HEALTH

Supreme Decree approving the Single Text of Administrative Procedures - TUPA of the National Institute of Health - INS

SUPREME DECREE
No. 010-2025-SA

THE PRESIDENT OF THE REPUBLIC

WHEREAS:

That, with Supreme Decree No. 004-2013-PCM, the National Policy for the Modernization of Public Management is approved, through which the principle of citizen-oriented public management is established, by which the State and its entities must define their priorities and interventions based on citizen needs and, based on them, establish the management functions and processes that allow them to respond to those needs;

That, Article 43 of the Single Ordered Text of Law No. 27444, Law of Administrative Procedure General (TUO of Law No. 27444), approved by Supreme Decree No. 004-2019-JUS, establishes that all entities prepare and approve or manage the approval, as the case may be, of their Single Text of Administrative Procedures (TUPA), which includes, among others, all procedures initiated by the party required by the administrators to satisfy their interests or rights through the pronouncement of any body of the entity, provided that this requirement has legal support; the clear and exhaustive description of all the requirements for the complete execution of each procedure; and, the list of the services provided exclusively, understood as the services that the entities are authorized to provide exclusively within the framework of their competence;

That, likewise, article 44 of the aforementioned TUO of Law No. 27444, provides that the TUPA is approved by Supreme Decree of the sector, as well as requires the correct publication of the aforementioned institutional management document;

That, by Legislative Decree No. 1203, the Single System of Procedures (SUT) is created as a computer tool for the preparation, simplification and standardization of the TUPA, as well as the official repository of administrative procedures and services provided exclusively, with their corresponding supporting information, formulated by the entities of the public administration, which is administered by the Presidency of the Council of Ministers, through the Management Secretariat.
Public, as the governing body of the Public Management Modernization System;

That, Article 7 of the aforementioned Legislative Decree No. 1203 establishes that the SUT for the registration, integration and optimization of administrative procedures and services provided exclusively, has the following content: i) Legal support for the administrative procedures and services provided exclusively, with the information provided in Article 37 of Law No. 27444 (currently, contained in Article 43 of the TUO of Law No. 27444); ii) Support for costs linked to each of the administrative procedures and services provided exclusively, in accordance with the provisions of the current cost determination methodology; iii) Tools that allow the simplification of administrative procedures and services provided exclusively, in accordance with the current methodology; and, iv) Real-time publication of approved TUPA;

That, numeral 9.1 of article 9 of the Regulations of Legislative Decree No. 1203, approved by Supreme Decree No. 031-2018-PCM, establishes that the administrative procedures and services provided exclusively to be registered in the SUT are those whose processing is carried out before the entities of the public administration, and comply with the regulations in the TUO of Law No. 27444, the Guidelines for the determination of processing fees, the Guidelines for the preparation of the TUPA and other current administrative simplification regulations;

That, likewise, numeral 9.2 of the aforementioned article 9 establishes that the entities of the Public Administration enter the SUT portal through the following web address http://sgp.pcm.gob.pe/sistema-unico-de-tramites/, or the one that takes its place, to register all the administrative procedures and services provided exclusively compiled in the TUPA;

That, by means of Resolution of the Secretariat of Public Management No. 004-2018-PCM/SGP, the new format of the TUPA is approved, specifying that it summarizes and systematizes the administrative procedures and services provided exclusively;

That, numeral 5.2 of article 5 of the Guidelines for the preparation and approval of the TUPA, approved by the Resolution of the Secretariat of Public Management No. 005-2018-PCM-SGP, establishes that public administration entities must approve or modify their TUPA when it is required to incorporate administrative procedures and/or services provided exclusively to the current TUPA, due to the approval of a law, legislative decree or other regulation of general scope that provides for the establishment or creation of the aforementioned procedures and/or services;

That, Article 6 of the Guidelines cited in the preceding recital, provides that the Secretariat of Public Management of the Presidency of the Council of Ministers issues a prior favorable opinion for the approval or modification of the TUPA in the case of entities of the Executive Branch;

That, likewise, article 7 of the aforementioned Guidelines establishes that the Ministry of Economy and Finance, in the case of entities of the Executive Branch, issues a favorable prior opinion and endorses the Supreme Decree approving or modifying the TUPA when it concerns the determination of the amount of processing fees;

That, in this regard, numeral 53.2 of article 53 of the TUO of Law No. 27444, prescribes that for the collection of processing fees in the case of entities of the Executive Branch, the endorsement of the Ministry of Economy and Finance must be obtained;

That, numeral 54.1 of article 54 of the TUO of Law No. 27444, provides that the amount of the processing fee is determined based on the amount of the cost that its execution generates for the entity for the service provided throughout its processing and, where applicable, by the actual cost of production of documents issued by the entity. Its amount is supported by the server in charge of the administration office of each entity;

That, for its part, Rule IV of the Single Ordered Text of the Tax Code, approved by Supreme Decree No. 133-2013-EF, establishes, among other aspects, that by Supreme Decree endorsed by the Minister of the competent Sector and the Minister of Economy and Finance, the amount of the rates is set;

