management, development or operation, can be executed by another State, through its own agencies, agencies, national or foreign public or private companies. Contracting from State to State is regulated under the scope of international trade and by the norms and principles of international law;

That, in response to the preceding recital, the cited norm specifies that, for this purpose, by means of a supreme decree endorsed by the proposing Minister, the Ministry, its attached Public Bodies, Special Programs or Projects are authorized to sign a State to State, for which it must meet the following requirements: i) Prepare a report that supports the advantages for the Peruvian State of contracting with another State; ii) Prepare a report in which potential States or States that can comply with what is required by the Peruvian State are identified; iii) In the case of investment projects or investment programs within the framework of the National Multiannual Programming and Investment Management System, there must be: (a) the opinion of the Sector's Multiannual Investment Programming Office (OPMI). functionally responsible for the alignment with the prioritized objectives and goals regarding the closing of infrastructure gaps or access to services established in the Multiannual Investment Programming and for compliance with the prioritization criteria approved by the Sector when the investment project or program investment is the responsibility of a regional or local government; and, (b) with the report of the Formulation Unit and/or Investment Execution Unit, as appropriate, on compliance with the specific sector methodologies and the technical standards that are applicable.

These documents must be registered in the Investment Bank's computer application; and, iv) Report from the Budget Office or the one that acts as the corresponding document, indicating that the document has the budgetary viability for the financing necessary for said contracting, as well as for the investment projects or investment program, unless it requires arranging a debt operation, in which case, it must be contemplated in the Annual Debt Program of the respective year. To do this, it must support that the budget required is part of the current Multiannual Budget Allocation and/or the resources to be incorporated through other financing sources in the institutional budget. The aforementioned report must be sent in copy to the General Directorate of Public Budget (DGPP) of the Ministry of Economy and Finance (MEF);

That, through Official Letter No. 1917-2023-MINSA/PRONIS-CG, the National Health Investment Program – PRONIS sends the documentation that supports the requirements set forth in Legislative Decree No. 1564, requesting in this case the issuance of the Supreme Decree that authorizes the Ministry of Health to sign a State-to-State Agreement, within the framework of the project "Improvement of Hospital Health Services Care in the Teaching Regional of Trujillo – Trujillo district of Trujillo of the Province of Trujillo of the Department of La Libertad" , with CUI No. 2573274;

In accordance with the provisions of Law No. 29158, Organic Law of the Executive Branch; Legislative Decree No. 1161, Law of Organization and Functions of the Ministry of Health, and amendments; Supreme Decree No. 008-2017-SA, Supreme Decree that approves the Regulation of Organization and Functions of the Ministry of Health and amendments; and, Legislative Decree No. 1564, Legislative Decree that modifies the Fourth Final Complementary Provision of Legislative Decree No. 1444, Legislative Decree that modifies Law No. 30225, State Contracting Law;

DECREE:

Article 1.- Declaration of national interest
Declare of national interest the actions necessary for the formalization of the State-to-State Agreement of the project "Improvement of hospital health services in Regional Teaching of Trujillo – Trujillo district of Trujillo of the province of Trujillo of the department of La Libertad."

Article 2.- Authorization to sign the State-to-State Agreement

Authorize the Ministry of Health to sign the State-to-State Agreement, within the framework of the project "Improvement of hospital health services in the Teaching Regional of Trujillo – Trujillo district of Trujillo of the province of Trujillo of the department of La Libertad."

Article 3.- Authorization to the Ministry of Health
Authorize the Ministry of Health to issue the necessary acts for the formalization of the State-to-State Agreement referred to in article 2 of this Supreme Decree.

Article 4.- Endorsement
This Supreme Decree is endorsed by the Minister of Health.

Given in the Government House, in Lima, at seventeen days of the month of October of the year two thousand twenty-three.

