance with the research protocol and applicable laws and regulations.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** shall ensure that the investigational product is used only for the purposes of the **CLINICAL TRIAL**, in accordance with the provisions of the research protocol, GCP, and the regulatory approvals obtained. Any other use of the investigational product or other material or product of the **CLINICAL TRIAL** will be the responsibility of the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR**, who will be liable for damages of any nature that may arise, in accordance with applicable laws and regulations.

Upon completion of the study, the **INSTITUTION** shall ensure that any remaining investigational product is returned, destroyed, or disposed of as directed by the **SPONSOR** or as set forth in the research protocol. The **SPONSOR** will bear the respective costs, unless otherwise agreed.

Clause 14. Informed consent process

The **PRINCIPAL INVESTIGATOR** or the duly qualified research team shall carry out appropriate informed consent processes to obtain authorization from each potential participant or, failing that, his or her legal representative, to participate in the **CLINICAL TRIAL**. The informed consent process must comply with applicable national laws and regulations and adhere to international ethical standards.

Clause 15. Responsibilities of the sponsor

The **SPONSOR** shall be responsible for:

a. requesting authorization for the **CLINICAL TRIAL** from *(name of the NRA)* before starting the study and maintaining such authorization until the study is completed; the **SPONSOR** shall be responsible for carrying out any procedures related to the **CLINICAL TRIAL** that are required by the *(name of the NRA)* and for submitting all information required by the authority within the established deadlines;

b. prospectively registering the **CLINICAL TRIAL** in *(name of national research registry)* and in a registry that feeds into the International Clinical Trials Registry Platform (ICTRP) of the World Health Organization;

c. providing the **PRINCIPAL INVESTIGATOR** with the research protocol, including all relevant documentation for the conduct of the study and any regulatory, institutional, or other authorizations obtained;

d. ensuring that all relevant information on the safety of the investigational product is promptly made available to the **PRINCIPAL INVESTIGATOR**; and

e. paying the **INSTITUTION** the total payment agreed between the parties for the performance of the **CLINICAL TRIAL**, within the established deadlines.

The consideration to be paid to the institution and the principal investigator will include items such as the following:

1. Costs related to:
   a. ethical oversight of the clinical trial by the REC (initial review and ethics approval, and additional reviews);
   b. the research center or unit (e.g., opening or start-up costs, pharmacy costs, storage costs);
   c. participants (e.g., reimbursement of expenses incurred for their participation in the clinical trial or provision of contraceptives); and
   d. activities and procedures provided for in the research protocol.
2. Institutional overhead costs (a percentage of the direct costs of the research center or unit agreed upon by the parties).
3. Remuneration of the principal investigator and study personnel.
4. Costs for the principal investigator's or research team's participation in scientific or academic activities.

The method for determining the amount and disbursement of payments will vary, depending on each institution and on the legal and financial regime applicable in each country. The total budget may also vary, and one or more addenda may be issued during the term of the agreement to reflect any changes in the amounts to be paid.

Clause 16. Appointment of the monitor by the sponsor

The **SPONSOR** shall promptly inform the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** of the **CLINICAL TRIAL** monitor's contact details (name, telephone, email, and other relevant information). This includes emergency contacts for the prompt reporting of any serious adverse events.

Clause 17. Monitoring visits

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** shall allow the **CLINICAL TRIAL** monitor to access relevant clinical information about participants as part of the monitoring and verification of source data. If the **SPONSOR** deems it appropriate, the monitor may also inspect the facilities used and the procedures and records related to the **CLINICAL TRIAL** to ensure compliance with the research protocol, GCP, and applicable laws and regulations. Monitoring visits should not disrupt the normal operation of the **INSTITUTION** or the conduct of other studies at the **INSTITUTION**.

If any findings are made during a monitoring visit, the **SPONSOR** will promptly notify the **INSTITUTION** so that it can respond or resolve the issue within *(number)*, unless the nature of the findings justifies a longer period. In the case of serious findings, the **SPONSOR** will also notify *(name of the NRA)*, if appropriate, under the applicable laws and regulations.