That, Article 6 of Legislative Decree No. 1504, Legislative Decree that strengthens the Institute The National Health Institute (INS) for the prevention and control of diseases establishes that the National Health Institute (INS), in matters of health, has national jurisdiction over research, innovation and health technologies, which include the following areas of public health: i) The prevention and control of communicable and non-communicable diseases; ii) Food, nutrition and food technologies; iii) Occupational health and environmental protection focused on people's health; iv) Interculturality in health and traditional and complementary medicine; (v) The production of biological products and goods of strategic importance to public health; and (vi) The quality control of pharmaceutical products, medical devices, and healthcare products;

That, by Supreme Decree No. 017-2005-SA, among others, the INS TUPA is approved, which was modified by Supreme Decree No. 020-2006-SA, Ministerial Resolution No. 007-2006/MINSA and Ministerial Resolution No. 921-2007/MINSA;

That, within the framework of the Regulatory Quality Analysis, by Supreme Decree No. 117-2019-PCM, twelve (12) administrative procedures of the INS were ratified, which are framed in accordance with the regulations of the Clinical Trials Regulation, approved by Supreme Decree No. 021-2017-SA; likewise, it was established that, without prejudice to the aforementioned analysis, the entities must continue with their work of administrative simplification;

That, for its part, by Supreme Decree No. 028-2023-SA, various articles are modified and incorporated into the Clinical Trials Regulation approved by Supreme Decree No. 021-2017-SA, which has a direct impact on some administrative procedures regulated in the INS TUPA;

That, likewise, Supreme Decree No. 164-2020-PCM approves the Administrative Procedure Standardized Access to Public Information created or obtained by the entity, which is in its possession or under its control, in charge of the entities of the Public Administration, as well as the right to process the aforementioned procedure;

That, on the other hand, by Supreme Decree No. 004-2023-SA, the Regulation that governs the medicinal and therapeutic use of cannabis and its derivatives is approved, which authorizes the INS to grant the administrators, through a prior evaluation procedure, a license to carry out scientific research activities on cannabis derivatives for clinical trials without cultivation, contemplating in its article 8, the necessary requirements to grant said license;

That, it is appropriate to point out that by Supreme Decree No. 064-2010-PCM the new methodology for determining the costs of administrative procedures and services provided exclusively for public entities is approved, which is mandatory in the processes of elaboration and/or modification of the administrative procedures and services provided exclusively contained in the TUPA;

That, on this matter, through Legislative Decree No. 1647, it is established that the entities of the Executive Branch that have not applied the current methodology for determining the costs of administrative procedures and services provided exclusively, approved by Decree
Supreme Court No. 064-2010-PCM or the regulation that replaces it, in determining the processing fees that are currently being charged, have until June 30, 2025 to comply;

That, it should be noted that numeral 41.1 of article 41 of the TUO of Law No. 27444, provides that entities are required to incorporate the administrative procedures and services provided exclusively standardized in their respective TUPA without the need for approval by another entity;

That, in this sense, it is necessary to approve the INS TUPA, in order to adapt and update it with current regulations, specifying that it has the favorable opinion of the Secretariat of Public Management of the Presidency of the Council of Ministers and the General Directorate of Public Revenue Policy of the Ministry of Economy and Finance, through Report No. D000118-2025-PCM-SSSAR and Report No. 0126-2025-EF / 61.01, respectively, which agree to continue with the approval of the aforementioned institutional management document that summarizes and systematizes the administrative procedures and services provided exclusively that are processed before the aforementioned entity, including the Standardized Administrative Procedure for Access to Public Information approved by Supreme Decree No. 164-

2020-PCM;

In accordance with the provisions of Law No. 29158, Organic Law of the Executive Branch; Legislative Decree No. 1504, Legislative Decree that strengthens the National Institute of Health for the prevention and control of diseases; Legislative Decree No. 1161, Legislative Decree that approves the Law of Organization and Functions of the Ministry of Health; the Consolidated Text of Law No. 27444, General Administrative Procedure Law, approved by Supreme Decree No. 004-2019-JUS; and, Resolution of the Secretariat of Public Management No. 005-2018-PCM-SGP, which approves the Guidelines for the preparation and approval of the Consolidated Text of Administrative Procedures (TUPA);

DECREES:

Article 1.- Approval of the Single Text of Administrative Procedures of the National Health Institute

Approve the Single Text of Administrative Procedures of the National Institute of Health, which as
Annex forms an integral part of this Supreme Decree.

Article 2.- Approval of the processing fee

Approve the processing fees corresponding to the administrative procedures of the Single Text of Administrative Procedures of the National Institute of Health, in accordance with the details established in the annex provided for in Article 1 of this Supreme Decree.

Article 3.- Approval of forms

Approve the forms corresponding to the procedures of the Single Text of Administrative Procedures of the National Institute of Health, in accordance with the details established in the annex provided in article 1 of this Supreme Decree.

Article 4.- Publication

This Supreme Decree and the Single Text of Administrative Procedures of the National Institute of Health, approved by article 1, are published on the Single Digital Platform of the Peruvian State for Citizen Guidance (www.gob.pe), on the digital headquarters of the National Institute of Health (www.gob.pe/ins) and on the Portal of the official newspaper El Peruano, on the same day of publication of this standard in the official newspaper El Peruano.