DINA ERCILIA BOLUARTE ZEGARRA
President of the Republic

CÉSAR HENRY VÁSQUEZ SÁNCHEZ
Health Minister

2226139-1

Supreme Decree that modifies and incorporates various articles in the Regulation of Clinical Trials, approved by Decree Supreme Court N° 021-2017-SA

Supreme decree
nº 028-2023-SA

THE PRESIDENT OF THE REPUBLIC

CONSIDERING:

That, articles 7 and 9 of the Political Constitution of Peru establish that everyone has the right to the protection of their health, that of the family environment and that of the community, as well as the duty to contribute to its promotion and defense.
The State determines the National Health Policy. The Executive Branch regulates and supervises its application, being responsible for designing and conducting it in a plural and decentralizing manner to facilitate equitable access to health services for all;

That, paragraphs I and II of the Preliminary Title of Law No. 26842, General Health Law, indicate that health is an indispensable condition for human development and a fundamental means to achieve individual and collective well-being; Therefore, health protection is of public interest, and it is the responsibility of the State to regulate, monitor and promote it;

That, paragraph XV of the aforementioned Preliminary Title states that the State promotes scientific and technological research in the field of health, as well as the training, training and training of human resources for health care;

That, numeral 9 of article 3 of the Legislative Decree No. 1161, Law of Organization and Functions of the Ministry of Health, establishes that the Ministry of Health is competent in health research and technologies; and its article 4 provides that the Health Sector is made up of the
Ministry of Health, as the governing body, the entities attached to it and those public and private institutions at the national, regional and local level, and natural persons that carry out activities linked to the powers established in said Law, and that have a direct or indirect impact on health, individual or collective;

That, article 4-A of the limited Legislative Decree, modified by Legislative Decree No. 1504, Decree
Legislative that strengthens the National Institute of Health

for the prevention and control of diseases, states that the governing power of the Ministry of Health includes the power it has to regulate, supervise, supervise and, when appropriate, sanction, in the areas that include health matters.
The stewardship of health matters within the sector is exercised by the Ministry of Health on its own behalf or, by express delegation, through its assigned public organizations and, within the framework and limits established in the aforementioned Law, the Organic Law of Power Executive, the substantive norms that regulate sectoral activity and the norms that govern the decentralization process;

That, in turn, in accordance with articles 4 and 6 of Legislative Decree No. 1504, Legislative Decree that strengthens the National Institute of Health for the prevention and control of diseases, the National Institute of Health (INS) is a body specialized technical public assigned to the Ministry of Health, with national competence in research, innovation and health technologies, in epidemics, epidemiological surveillance and health intelligence, which include the following areas of public health: a) The prevention and control of communicable and non-communicable diseases; b) Food, nutrition and food technologies; c) Occupational health and environmental protection focused on people's health; d) Interculturality in health and traditional and complementary medicine; and) The production of biologicals and goods of strategic importance in public health; and, f) Quality control of pharmaceutical products, medical devices and health products;

That, the Clinical Trials Regulation, approved by Supreme Decree No. 021-2017-SA, establishes the procedure for the authorization, execution and actions after the execution of clinical trials in the country;

That, paragraph 10 of section 2.1 of article 2 of the aforementioned Regulations defines the amendment as that written description of change(s) or formal clarification of a research protocol and/or informed consent; That it is necessary to make modifications and incorporate various articles to the Clinical Trials Regulations, in order to regulate minor changes to the protocol and/or informed consent format, excluding them from the amendment act;

That, by virtue of paragraph 18 of paragraph 28.1 of article 28 of the Regulation that develops the Institutional Framework that governs the Regulatory Quality Improvement Process and establishes the General Guidelines for the application of the Ex Ante Regulatory Impact Analysis, approved by Supreme Decree No. 063-2021-PCM, this regulatory project is considered excluded from the scope of the AIR Ex Ante, since it does not incorporate or modify rules, prohibitions, limitations, obligations, conditions, requirements, responsibilities or any requirement that generates or implies variation in costs in its compliance, since only the regulation of minor changes to the protocol and/or the informed consent format is being included, differentiating them from the act of amendment, because, as they refer to non-substantial modifications, they would only proceed with the approval of the same Institutional Committee of Research Ethics – CIEI, which approved its current version;