Clause 18. Ethical oversight

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** shall allow the *(name of the relevant REC)* to carry out ethical monitoring of the **CLINICAL TRIAL**, in accordance with international ethical standards, applicable national laws and regulations, and the committee's standard operating procedures.

Clause 19. Clinical trial oversight by the NRA

All relations and communication with *(name of the NRA)* shall be the responsibility of the **SPONSOR**. The **SPONSOR** shall promptly notify the **INSTITUTION** and **PRINCIPAL INVESTIGATOR** in case of inspection by *(name of the NRA)*.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** shall allow the oversight of the **CLINICAL TRIAL** by *(name of the NRA)* in compliance with GCP and applicable national laws and regulations.

Clause 20. Request for visit or access to information by competent local authorities

If a competent local authority requests to visit or otherwise access information, data, or materials related to the **CLINICAL TRIAL**, the **INSTITUTION** shall immediately notify the **SPONSOR** before allowing any authority access, unless prior notice was not possible. The **INSTITUTION** shall also provide the **SPONSOR** with a copy of such request and with any other relevant request received.

The **INSTITUTION** will allow the competent authority to visit or access information in accordance with applicable national laws and regulations. The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** will also make reasonable efforts to separate information and materials related to the **CLINICAL TRIAL**, including the investigational product, from any information, data, or materials that gave rise to the visit or access request, and will only disclose information that is strictly necessary in response to the authority's request.

Clause 21. Visits or meetings with competent local authorities

The **INSTITUTION** will allow the **SPONSOR** or its representatives to attend visits or meetings with competent local authorities. At the **SPONSOR**'s request and by mutual agreement, the **INSTITUTION** will support the **SPONSOR** in addressing relevant considerations raised by any authority in relation to the **CLINICAL TRIAL** carried out by the **INSTITUTION**.

Clause 22. Measures imposed by competent local authorities

If any competent authority takes any action against the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or study personnel that could affect the conduct of the **CLINICAL TRIAL**, the **INSTITUTION** shall immediately notify the **SPONSOR** and forward the related documentation.

Clause 23. Participants' medical records

All participant information related to the **CLINICAL TRIAL** shall be recorded in the participant's medical record. The **PRINCIPAL INVESTIGATOR** shall be responsible for ensuring that the data in the medical records are legible, complete, accurate, attributable, current, original, and logical. Medical records are the property of patients and are subject to confidentiality obligations, in accordance with applicable national laws and regulations.

Clause 24. Confidential proprietary information of the sponsor and the institution

The parties agree that the following confidential information is the property of the **SPONSOR**:

a. data, records, materials, and other information related to the **CLINICAL TRIAL** or this Agreement, including the research protocol, the investigator's brochure, and any other information related to the investigational product that is disclosed by the **SPONSOR** to the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** as part of their role in conducting the **CLINICAL TRIAL**; and

b. all data, materials, and information that the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, the research team, or other party involved in conducting the **CLINICAL TRIAL** develops, generates, or collects as part of their role in conducting the **CLINICAL TRIAL**.

The parties also acknowledge that "confidential proprietary information of the **INSTITUTION**" means any information that is not publicly available and whose unauthorized disclosure could cause harm to the **INSTITUTION**, its personnel, its operations, or its reputation.

Clause 25. Obligation of confidentiality

During the term of this Agreement and for a period of *(number)* years after its termination, the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, and the **SPONSOR** shall not disclose confidential information to third parties and shall use such information only for purposes related to the **CLINICAL TRIAL**, unless otherwise authorized in writing by any of the parties. The **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, and the **SPONSOR** shall:

a. limit the disclosure of confidential information only to those study personnel or other parties involved in the conduct of the **CLINICAL TRIAL** who need to know the confidential information because of their role in the **CLINICAL TRIAL**;

b. notify all study personnel or other stakeholders involved in the conduct of the study who receive confidential information about the confidential nature of such information; and

c. not disclose confidential information, directly or indirectly, to financial, securities, or industry analysts or to the media, or use confidential information for the purpose of buying or selling securities. This obligation extends, without limitation, to unpublished **CLINICAL TRIAL** information and to any opinion of the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or the **SPONSOR** that is informed, in whole or in part, directly or indirectly, by access to confidential information or unpublished study information.