Article 5.- Endorsement

This Supreme Decree is endorsed by the Minister of Health and the Minister of Economy and Finance.

SUPPLEMENTARY PROVISION
REPEAL

Sole.- Repeal

Repeal the Single Text of Administrative Procedures of the National Institute of Health, approved by Supreme Decree No. 017-2005-SA, and its amendments.

Given at the Government House, in Lima, on the thirtieth day of the month of June of the year two thousand twenty-five.

Dina Ercilia Boluarte Zegarra
President of the Republic

Jorge Luis Montero Cornejo
Minister of Energy and Mines
Head of the Office of the Ministry of
Economy and Finance

Cesar Henry Vasquez Sanchez
Minister of Health

SINGLE TEXT OF ADMINISTRATIVE PROCEDURES – TUPA
FROM THE "NATIONAL INSTITUTE OF HEALTH"

Regulations approved or modified by the TUPA

Approves	Supreme Decree.

INDEX

SECTION NO. 1: ADMINISTRATIVE PROCEDURES

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Access to Public Information created or obtained by the entity, which is in its possession or under its control"

Code: PE123299E43

Description of the procedure

Procedure through which any person, natural or legal, requests public information (information created, obtained, in possession or under the control of a public entity), without stating the reason for their request, and receives it in the form or by the means requested, provided that they assume the cost of its physical reproduction or free of charge when it is requested that it be delivered by virtual means. The response period is 10 business days; however, when it is materially impossible to comply with the indicated deadline due to justified causes, the entity informs the applicant for the only time of the date on which it will provide the requested information in a duly substantiated manner, within a maximum period of two (2) business days of receiving the request for information.

Requirements

1.- Application submitted via form or document containing the same information.

2.- If applicable, indicate the payment receipt number and date if the payment was made at the bank. If the payment was made at the Banco de la Nación, attach a copy of the payment receipt*.
This requirement is submitted after the application is submitted. The entity notifies the applicant of the settlement of the cost of Reproduction containing the required information, at most, until the ninth (9) business day after receiving the request.

Grades:

1.- The request for information must be addressed to the Official Responsible for handling Access to Information requests. If this person has not been designated, the request is addressed to the official in possession of the requested information or to the immediate superior.

2.- The request for access to public information may be submitted by any natural or legal person to the entity's document reception unit, through a digital form, an email address established for this purpose, or through any other suitable means established by the entities for such purposes.

3.- The applicant will be notified of the cost of reproducing the information required no later than the ninth (9) business day after receiving the request. In such cases, the applicant must pay the amount by contacting the entity or through the remote payment or digital payment mechanisms that each entity makes available. The payment must be made known to the entity so that it can carry out the corresponding reproduction and deliver the information within the deadline.

4.- Information cannot be denied when it is requested to be delivered in a specific form or medium, provided that the requester assumes the cost of the request.

5.- In the case of an Appeal, the maximum submission period is 15 business days. In the case of a tacit denial, there is no peremptory deadline. The maximum response period is ten (10) business days, counted from the admissibility of the appeal by the Transparency and Access to Public Information Tribunal. The deadline to declare the admissibility of the appeal is seven (7) business days, counted from the next business day after its receipt by the Court. If the Court declares the appeal inadmissible, it requires the appellant to correct the problem within a maximum period of two (2) business days counted from the next business day after its notification. If the appellant does not correct the problem within this period, the appeal is considered not to have been filed.

Forms

Excel Form: Request for Access to Public Information created or obtained by the entity, which is in its possession or under its control.
Location: http://sut.pcm.gob.pe/sutArchivos/file_100_20201216_153200.PDF

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Assistance: https://web.ins.gob.pe/es/transparencia/solicitud-de-acceso-a-la-informacion-publica

Payment for processing fees

Information on CD (per unit)
Amount - S/ 1.00

Information by Email (free)
Amount - S/ 0.00

Simple copy A4 format (per unit)
Amount - S/ 0.10

Payment Methods

Entity's Box
Cash: Payment in soles at the National Health Institute cashier

Term of attention

10 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

GG AIP (GENERAL MANAGEMENT - ACCESS TO PUBLIC INFORMATION): NATIONAL INSTITUTE OF HEALTH

Organizational unit responsible for approving the request

GG AIP (GENERAL MANAGEMENT - ACCESS TO PUBLIC INFORMATION)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2404
Email: transparencyins@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	- Not applicable	- Transparency and Access to Public Information Tribunal
Maximum submission deadline	Not applicable	15 business days
Maximum response time	Not applicable	10 business days

Legal basis

Article	Denomination	Guy	Number	Date Publication
16, 17 18 19 and 20	Consolidated Text of Law No. 27806, Law 10, 11, 12, 13, 14, 15, of Transparency and Access to Public Information	Supreme Decree	No. 021-2019-JUS	11/12/2019
13, 15, 17, 21 22, 25, 26, 29 and 30	Regulation of the Law on Transparency and Access to Information Public Information	Supreme Decree 28,	No. 007-2024-JUS	05/16/2024
6 9 and 7 First a provision	Legislative Decree creating the National Authority of Transparency and Access to Public Information, strengthens the complementary Personal Data Protection Regime and the amending regulation interest management	Legislative Decree	No. 1353	07/01/2017

page 5

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Accreditation of Institutional Research Ethics Committees"

