HEALTH SECTOR

NATIONAL INSTITUTE OF HEALTH

No 435-2024-DIIS/INS

DIRECTOR'S RESOLUTION

Lime, 15 de octubre de 2024

Having seen file No. 00025375-2024, which contains **Report No. 1184 -2024-ETEC-SUDEC-DIIS/INS,** issued by the Clinical Trials Working Group; and **Information Note No. 1823-2024-SUDEC-DIIS/INS,** issued by the Clinical Trials Subdirectorate of the Health Research and Innovation Directorate of the National Institute of Health, and;

WHEREAS:

That, numeral XV of the Preliminary Title of Law No. 26842, the General Health Law, establishes that the State promotes scientific and technological research in the field of health; likewise, in its article 28, it stipulates that experimental research with people must adhere to the special legislation on the matter and to the ethical postulates contained in the Declaration of Helsinki and successive declarations that update the aforementioned postulates;

That, Article 4-A of Legislative Decree No. 1161, Law on the Organization and Functions of the Ministry of Health, amended by Legislative Decree No. 1504, Legislative Decree that strengthens the National Institute of Health for the prevention and control of diseases, states that the governing authority of the Ministry of Health includes the power to regulate, supervise, inspect, and, where appropriate, sanction, in the areas that comprise health matters. The leadership in health matters within the sector is exercised by the Ministry of Health on its own behalf or, by express delegation, through its attached public agencies, and within the framework and limits established in the aforementioned law, the Organic Law of the Executive Branch, the substantive norms that regulate sectoral activities, and the norms that govern the decentralization process;

That, through literal a) numeral 136.1 of article 136 of the Regulation of Organization and Functions of the Ministry of Health, approved by Supreme Decree No. 008-2017-SA, it is established that the National Institute of Health is a Public Body attached to the Ministry of Health, in accordance with the provisions of Legislative Decree No. 1161, Law of Organization and Functions of the Ministry of Health, which establishes in its articles 3 and 4 that the Ministry of Health is the Governing Body of the Health Sector and includes, among several matters within its scope of competence, those of health research and technology;

That, in this line, articles 1 and 2 of the First Section of the Regulations of Organization and Functions of the Institute National Health, approved by Supreme Decree No. 016-2023-SA, ratify and specify that the Institute National Health is a Specialized Technical Public Agency attached to the Ministry of Health;

That, likewise, the Integrated Text of the Regulation of Organization and Functions of the National Institute of Health, approved by Executive Presidential Resolution No. 006-2023-PE/INS, restructures the organization of the National Institute of Health, and it should be understood for the purposes of clinical trials that the Head of the Institute The National Health Institute is now called the Executive Presidency of the National Health Institute; for its part, the Directorate of Health Research and Innovation – DIIS, is what was previously called the General Office of Research and Technology Transfer – OGITT; and the Clinical Trials Subdirectorate, instead of the Office Research Executive – OEI;

That, likewise, numeral 4.2 of article 4 of the Integrated Text of the Regulations of Organization and Functions of the National Institute of Health, the Institute has as general functions the promotion and development of research,

technological transfer and innovation in health within the framework established in the National Health Policy and the National Policy on Science, Technology, and Innovation, as well as the generation and dissemination of scientific evidence and information on health that contribute to public health actions and interventions; among others;

That, in this sense, article 32 of the aforementioned Regulation determines that the Directorate of Research and Innovation in Health – DIIS (formerly the General Office of Research and Technology Transfer - OGITT), is the line, technical, regulatory and service provision body responsible, among other things, for authorizing and supervising clinical trials carried out in the country, to contribute to the health of the population;

That, for its part, the Clinical Trials Regulation, approved by Supreme Decree No. 021-2017-SA, in its articles 6 and 7 establishes that the National Institute of Health is the authority in charge at the national level of ensuring compliance with this Regulation and other related regulations that govern the authorization and execution of clinical trials, through the Directorate of Research and Innovation in Health - DIIS (formerly, General Office of Research and Technology Transfer);