The parties shall be liable for unauthorized disclosure of confidential information by any person to whom such information was disclosed. Information is not confidential if:

a. it is or becomes part of the public domain, as long as this is not due to negligence on the part of the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or the **SPONSOR**, nor in contravention of this Agreement;
b. it is disclosed to the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or the **SPONSOR** by a third party with a legal right to disclose such information and with no restrictions on its use, as evidenced in writing or by other tangible evidence;
c. it is previously known to the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or the **SPONSOR**, as evidenced in writing or by other tangible evidence; and
d. it is developed independently by the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or the **SPONSOR** without the use or benefit of confidential information.

Clause 26. Authorized disclosure of confidential information

Confidentiality and nondisclosure obligations shall not apply to information that must be disclosed as required by a competent authority, a law, or a court order. Notwithstanding the above, (i) prior notice shall be given to any of the parties regarding such disclosure, and (ii) the parties shall make every reasonable effort to limit the scope of such disclosure to information that is strictly required.

Clause 27. Return of confidential information

Upon termination or expiration of this Agreement, or upon written request by any party, the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, and the **SPONSOR** shall return all confidential information in their possession or control to its owner, or destroy it upon request. In the latter case, certification of destruction shall be provided in writing. The return or destruction of confidential information includes all copies, summaries, or analyses, regardless of the format in which the information is stored or found.

The parties may retain a copy of confidential information for the sole purpose of determining their obligations under this Agreement, provided they continue to adhere to the confidentiality and non-use obligations set forth in this Agreement.

Clause 28. Use of confidential information by the sponsor

All results, documents, data, reports, technical know-how and formulas derived from the conduct of the **CLINICAL TRIAL** shall be and remain the property of the **SPONSOR**. The **SPONSOR** may use them in any manner it deems appropriate for its interests, including commercial interests.

Clause 29. Irreparable harm

The parties acknowledge that breach of confidentiality obligations will cause irreparable harm to the affected party, for which financial compensation would be an inadequate remedy. Therefore, in the event of any breach of confidentiality, the affected party shall be entitled, in addition to any other remedy available at law or in equity, to injunctive relief or an order for specific performance.

Clause 30. Personal data protection

For the purposes of this Agreement, “personal data” is any information relating to an identified or identifiable person. Personal data of study participants transferred to the **SPONSOR** shall be anonymized or coded in accordance with the research protocol. The parties to this Agreement shall, in accordance with applicable national laws and regulations, adopt and implement reasonable and appropriate security mechanisms to protect the processing of, access to, and use or disclosure of participants’ personal data and to prevent its modification, loss, or unauthorized or illegal use.

Clause 31. Participants' authorization

As part of the informed consent process, the **PRINCIPAL INVESTIGATOR** must obtain the participants' authorization to access and use their personal data in accordance with the research protocol and applicable national laws and regulations. It should be explained as part of this process that the NRA, the REC, the **SPONSOR**, and other parties involved in the **CLINICAL TRIAL** may have access to participants' personal data.

Clause 32. Infringement of personal data protection

The **INSTITUTION** or the **PRINCIPAL INVESTIGATOR** shall immediately notify the **SPONSOR** in writing in the event of any loss or harm or any unauthorized or illegal disclosure, access to, or processing of personal data.

The **INSTITUTION** or the **PRINCIPAL INVESTIGATOR**, at their own expense, shall investigate and shall take responsibility for such incidents, including by notifying the affected participants, who will have the right to request provisional relief or another equivalent remedy against the person or persons who have violated or attempted to violate the security of their personal data, in accordance with applicable laws and regulations.

Clause 33. Participants' rights regarding their personal data

Any of the parties shall, without undue delay, inform the others if that party receives a request from a participant to access, correct, or delete their personal data in the context of the **CLINICAL TRIAL**. The **INSTITUTION** or the **PRINCIPAL INVESTIGATOR** will handle such requests in accordance with the applicable laws and regulations and the **SPONSOR**'s instructions.