Code: PA1000FD74

Description of the procedure

Procedure by which an Institutional Research Ethics Committee (IREC) is accredited to comply with the accreditation standards established in the Clinical Trials Regulations and Procedures Manual for the ethical evaluation of research protocols.
Objective: To ensure that Ethics Committees conduct an appropriate evaluation of the protocol and Informed Consent Form (ICF) using the same standard for assessing compliance with ethical principles for experimental research involving human subjects.
It may be requested by institutional research ethics committees that evaluate protocols for clinical trials.
It must be obtained because when an Ethics Committee is enabled through accreditation, it ensures that it meets standards that allow it
Properly assess compliance with ethical principles in the protocol and informed consent form. In this way, the Ethics Committee balances the risk and benefit for the research subjects, enabling it to approve the protocol and informed consent form for a clinical trial.

The deliverable is a CIEI Accreditation Letter and is not subject to renewal.

Requirements

1.- Request for accreditation addressed to the INS.

2.- Copy of the Resolution of the highest authority of the research institution that authorizes the operation of the Institutional Research Ethics Committee (CIEI)

3.- Regulations and Procedures Manual approved by the Research Institution to which they belong. These documents are presented in electronic media (PDF format to copyable text).

4.- Affidavit indicating compliance with the accreditation standards established in the Procedures Manual of Clinical Trials.

5.- Undocumented curriculum vitae for each member of the Institutional Research Ethics Committee (CIEI). These documents are submitted electronically.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 3927.10

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

page 6

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
Article XV of the Title Preliminary, article 28 and 123	General Health Law.	Law	26842	20/07/1997
Literal a) of article 32 and Law of the Ministry of Health. Literal a) of article 33		Law	27657	01/29/2002
Article 63	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

page 7

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Clinical trial authorization."

Code: PA10006170

Description of the procedure

The authorization of a clinical trial (experimental research in humans) is a procedure that authorizes the execution of this type of research in the country, after reviewing the technical, scientific, and administrative information presented. It is carried out within the ethical, legal, and applicable scientific evidence framework to: Safeguard the rights and well-being of the subjects participating in the research; Ensure that the research will be carried out with the required scientific rigor; that the protocol has an adequate methodological design and the scientific purpose of the research is evident; and to prevent, reduce, and/or avoid any health risks in the use and handling of the study intervention or in the procedures involving the proposed research. The RD deliverable is not subject to renewal.

Requirements

1.- Application for authorization of the clinical trial, according to the registration form established in the REPEC (Peruvian Registry of Clinical Trials) which includes payment receipt information.

2.- Copy of the approval document issued by the legal representative of the research institution(s) where the clinical trial will be conducted according to the model established in the Clinical Trials Procedures Manual.

3.- Research protocol in Spanish and in the original language if not Spanish, and Informed Consent Form(s), according to Annex 1 and Annex 4 of the Clinical Trials Regulations, approved by the CIEI accredited by the INS, also attaching to each of them a copy of the approval document issued by the respective CIEI, according to the model established in the Clinical Trials Procedures Manual. These documents must be submitted electronically (PDF to copyable text format).

4.- In the case of a foreign sponsor: Copy of the certificate of delegation of functions to the sponsor's representative, duly apostilled, otherwise legalized by the Ministry of Foreign Affairs of Peru.

5.- Affidavit according to the model established in the Clinical Trial Procedures Manual, signed by the sponsor and principal investigator, establishing that there is no financial conflict of interest in the execution of the clinical trial.

6.- Affidavit signed by the sponsor and principal investigator on the conditions of the research center where the clinical trial will be carried out, according to the model established in the Clinical Trials Procedures Manual.

7.- Copy of the current insurance policy (insurance contract) purchased by the sponsor.

8.- Affidavit from the sponsor stating that it has a financial fund that guarantees immediate free care and treatment for the research subject, in the event that they suffer any adverse event as a result of the clinical trial, until the insurance policy is activated and according to the model established in the Clinical Trials Procedures Manual.

9.- Updated Researcher's Manual, in Spanish and in the original language if not Spanish. This may be replaced according to the conditions set forth in Annex 2 of these Regulations. These documents must be submitted electronically (PDF to copyable text).

10.- Information related to the quality of the product under investigation (electronic media) according to Annex 5 of this Regulation.

11.- Updated undocumented curriculum vitae of the entire research team of each research center, according to the model established in the Clinical Trials Procedures Manual, attaching a copy of the documents that prove training in Good Clinical Practices and Ethics in Research in human beings of the entire research team, with a validity of no more than three (3) years old.

12.- Detailed national total budget of the clinical trial, according to the model established in the Trial Procedures Manual Clinicians.