That, Article 79 of the Integrated Text of the aforementioned Regulation, determines that the Directorate of Research and Innovation in Health - DIIS (formerly, OGITT), is the line, technical, regulatory and service provision body, responsible, among others, for regulating and standardizing clinical trials carried out in the country, to contribute to the health of the population;

That, by Chief Resolution No. 279-2017-J-OPE/INS dated November 17, 2017, the MAN is approved-INS-001-V03 “Clinical Trial Procedures Manual”, with the purpose of establishing the details of the procedures, flowcharts, formats, forms, standards, parameters and formalities that allow an adequate prior evaluation of the requests of the administered;

That, with respect to what was previously indicated, since 2017, different Directorial Resolutions have been approved forms, formats, and instructions, so that administrators can comply with presenting the prerequisites for the procedures established by the REC, and currently there are 39 FOR- formats OGITT so that the administrators can submit the procedures they require;

That, in accordance with the new structure established in the Regulations of Organization and Functions of the Institute National Health, it has been necessary to update the following forms: **FOR-OGITT-020** (Registry of Sponsor, Edition No. 02), **FOR-OGITT-021** (Application for Registration of Contract Research Organization, Edition No. 01); **FOR-OGITT-023** (Affidavit of Compliance with the Minimum CI Requirements, Edition No. 01); **FOR-OGITT-022** (Research Center Registration Application, Edition No. 02); **FOR-OGITT-026** (Statement Jury of Compliance with the Accreditation Standards of the Institutional Research Ethics Committee – CIEI, Edition No. 02); **FOR-OGITT-029** (Sponsor's Affidavit that it has a Financial Fund, Edition No. 03); **FOR- OGITT-063** (Affidavit of Absence of Financial Conflict of Interest, Edition No. 01); **FOR-OGITT-064** (Affidavit of Conditioning of the Research Center, Edition No. 01); **FOR-OGITT-031** (Research Team Curriculum Vitae, Issue No. 02); **FOR-OGITT-032** (Total Budget National Detailed Clinical Trial Report, Edition No. 02); **FOR-OGITT-036** (Request for Expansion of the Number of Research Centers, Edition No. 02); **FOR-OGITT-037** (Request for Extension of Time for the Execution of the Clinical Trial, Issue No. 02); **FOR-OGITT-038** (Request for Change of Principal Investigator, Issue No. 02); **FOR-OGITT-039** (Request for Change of Sponsor or Contract Research Organization, Edition No. 02); **FOR-OGITT-040** (Application for Closure of a Clinical Trial Research Site, Issue No. 02); **FOR-OGITT-041** (Clinical Trial Suspension Request, Edition No. 02); **FOR-OGITT-042** (Clinical Trial Cancellation Request, Edition No. 043); Clinical Trial, Edition No. 02); **FOR-OGITT-043** (Clinical Trial Title Change Request, Edition No. 02); **FOR-OGITT-044** (Request for Authorization of Clinical Trial Amendment Report, Edition No. 02); **FOR-OGITT-025** (Application for Accreditation of the Institutional Research Ethics Committee, Edition No. 03); **FOR-OGITT-027** (Verifier of Compliance with the Accreditation Standards of the Institutional Research Ethics Committee – CIEI, Edition No. 01); **FOR-OGITT-028** (Clinical Trial Authorization Application, Edition No. 03); **FOR-OGITT-033** (List of Products and Supplies to be Imported in the Clinical Trial, Edition No. 03b); **FOR-OGITT-046** (Report of Serious Adverse Events, Issue No. 02); **FOR-OGITT-047** (Pregnant Woman and Newborn Reporting in Clinical Trials, Issue No. 01); **FOR-OGITT-048** (Summary of the Annual Product Safety Report in