Clause 34. Collection, storage, and use of biological materials and related data

Any biological materials and related data collected must be used for the purposes of the **CLINICAL TRIAL**, as authorized in the informed consent process. Storage, processing, and transfer must be carried out in accordance with applicable laws and regulations, international standards, and GCP, including material transfer agreements that specify responsibilities to ensure traceability. All use of such materials and related data is subject to the terms of this Agreement, including those relating to publication, confidentiality, intellectual property, and ownership of the materials and related data.

Clause 35. Management of clinical trial documentation

The **PRINCIPAL INVESTIGATOR** will be responsible for ensuring that the storage and safekeeping of all documentation related to the clinical trial complies with GCP, applicable national laws and regulations, and institutional policies. Records will be protected by the necessary security measures to ensure that only authorized persons have access.

Clause 36. Post-clinical trial records retention

Upon completion of the study, the **INSTITUTION** shall retain the **CLINICAL TRIAL** documentation for *(number)* years thereafter, at its own expense and using its own resources. The **SPONSOR** shall be responsible for reimbursing the **INSTITUTION** for any extraordinary costs incurred as a result of requests for access to information related to the **CLINICAL TRIAL** during this retention period.

Once the document retention period has expired, the **INSTITUTION** may transfer the information to the **SPONSOR** (excluding confidential information about participants) or destroy the documentation, with prior authorization from the **SPONSOR**. If, one year after having requested authorization, the **INSTITUTION** has received no response from the **SPONSOR**, the **INSTITUTION** may destroy the documentation related to the **CLINICAL TRIAL** without such destruction being considered a breach of this Agreement.

Clause 37. Direct payments and reimbursements for harms to participants

The **SPONSOR** agrees to cover the costs of treatment and rehabilitation arising from any harm caused to participants by the investigational product or procedures performed during their participation in the **CLINICAL TRIAL**.

Any payment or reimbursement of expenses made by the **SPONSOR** to participants in the **CLINICAL TRIAL** under this article must be reasonable, fair, appropriate, and timely.

Clause 38. Exclusions from payments and reimbursements

The **SPONSOR** is not obligated to reimburse the following:

a. costs related to other injuries or illnesses;
b. expenses arising from negligent performance of the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR**, or any member of the research team or any expenses arising from fraudulent conduct;
c. expenses arising from noncompliance with applicable laws and regulations, this Agreement, the research protocol, or any written instructions or information provided by the **SPONSOR**; and
d. expenses related to the progression of a participant's preexisting diseases, conditions, or ailments, unless these have been aggravated by the investigational product or the procedures established in the protocol carried out during his or her participation in the **CLINICAL TRIAL**.

Clause 39. Clinical trial insurance policy

The **SPONSOR** undertakes to secure civil liability insurance issued by a legally registered entity in the country that provides coverage to the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** against any claims for harms that may be caused to participants by the conduct of the **CLINICAL TRIAL**. Such insurance must remain in force for at least *(number)* years after the end of the study.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** must also obtain malpractice insurance for clinical trials, which is separate from the clinical trial insurance policy.

Clause 40. Indemnification by the sponsor

The **SPONSOR** shall indemnify the **INSTITUTION** (including its authorities), the **PRINCIPAL INVESTIGATOR**, and the research team against losses or expenses arising from any claim, legal proceeding, or interim relief related to:

a. harm caused to the participant in the **CLINICAL TRIAL**, including death, if such harm is a consequence of the investigational product or the procedures performed in the **CLINICAL TRIAL**;
b. the inappropriate use of study-related information provided to the **SPONSOR** under this Agreement;
c. any infringement of third-party intellectual property rights or trade secret misappropriation resulting from the use of the investigational product under this Agreement;
d. the handling, use, or subsequent transfer of samples and data as required by the research protocol, by written instructions from the **SPONSOR**, or by subsequent use by the **SPONSOR** of the samples and data; and
e. the **SPONSOR**'s use of any invention resulting from the study.