13.- List of supplies necessary for the development of the clinical trial, according to the format established in the Manual of Clinical Trial Procedures.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 3446.50

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

Qualification of the procedure

page 8

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

30 business days	Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	, General Health Law. of the	Law	26842	June 30, 2017
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
67	, Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures

"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Clinical trial cancellation"

Code: PA1000DAAB

Description of the procedure

Procedure for the definitive interruption of all clinical trial activities at all research centers for justified reasons. Its purpose is to authorize the cancellation of a clinical trial, specifying compliance with the measures established for the monitoring and adequate care of research subjects. It is requested by the clinical trial sponsor. The deliverable is the RD. It is not subject to

for renewal.

Requirements

1.- Request for cancellation of the clinical trial justifying the reasons for cancellation and describing the data obtained up to that point.

2.- Report on the measures to be adopted with the research subjects, if applicable.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 304.80

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
81	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures

"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Amendments to the research protocol: For authorization of a change in the title of a clinical trial."

Code: PA10002F6B

Description of the procedure

Procedure by which an amendment or variation is authorized solely in the title of the clinical trial without any modification having occurred or going to occur in the objective and other characteristics of the previously approved study; this modification must not compromise the safety and rights of the research subjects or the reliability or solidity of the data that will be obtained in the clinical trial. Its objective is to guarantee that the change of title of a clinical trial remains consistent with the objectives of the authorized clinical trial and that the new title does not affect the

Reliability and robustness of the data to be obtained in the clinical trial. This is requested by the clinical trial sponsor. The deliverable is the RD and is not subject to renewal.

Requirements

1.- Request for Change of Title of a Clinical Trial justifying the reasons, including the number and date of the payment receipt for the processing fee.

Grades:

1.- Approval of the change of title of the clinical trial by a CIEI accredited by the INS

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 305.10

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
The appeal will be filed when the challenge is based on a different interpretation of the evidence produced or when it involves questions of pure law,

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

You must contact the same authority that issued the act being challenged so that it can raise the matter to the hierarchical superior.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
87	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

page 13

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Amendments to the research protocol: By authorization of Amendment Report."

Code: PA10008AEF

Description of the procedure

Procedure by which, if appropriate, the formal change or clarification of a research protocol and/or informed consent for an authorized clinical trial is authorized. These changes are the result of a new version of the clinical trial protocol and/or a new version of the informed consent form.
Informed consent. Its purpose is to ensure that proposed amendments to the protocol and/or ICF are formulated in accordance with the initially approved objectives, complying with national guidelines and good clinical practices and ethical standards, to prevent risks and harm to clinical trial subjects. It is requested by the clinical trial sponsor. The deliverable is a letter, not subject to renewal.

Requirements

1.- Request for an amendment report that includes the list of documents to be amended (document, version and date), including the number and date of the payment receipt for the processing fee.

2.- Justification of the proposed changes.

3.- Informed consent protocol and/or form(s) with change control in the Spanish version and also in the original language if not Spanish. These documents must be submitted electronically (PDF to copyable text).

4.- Research protocol with the amendment incorporated in the Spanish version and in the original language if not Spanish, and/or final Informed Consent Form(s), also attaching a copy of the research protocol amendment approval document and/or informed consent form(s) issued by a National Institute of Statistics (CIEI) accredited by the National Institute of Statistics (INS). These documents must be submitted electronically (PDF to copyable text).

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 726.60

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum term of	15 business days	15 business days

page 14

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

presentation		
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
88	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of the clinical trial authorization: Due to the expansion of the number of research centers."

Code: PA1000AE98

Description of the procedure

Research protocol with the amendment incorporated in the Spanish version and in the original language if not Spanish, and/or final Informed Consent Form(s), also attaching a copy of the research protocol amendment approval document and/or informed consent form(s) issued by a CIEI accredited by the INS. These documents are submitted electronically (PDF to copyable text). Their objective is to ensure that the research centers proposed for inclusion in the clinical trial meet the same requirements and conditions as the research centers initially authorized to conduct the clinical trial. The request is made by the sponsor; the deliverable is the RD, and it is not subject to renewal.

Requirements

1.- Request to expand the number of research centers, justifying the reasons for the expansion and including information on proof of payment.

2.- Copy of the approval document issued by the legal representative of the research institution(s) where the clinical trial will be conducted, according to the model established in the Clinical Trials Procedures Manual, for the additional research center

3.- Copy of the research protocol approval document and informed consent form(s) issued by the respective CIEI accredited by the INS, according to the model established in the Clinical Trials Procedures Manual, for the additional research center.

4.- Informed consent format(s) according to Annex 4 of this Regulation approved by the CIEI

5.- Affidavit according to the model established in the Clinical Trial Procedures Manual, signed by the sponsor and principal investigator, establishing that there is no financial conflict of interest in the execution of the clinical trial.

6.- Affidavit signed by the sponsor and principal investigator on the conditions of the research center where the Clinical Trial will be carried out, according to the model established in the Clinical Trial Procedures Manual.

7.- Updated undocumented curriculum vitae of the entire research team of each research center, according to the model established in the Clinical Trials Procedures Manual, attaching a copy of the documents that prove training in Good Clinical Practices of the entire research team, with a validity of no more than three (3) years.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 450.60

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

Consultation on the procedure

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
76	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures

"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of clinical trial authorization: Due to change of sponsor or contract research organization."