In accordance with the provisions of paragraph 8 of article 118 of the Political Constitution of Peru; and in Law No. 29158, Organic Law of the Executive Branch;

DECREE:

Article 1.- Modification of the Clinical Trials Regulations, approved by Supreme Decree No. 021-2017-SA

Modify paragraph 10 of section 2.1 of article 2; literal b) of article 34; literal b) of article 40; literal e) of article 52; the title of Chapter III of Title V; the first paragraph of Annex 1 – Guide to the research protocol; as well as literal b) of section 22 of Annex 4 - Guide for the informed consent format, of the Clinical Trials Regulations, approved by Supreme Decree No. 021-2017-SA, which are drafted in accordance with the following detail:

"Article 2. Operational definitions and abbreviations
(…)

2.1. Operational definitions
(…)

10. Amendment.- Act that specifically refers to a substantial change(s) to the research protocol and/or the informed consent format, other than the minor change(s) in the protocol and/or the informed consent form. The amendment changes the version of the protocol and/or the informed consent format. It is regulated in accordance with the provisions established, for this purpose, in this Regulation.

(...)".

"Article 34. Requirements for the format of informed consent
The informed consent form for the research subject is subject to the following requirements:

(...)
b) Be reviewed and approved by a CIEI registered and accredited by the INS, in accordance with the provisions of Chapter VII of Title IV of this Regulation.
(...)"

"Article 40. Responsibilities of the sponsor
The sponsor is responsible for:

(...)
b) Ensure the review and approval by a CIEI registered and accredited by the INS of all documents linked to the conduct of a clinical trial for subsequent presentation to the INS, as established in this Regulation, as well as the authorization of the execution of the clinical trial by the research institution where it will be carried out, before its start.
Likewise, when applicable, guarantee that the minor change proposed to the protocol and/or the informed consent format complies with the provisions of this Regulation and the standards issued by the Directorate of Health Research and Innovation – DIIS of the National Institute. of Health, with the responsibility for the execution of the protocol remaining with the sponsor.
(...)"

"Article 52. Obligations of the principal investigator

The following are the obligations of the principal investigator:

(...)
e) Obtain approval of the clinical trial by a CIEI registered and accredited by the INS, before its start.
(...)"

"Title V
(...)
CHAPTER III
OF AMENDMENTS AND MINOR CHANGES"

"Annex 1
GUIDE TO THE RESEARCH PROTOCOL

The clinical trial protocol must contain the necessary information to understand the reasonableness of the research question, the design and procedures of the clinical trial and the measures that guarantee the protection of the rights of the research subjects; among other data required in this Regulation. The indications for developing the research protocol are provided below:

(...)"

"ANNEX 4
GUIDE TO THE CONSENT FORM
Informed

(...)
22)Contact information

(...)
b) Contact details of the Regulatory Authority (INS). Include the following text:
"When you consider that your rights are violated or in the event of any complaint, you can contact the INS (Directorate of Research and Innovation in Health, DIIS; or whatever takes its place), the regulatory entity for clinical trials, by telephone [enter telephone number established by the INS] or through written communication, through email consultaensayos@ins.gob.pe, or through a formal document presented through the institution's physical or virtual party table, or go in person to the DIIS facilities at the INS at the following address: [insert address of the INS headquarters where the DIIS is located].
(...)".

Article 2.- Incorporation into the Clinical Trials Regulations, approved by Supreme Decree No. 021-2017-SA

Incorporate paragraphs 48 and 49 to section 2.1 of article 2, the third paragraph to article 6, literal i) to article 60, as well as articles 85-A and 85-B to the Clinical Trials Regulations, approved by Supreme Decree N ° 021-2017-SA, in accordance with the following detail:

"Article 2.- Operational definitions and abbreviations
(...)