Any liability for harm caused to participants by the investigational product or procedures performed as part of the clinical trial will at all times lie with the sponsor, who agrees to take out insurance as a safeguard. The sponsor will remain liable for any items not covered by the policy. Therefore, it is important to verify the content of the clauses in the clinical trial agreement referring to compensation for harms and insurance policies, since, if the coverage is insufficient, claims could be made against the institution, the principal investigator, or the sponsor, without prejudice to the indemnification clauses.

The term of the insurance policies will depend on the type of study and the characteristics of the investigational product, without prejudice to the statutes of limitation on legal actions provided for in the applicable national laws and regulations. The insurance should be valid for at least one year after the end of the study.

Obtaining malpractice insurance for clinical trials protects both the institution and the principal investigator from any financial claims. If no insurance is obtained, the institution and the principal investigator will be liable with their own assets for any negligence or malpractice arising from the conduct of the clinical trial. Such claims are not covered by the insurance purchased by the sponsor.

Clause 41. Exclusions from sponsor indemnification

The **SPONSOR**'s indemnification obligations under the preceding article shall not apply to the extent that such claims, legal proceedings, or interim relief arise from:

a. negligence, recklessness, or intentional fraudulent conduct;
b. a breach of this Agreement, the research protocol, any written instructions or information provided by or on behalf of the **SPONSOR**, or applicable national laws and regulations, unless such breach was necessary to protect the health, well-being, or safety of a study participant; or
c. the progression of a **CLINICAL TRIAL** participant's preexisting diseases, conditions, or ailments, unless these have been aggravated by the investigational product or procedures performed as part of the **CLINICAL TRIAL**.

Clause 42. Indemnification by the institution

The **INSTITUTION** shall indemnify the **SPONSOR** against any losses or expenses arising from any claims, legal proceedings, or interim relief directly attributable to the negligence of the **INSTITUTION** or the **PRINCIPAL INVESTIGATOR** in the conduct of the **CLINICAL TRIAL**.

The **INSTITUTION** shall have no obligation to indemnify the **SPONSOR** to the extent that such claims, legal proceedings, or interim relief arise in connection with the proper implementation of the **SPONSOR**'s protocol or instructions.

Clause 43. Indemnification procedures

To be entitled to indemnification under the preceding articles, the indemnified party must notify the indemnifying party immediately and no later than *(number)* days after receiving a claim or legal proceeding (actual or potential) and provide a copy of all relevant documentation.

The indemnifying party shall be authorized to assume the defense of the indemnified party and the indemnified party shall cooperate fully throughout the proceedings, unless otherwise agreed. If joint representation of the indemnifying and indemnified parties by the same attorney creates a conflict of interest, the indemnified party shall hire independent legal counsel acceptable to the indemnifying party, at the expense of the indemnifying party.

If the indemnified party fails to notify or cooperate with the indemnifying party as stipulated in this article, the indemnifying party shall be exempt from its indemnification obligations to the extent that it has been harmed by such failure to notify or cooperate.

In the case of public institutions, the defense will be asserted in accordance with applicable national laws and regulations.

Clause 44. Publication of the clinical trial

All data and results derived from the conduct of the **CLINICAL TRIAL** shall be deemed the property of the **SPONSOR** and may not be used for the commercial, professional, or academic benefit of the **INSTITUTION** or the **PRINCIPAL INVESTIGATOR**.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** agree that the **SPONSOR** will have the right to publish the results of the **CLINICAL TRIAL**, with fair acknowledgment in the publication of the participation of the **INSTITUTION**, the **PRINCIPAL INVESTIGATOR** and the research team in conducting the **CLINICAL TRIAL**. The **PRINCIPAL INVESTIGATOR** and the research team have the right to publish the results of the study (including undesired results), as long as this has been agreed in advance with the **SPONSOR** and does not lead to a breach of this Agreement.

All publications related to the **CLINICAL TRIAL** must also adhere to the recommendations of the International Committee of Medical Journal Editors (ICJME).

As stated in CIOMS guideline 24, sponsors may not prohibit researchers from publishing. Institutions and sponsors should negotiate specific terms for the publication of clinical trial results by the research team, with clear deadlines and procedures. In the case of multicenter studies, sponsors often establish a specific waiting period for publication.