Code: PA100044AB

Description of the procedure

Procedure that evaluates and authorizes (if applicable) the change of the sponsor of a clinical trial or the change of the Contract Research Organization (CRO) that represents a sponsor in the country and therefore recognizes the new sponsor or the new CRO that assumes the commitment to continue conducting the clinical trial under the authorized conditions, assuming the responsibilities that the regulations attribute to the sponsor or the CRO that represents it in the country. (responsibilities indicated in article 40, 89, title VIII and title IX of the Clinical Trials Regulation: DS 021-2017-SA). Its objective is to guarantee that the proposed sponsor or CRO meets the requirements that ensure its performance in the event of any eventuality that compromises the integrity and health of the research subjects and/or the safety and quality of the study results. It is requested by the current sponsor or CRO, its deliverable is an RD, it is not subject to renewal.

Requirements

1.- Request to change sponsor or OIC justifying the reasons, including the number and date of the payment receipt for the processing fee.

2.- Copy of the letter of acknowledgement from the CIEI that approved the study, if it has acknowledged the new sponsor or the new OIC

3.- Copy of the delegation of functions of the foreign sponsor to the new OIC, issued no more than ninety years ago
(90) calendar days, duly apostilled otherwise legalized by the Ministry of Foreign Affairs of Peru.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 433.40

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum term of	30 business days	30 business days

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

answer		

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
Article XV of the Title Preliminary, article 28 and 123	, General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
39, 40 and 78	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of clinical trial authorization: Due to change of principal investigator."

Code: PA1000EB15

Description of the procedure

Procedure authorizing the change of principal investigator at a research center conducting a specific clinical trial. This procedure recognizes the new investigator, who undertakes to continue conducting the clinical trial under authorized conditions, in accordance with Articles 51, 52, and 109 of the Clinical Trials Regulations, approved by Supreme Decree 021-2017-SA. Its objective is to ensure that the principal investigator proposed by the sponsor meets the requirements that ensure they are in equal or better condition than those initially authorized to conduct the clinical trial. It is requested by the clinical trial sponsor; its deliverable is a RD, which is not subject to renewal.

Requirements

1.- Request for change of principal investigator justifying the reasons, including the number and date of the payment receipt for the processing fee.

2.- Updated undocumented curriculum vitae of the proposed principal investigator, according to the model established in the Manual of Clinical Trial Procedures.

3.- New informed consent form(s) approved by the CIEI that approved the study, including the data of the proposed principal investigator.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 299.00

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
51, 52 and 79	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of the clinical trial authorization: Due to extension of the clinical trial's conduct time."

Code: PA100029C3

Description of the procedure

Administrative procedure by which the extension of the total time initially scheduled for the execution of a clinical trial is authorized,
The objective is to ensure that the sponsor takes the necessary measures to comply with its obligations, national guidelines, ethics, and good clinical practices during the clinical trial extension period. It is requested by the sponsor of a clinical trial. Its deliverable is a RD, which is not subject to renewal.

Requirements

1.- Request for an extension of the clinical trial duration, justifying the reasons for the request, including the number and date of the payment receipt for the processing fee.

2.- Copy of the approval document for the extension of time granted by the legal representative of the research institution(s) where the clinical trial will be conducted.

3.- Copy of the document approving the extension of time by a CIEI accredited by the INS.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 306.40

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
The appeal will be filed when the challenge is based on a different interpretation of the evidence produced or when it involves questions of pure law,

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

You must contact the same authority that issued the act being challenged so that it can raise the matter to the hierarchical superior.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
80	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of clinical trial authorization: Due to closure of a research center for a clinical trial."

Code: PA10000549

Description of the procedure

An administrative procedure through which all clinical trial activities being conducted at a research center are canceled early. It is requested by the sponsor; the deliverable is a RD, and it is not subject to renewal.

Requirements

1.- Request for closure of a research center justifying the reasons for the closure.

2.- Final report from the research center, including all data obtained up to the time of closure.

3.- Report on the measures to be adopted with the research subjects, if applicable.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 308.40

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Article	Denomination	Guy	Number	Date Publication
Article XV of the Title Preliminary, article 28 and 123	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
82	, Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures

"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Modification of the clinical trial authorization: Due to suspension of the clinical trial."

Code: PA10008F36

Description of the procedure

Procedure by which the temporary interruption of the activities of a clinical trial in all research centers is formalized, sponsor's request, the deliverable is an RD, and is not subject to renewal.

Requirements

1.- Request for suspension of the clinical trial justifying the reasons for the suspension and describing the data obtained up to that point.

2.- Report on the measures to be adopted with the research subjects, if applicable.

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 303.00

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law.	Law	27657	01/29/2002
83	Clinical Trials Regulations.	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"Register of research centers."

Code: PA100016B9

Description of the procedure

Research center registration consists of the authorization of a physical unit within a research institution (healthcare provider) where clinical trials will be conducted. Authorization is subject to document evaluation and facility verification to determine whether the physical unit is authorized to care for research subjects during the conduct of a clinical trial. The objective is to ensure that research centers have the capacity to conduct trials.

Clinical trials verify compliance with minimum infrastructure, equipment, and human resources requirements to conduct trials, thereby ensuring that research subjects are not exposed to additional risks beyond those inherent to the clinical trial. Upon request, the legal representative of the research institution provides a Certificate of Registration.