2.1. Operational definitions

(...)
48. Minor change to the protocol and/or informed consent format.- Change that is made at the proposal of the sponsor and under its responsibility, in accordance with the considerations established in this Regulation and in the standards issued by the Research and Innovation Directorate. in Health – DIIS of the National Institute of Health, which deals with exhaustive and non-substantial changes to the current version of the protocol and/or the informed consent format, being different from the approval of an amendment.
49. Approval of the Institutional Research Ethics Committee (CIEI).- Favorable opinion to the documents related to the conduct of a clinical trial, as established in this Regulation, which a registered and accredited CIEI grants by document at the request of the researcher. major."

"Article 6. Authorization to carry out clinical trials

(...)
The minor change(s) only requires the approval of the CIEI registered and accredited by the INS, in accordance with the provisions of this Regulation."

"Article 60. Functions of the Committees Institutional Research Ethics
The CIEI have the following functions regarding the clinical trials submitted for your consideration:

(...)

i) Review and approve the documents linked to the conduct of a clinical trial for presentation to the INS, as established in this Regulation.
The initial approval of the documents for the conduct of a clinical trial can be carried out by a single registered and accredited CIEI of any of the research institutions where the clinical trial is carried out when it is a multicenter trial, provided that the Institution's standards of Research allow it. In the case of trials with a single center, the initial approval of the documents for carrying out a clinical trial must be carried out by a CIEI registered and accredited by the INS. The CIEI that carries out the approval is in charge to carry out the supervision and monitoring of the clinical trial, in accordance with the provisions of the Regulation and those established for this purpose by the INS."

"Article 85-A. Authorization of minor changes to the research protocol and/or informed consent

The minor change(s) to the research protocol and/or informed consent proceed with the approval of the same CIEI that approved its current version, and the Sponsor must communicate it in writing to the Research and Innovation Directorate - DIIS of the National Institute of Health - INS within a period of no more than ten (10) business days prior to its implementation. A minor change does not generate a new version of the authorized protocol or informed consent form; being that, if a subsequent amendment is made to the protocol, it must also contain the minor change made. The DIIS of the INS approves by Resolution the list of the exhaustive and non-substantial assumptions that are considered the minor change(s) to the protocol and/or informed consent.

"Article 85-B. Minor amendments and changes in multicenter and single research center clinical trials

When the clinical trial is carried out in more than one research center, the approval of amendments and minor changes to the research protocol and/or informed consent format is carried out only by the CIEI that approved the current version of the research protocol and/or or informed consent form, the same one that is in charge of carrying out the supervision and monitoring of the clinical trial. In the case of clinical trials with a single research center, the review and approval of amendments and minor changes to the research protocol and/or informed consent format is carried out only by the CIEI that approved the current version of the research protocol. and/or informed consent form.
Likewise, the Sponsor, the research institutions and the CIEIs involved may agree by document that a single accredited CIEI from any of the research institutions where a multicenter clinical trial is being carried out, can evaluate and approve minor amendments and changes to the clinical trial. in its entirety, and may also be entrusted with carrying out the supervision and monitoring of the clinical trial, or this responsibility may be maintained in the CIEI that approved the current version."

Article 3.- Endorsement
This Supreme Decree is endorsed by the Health Minister.

FINAL COMPLEMENTARY PROVISION

Sole.- Reference to the competent body in clinical trials of the National Institute of Health
Any reference to the General Office of Information and Technology Transfer – OGITT of the National Institute of Health contained in the Clinical Trials Regulations, approved by Supreme Decree No. 021-2017-SA, must be understood as being made to the Directorate of Research and Innovation in Health – DIIS of the National Institute of Health.

TRANSITIONAL COMPLEMENTARY PROVISION

Sole.- Transitory Regulation The administrative procedures in progress are governed by the provisions approved in this Supreme Decree.

Given in the Government House, in Lima, at seventeen days of the month of October of the year two thousand twenty-three.

DINA ERCILIA BOLUARTE ZEGARRA
President of the Republic

CÉSAR HENRY VÁSQUEZ SÁNCHEZ
Health Minister

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