Clause 45. Access to beneficial interventions

The **SPONSOR**, in coordination with the **PRINCIPAL INVESTIGATOR**, must provide ongoing access to interventions that have been shown to be beneficial, as appropriate, to individuals who have completed their participation in the **CLINICAL TRIAL**, including after the **CLINICAL TRIAL** has ended. The period and conditions for providing interventions should be established in accordance with international ethical standards and applicable regulatory requirements.

Given the diversity of trial types, study interventions and possible outcomes, the implementation of the ethical obligation to provide access to interventions shown to be beneficial poses challenges that should be assessed in the light of CIOMS guidelines 2 and 6.

Clause 46. Responsible conduct of research

If the **SPONSOR**, the **INSTITUTION** or the **PRINCIPAL INVESTIGATOR** reasonably believes that there has been a breach of responsible conduct of research at the research center or unit during the **CLINICAL TRIAL**, they shall notify the relevant regulatory and institutional authorities so that the appropriate investigations can be opened in accordance with applicable laws and regulations. The parties shall provide all necessary assistance to ensure that investigations are conducted in an impartial, objective, and timely manner.

Clause 47. Transfer of responsibilities and obligations

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** must obtain the **SPONSOR**'s authorization to delegate or transfer their obligations to a third party. Both the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** shall be responsible for hiring and supervising said third party and all activities performed by said third party. The third party will assume the responsibilities and obligations established in this Agreement, although the **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** will bear ultimate responsibility for the proper performance of the transferred obligations.

Clause 48. Sponsor’s intellectual property rights

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** acknowledge that the **SPONSOR** owns or may own inventions, procedures, know-how, trade secrets, or other intellectual property rights or property and assets that have been developed independently by the **SPONSOR** and that relate to its business or operations. In addition, all CRFs and other information (which may include any written, printed, graphic, video, or audio material or content in any database) generated by the **PRINCIPAL INVESTIGATOR** and the **INSTITUTION** as part of the **CLINICAL TRIAL** will be the exclusive property of the **SPONSOR**, who may use them in any manner it deems appropriate in accordance with the applicable laws and regulations.

The copyright of any material developed as part of the **CLINICAL TRIAL** (except as provided in the clause in this Agreement referring to the research team’s right of publication), whether published or unpublished, shall belong to the **SPONSOR**.

Neither the **INSTITUTION** nor the **PRINCIPAL INVESTIGATOR** may use the data obtained during the **CLINICAL TRIAL** to apply for patents or to support applications for patents or any other exclusive rights, whether pending or future, or for commercial purposes of any kind.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** are responsible for verifying that study personnel and third parties involved in conducting the **CLINICAL TRIAL** handle the **SPONSOR**’s information in accordance with the provisions of this Agreement.

The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** agree that the obligations arising from this article will be effective from the date of entry into force of this Agreement and will expire after *(number)* years from the date of the last transfer of data from the **CLINICAL TRIAL** to the **SPONSOR** by the **INSTITUTION** or the **PRINCIPAL INVESTIGATOR**.

The data to be transferred should be relevant to the sponsor’s proprietary rights.

Clause 49. Authorization for the use of names, logos, symbols, trademarks, or distinctive signs

The **INSTITUTION** and the **SPONSOR** undertake to obtain prior written authorization from the other party for any use of names, logos, symbols, trademarks, or any other distinctive signs in advertising, promotional, or informational materials related to the **CLINICAL TRIAL**. The parties may not use the aforementioned identifying elements in a manner that implies sponsorship, association, or endorsement other than as expressly provided for in this Agreement, unless specific written authorization for such use has been granted.

Clause 50. Relationship between the parties

This Agreement does not establish any type of partnership, association, mandate, representation, agency, or consortium between the parties. Each party assumes its obligations under this Agreement and neither the **PRINCIPAL INVESTIGATOR** nor the study personnel will be considered employees or agents of the **SPONSOR** under any circumstances.

Clause 51. Communications between the parties

The parties shall communicate with one another at the following telephone numbers, email addresses, and postal addresses:

Sponsor: *(complete details)*

Institution: *(complete details)*

Investigator: *(complete details)*

Clause 52. Notice of breach

The parties shall report any breach of the protocol or violation of international standards by any of the parties as soon as they become aware of such breach. Where applicable, they must also inform the relevant regulatory or institutional authorities of the facts within *(number)* days so that the appropriate measures can be taken.