Requirements

1.- Registration application submitted by the legal representative of the research institution, including the RENIPRESS code and information from the Categorization Resolution of the research institution interested in obtaining registration as a research center for the conduct of clinical trials, as well as the number and date of the payment receipt for the processing fee.

2.- Form prepared according to Annex 3 of this Regulation duly completed

Grades:

Forms

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 2524.60

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

DIIS TD (HEALTH RESEARCH AND INNOVATION DIRECTORATE - DOCUMENTARY PROCESSING): NATIONAL HEALTH INSTITUTE

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum submission deadline	15 business days	15 business days
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
28 and 123 of Article XV Preliminary Title,	General Health Law.	Law	26842	20/07/1997
32 and 33	Ministry of Health Law	Law	27657	01/29/2002
53 and 54	Clinical Trials Regulations	Supreme Decree	021-2017-SA	June 30, 2017

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

Name of the Administrative Procedure

"License for scientific research on cannabis derivatives for clinical trials without cultivation."

Code: PA100084E1

Description of the procedure

It is the license for scientific research of cannabis derivatives without cultivation, which is granted to universities or research institutions to carry out scientific research in health for medicinal purposes.

Requirements

1.- a. Research license application that must contain the following information:
- Company name, as well as legal address and Unique Taxpayer Registry (RUC) number, telephone number, email address, and official contact information.

- Name of the legal representative, with the respective accreditation in Public Registries.
- Name and address of the research centers where the research is conducted.
- Payment voucher number and issue date - Certificate number of compliance with security devices for the development of activities with cannabis and its derivatives, regulated for medicinal and therapeutic use, issued by the Anti-Drug Directorate of the National Police of Peru - DINANDRO of the PNP.

2.- The description and support of the research institution's capacity to carry out projects 2.- b. Technical report that describes and supports the scientific research for clinical trials without culture, in accordance with the provisions approved by the INS through a Chief Resolution.

Grades:

Forms

PDF form: PA100084E1-ANNEX 1
Location: http://sut.pcm.gob.pe/sutArchivos/file_100_20250522_162725.pdf

Service channels

In-Person Care: Headquarters of the National Institute of Health
Virtual Support: mesadepartesvirtual@ins.gob.pe

Payment for processing fees

Amount - S/ 441.10

Payment Methods

Entity Box Cash : soles
Other options

Bank Agency: Banco de la Nación Account No. 0000282413
Transfer: Banco de la Nación CCI 01800000000028241304

Term of attention

30 business days

Qualification of the procedure

Preliminary Evaluation - Negative Administrative Silence: If you do not receive a response after the deadline, you can file administrative appeals.

Locations and opening hours

NATIONAL INSTITUTE OF HEALTH	Monday to Friday from 8:00 a.m. to 4:30 p.m.
HEADQUARTERS	Monday to Friday from 8:00 a.m. to 4:30 p.m.

Organizational unit where the documentation is submitted

Organizational unit responsible for approving the request

SUDEC (CLINICAL TRIALS SUB-DIRECTORATE)

Consultation on the procedure

Telephone: 01 748 1111
Annex: 2191
Email: consultaensayos@ins.gob.pe

Appeal resolution instances

	Reconsideration	Appeal
Competent authority	Director of the DIIS - DIIS (DIRECTORATE OF RESEARCH AND INNOVATION IN HEALTH)	Executive President - AD (SENIOR MANAGEMENT)
Maximum term of	15 business days	15 business days

page 30

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

presentation		
Maximum response time	30 business days	30 business days

The appeal for reconsideration must be filed before the same body that issued the first act that is the subject of the challenge and must be supported by new evidence.
An appeal may be filed when the challenge is based on a different interpretation of the evidence produced or when it involves purely legal issues. The appeal must be addressed to the same authority that issued the challenged act so that the matter may be referred to a superior authority.

Legal basis

Article	Denomination	Guy	Number	Date Publication
7 and 8	Regulation governing the medicinal and therapeutic use of cannabis and its derivatives	Supreme Decree on	004-2023-SA	28/02/2023

SECTION NO. 2: SERVICES PROVIDED EXCLUSIVELY

SECTION 3: FORMS

ANEXO 1
FORMATO PARA SOLICITUD DE LA LICENCIA EN LA INVESTIGACIÓN CIENTÍFICA DE DERIVADOS DEL CANNABIS PARA ENSAYO CLÍNICO SIN CULTIVO – DS-004-2023-S

TIPO DE SOLICITUD: ☐ *NUEVA LICENCIA* ☐ *CANCELACIÓN DE LICENCIA*

1. DATOS DE LA INSTITUCIÓN DE INVESTIGACIÓN *(Establecimiento de Salud público o privado debidamente autorizado y categorizado por la autoridad de salud correspondiente)*			
1.1. NOMBRE DE LA INSTITUCIÓN DE INVESTIGACIÓN:			
RUC: *(Datos de su representante legal agregarlos en el numeral 1.2 y 1.3)*		Razón Social:	
Nombre Comercial:		Tipo de Institución:	
Dirección de la Institución de Investigación:			
Distrito:		Provincia:	
Departamento:		Teléfono y anexo:	
Red Prestacional o Asistencial: *(Completar este ítem sólo si es entidad pública y si aplica)*		Correo electrónico:	
1.2. REPRESENTANTE LEGAL (Para empresa, acreditado en la vigencia de poder / para entidad pública, acreditado en la Resolución que lo designa): *(De existir una persona diferente al representante legal como un apoderado, debe contar con el poder especial el cual debe indicar expresamente él o los actos para los cuales fue conferido)*			
Apellido Paterno:		Apellido Materno:	
Nombres:		D.N.I/ C.E/ PAS:	
Poder registrado en la Oficina:		Partida electrónica N°:	
Asiento N°:		Teléfono y anexo:	
N° de Resolución que lo designa: *(Completar este ítem solo si es entidad pública y detallar el nombre completo de la resolución)*		Fecha: *(Día, mes y año)*	
Cargo en la organización o en la entidad:		Correo electrónico:	
1.3. DOMICILIO LEGAL			
Dirección:		Distrito:	
Provincia:		Departamento:	

2. CARACTERÍSTICAS DE LA INSTITUCIÓN DE INVESTIGACIÓN		
Sector al que pertenece:	Público ☐	*Privado* ☐
Código RENIPRESS:		
Categoría del Establecimiento de Salud:		
N° y fecha de la Resolución de categorización:		

3. DATOS DEL DIRECTOR MÉDICO DE LA INSTITUCIÓN DE INVESTIGACIÓN *(Acreditado en documento legal que describa tal condición, el cual debe estar suscrito el representante legal de la Institución de Investigación facultado para contratar)*			
Apellido Paterno:		Apellido Materno:	
Nombres:		D.N.I/ C.E/ PAS:	
Teléfono y anexo:		Correo electrónico:	

4. DATOS DEL CENTRO DE INVESTIGACIÓN			
Nombre del Centro de Investigación:			
N° Registro de Centro de Investigación (RCI)	RCI -		
4.1 DATOS DEL RESPONSABLE DEL CENTRO DE INVESTIGACIÓN			
Apellido Paterno:		Apellido Materno:	
Nombres:		D.N.I/ C.E/ PAS:	
Teléfono y anexo:		Celular:	
Correo electrónico:			
Detallar la especialidad(es) en la(s) que se harán ensayos clínicos:			
Número de comprobante de pago y fecha de emisión:			
Número de certificado de cumplimiento de dispositivos de seguridad para el desarrollo de actividades con cannabis y sus derivados, regulado para el uso medicinal y terapéutico, emitido por la Dirección Antidrogas de la Policía Nacional del Perú - DIRANDRO de la PNP:			

5. SOLICITUD DE LA LICENCIA EN LA INVESTIGACIÓN CIENTÍFICA DE DERIVADOS DEL CANNABIS PARA ENSAYO CLÍNICO SIN CULTIVO		
a)	Constancia de Registro de Centro de Investigación vigente en la DIIS del INS (RCI)**	SI: ☐ NO ☐
b)	Formato para solicitud de registro remitida por el representante legal de la institución de investigación que incluya lo establecido en el Artículo 8, acápite a), del DS-004-2023-S. (ANEXO 1). *	SI: ☐ NO ☐
c)	FORMATO PARA DECLARACIÓN JURADA DEL CUMPLIMIENTO DE LAS DISPOSICIONES REQUERIDAS PARA LA EXPEDICIÓN DE LA LICENCIA EN LA INVESTIGACIÓN CIENTÍFICA DE DERIVADOS DEL CANNABIS PARA ENSAYO CLÍNICO SIN CULTIVO EN EL MARCO DEL DS N°004-2023-SA, que incluye lo establecido en el Artículo 8, acápite b), del DS-004-2023-S. (ANEXO 2). *	SI: ☐ NO ☐
*__Obligatorio__: documentos deben estar debidamente firmados por el Representante Legal de la Institución. **__Obligatorio__: Requisito indispensable para el presente procedimiento.		

7. FIRMA

Manifiesto que la información proporcionada es verdadera y autorizo la verificación a lo declarado en atención al "Principio de Presunción de Veracidad" del numeral 1.7 del artículo IV del Título Preliminar del Texto Único Ordenado de la Ley N° 27444 - Ley de Procedimiento Administrativo General, aprobado con Decreto Supremo 004-2019-JUS.

En señal de conformidad firmo el presente documento.

Fecha:

Sr.

Representante Legal de la Institución de Investigación

SECTION NO. 4: SERVICE LOCATIONS

Single Text of Administrative Procedures
"NATIONAL INSTITUTE OF HEALTH"

HEADQUARTERS	ADDRESS	BUSINESS HOURS
NATIONAL INSTITUTE OF HEALTH	JESUS MARIA - LIMA - LIMA - CÁPAC YUPANQUI Nº 1400	Monday to Friday from 8:00 a.m. to 4:30 p.m.
HEADQUARTERS	JESUS MARIA - LIMA - LIMA - CAPAC YUPANQUI 1400 - LIMA - PERU	Monday to Friday from 8:00 a.m. to 4:30 p.m.