Clause 53. Amendment of the agreement

Any changes to this Agreement must be made in writing and approved by agreement between the parties.

Clause 54. Termination of the agreement

This Agreement may be terminated:

a. by agreement of the parties;
b. by any of the parties, in the following cases:
    i. if necessary to protect the rights, well-being, and safety of participants;
    ii. for breach of obligations or responsibilities, provided that the breach has been notified by the defaulting party and has not been remedied within *(number)* days of notification;
    iii. on other grounds established in the research protocol; and
    iv. without cause, with *(number)* days' prior written notice.

The termination of this Agreement will not affect the rights or obligations of the parties prior to the effective date of termination, including payments agreed upon by the **SPONSOR**. The rights and obligations of the parties that remain valid beyond the termination of this Agreement, including proprietary rights, confidentiality, indemnification, and liability, shall survive the termination or expiration of this Agreement.

Clause 55. Procedure for terminating the agreement

After the termination of this Agreement, the parties will meet and agree on how to safely, appropriately, and gradually end the participants' involvement in the **CLINICAL TRIAL**. The **INSTITUTION** and the **PRINCIPAL INVESTIGATOR** will also immediately suspend participant recruitment. Confidential information will be returned in accordance with the respective clause of this Agreement.

Clause 56. Term of the agreement

This Agreement shall enter into force once signed by the parties and shall remain in force until the study is completed or terminated early under the terms set forth herein.

Clause 57. Governing law and jurisdiction in the event of a dispute

The parties agree to submit any disagreement or dispute to the jurisdiction of *(name of place)* and to apply the law of *(name of place)*. In the event that this Agreement is drafted in other languages, the version drafted in the local language of the **INSTITUTION** shall prevail.

The parties waive any other jurisdiction or applicable law.

It is recommended that the agreement be governed by and construed under the laws of the place where the clinical trial is conducted. For bilingual agreements, the agreement drafted in the language of the place where the research is conducted should prevail.

Clause 58. Final agreement

This Agreement, including its annexes, constitutes the sole and final, complete, and exclusive agreement between the parties, and supersedes all prior understandings and agreements relating to its subject matter. In the event of a conflict between the terms of this Agreement and the clinical trial protocol, this Agreement will prevail with regard to administrative and commercial terms, but the protocol will prevail with regard to the conduct of the **CLINICAL TRIAL**.

The following should be included as annexes: the clinical trial protocol, the investigator's brochure, the informed consent documents, and all related documentation, as well as the budget.

*(Signature of the **PRINCIPAL INVESTIGATOR**)*
(Date)

*(Signature of the **INSTITUTION**)*
(Date)

*(Signature of the **SPONSOR**)*
(Date)

References

1. Pan American Health Organization. Policy on research for health: Final report. 62nd Directing council. Washington D.C.: PAHO; 29 September - 3 October 2025. Available from: https://iris.paho.org/bitstream/handle/10665.2/68315/cd62-inf-7-e-policy-research-health-final-report.pdf.
2. Council for International Organizations of Medical Sciences. International ethical guidelines for health-related research involving human beings. Fourth edition. Geneva; CIOMS; 2016. Available from: https://www.paho.org/en/documents/international-ethical-guidelines-health-related-research-involving-humans.
3. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Guideline for Good Clinical Practice E6(R3); 2025. Available from: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf.
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5. Pan American Health Organization. Catalyzing ethical research in emergencies. Ethics guidance, lessons learned from the COVID-19 pandemic, and pending agenda. Washington, D.C.: PAHO; 2022. Available from: https://iris.paho.org/handle/10665.2/56139.
6. Pan American Health Organization. Final report of the regional workshop: Strengthening clinical trials to provide high-quality evidence on health interventions, and to improve research quality and coordination. Washington, D.C.: PAHO; 2022. Available from: https://www.paho.org/en/documents/final-report-regional-workshop-strengthening-clinical-trials-provide-high-quality.

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