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Research, Edition No. 01); **FOR-OGITT-049** (Clinical Trial Inspection Form, Edition No. 02); **FOR-OGITT-053** (Notification of Deviations to the Protocol, Edition No. 01); **FOR-OGITT-054** (Progress Report of the Protocol) Clinical Trial, Edition No. 01); **FOR-OGITT-055** (Final Report of the Research Center, Edition No. 01); **FOR-OGITT-056** (National Final Report, Edition No. 01); **FOR-OGITT-057** (International Final Report, Edition No. 01); **FOR-OGITT-058** (Clinical Trial Results Report to be Published in REPEC, Edition No. 01); **FOR-OGITT-059** (Other Relevant Notifications, Edition No. 01); **FOR-OGITT-060** (Affidavit of Compliance with the Obligations and Requirements Established in the Clinical Trials Regulations – Principal Investigator, Edition No. N° 01); **FOR-OGITT-065** (Confidentiality Declaration of the National Institute of Health Research Team, under any employment relationship, and of those responsible for collaborating institutions, who are in charge of planning and executing a research project, Edition N° 01); and, **FOR-OGITT-066** (Virtual Trial Supervision).
Clinicians, Edition No. 01); which will be renamed FOR-DIIS;

That, according to the information provided, it is concluded that it is necessary to update each of these current formats, since this renewal not only responds to a need for regulatory adaptation, but also has a significant impact on the optimization and improvement of the registration of information related to the execution of clinical trials in the country;

That, based on the above, the new FOR-DIIS forms should be approved. They are designed to be more intuitive and efficient, allowing users to submit their applications more quickly and accurately, benefiting all institutions involved and contributing to the advancement of science and research.

With the approval of the Deputy Director II, Subdirectorate of Clinical Trials of the Directorate of Health Research and Innovation of the National Institute of Health;

In accordance with the provisions of Law No. 26842, the General Health Law; the Clinical Trials Regulations, approved by Supreme Decree No. 021-2017-SA; and the Consolidated Text of Law No. 27444, the General Administrative Procedure Law, approved by Supreme Decree No. 004-2019-JUS; and in exercise of the powers established in section m) of article 80 of the Integrated Text of the Regulations on the Organization and Functions of the National Institute of Health, approved by Executive Presidential Resolution No. 006-2023-PE/INS;

IT IS RESOLVED:

Article 1.- APPROVE the thirty-seven (37) FOR-DIIS formats that are part of this Directorial Resolution in the attached annex, which are related to the administrative procedures for clinical trials.

Article 2°.- LEAVE WITHOUT EFFECT the following Resolutions:

- **Directorial Resolution No. 393-2021-OGITT/INS,** which approved FOR-OGITT-020 (Sponsor Registration, Edition No. 02)
- **Directorial Resolution No. 586-2017-OGITT-OPE/INS,** which approved FOR-OGITT-021 (Application for Contract Research Organization Registry, Edition No. 01); and, FOR-OGITT-023 (Declaration Jury of Compliance with the Minimum CI Requirements, Edition No. 01)
- **Directorial Resolution No. 423-2019-OGITT/INS,** which approved FOR-OGITT-022 (Request for Registration of the Research Center, Edition No. 02); FOR-OGITT-026 (Affidavit of Compliance with the

Accreditation Standards of the Institutional Research Ethics Committee – CIEI, Edition No. 02); FOR-OGITT-029 (Sponsor's Affidavit of Financial Funding, Edition No. 03);
FOR-OGITT-063 (Affidavit of Absence of Financial Conflict of Interest, Edition No. 01); FOR-OGITT-064 (Affidavit of Conditioning of the Research Center, Edition No. 01); FOR-OGITT-031 (Research Team Curriculum Vitae, Issue No. 02); FOR-OGITT-032 (Budget)
Detailed National Total of the Clinical Trial, Edition No. 02); FOR-OGITT-036 (Request for Extension of the

• Number of Research Sites, Edition No. 02); FOR-OGITT-037 (Request for Extension of Clinical Trial Time, Edition No. 02); FOR-OGITT-038 (Request for Change of Principal Investigator, Edition No. 02); FOR-OGITT-039 (Request for Change of Sponsor or Contract Research Organization, Edition No. 02); FOR-OGITT-040 (Request for Closure of a Research Site for a Clinical Trial, Edition No. 02); FOR-OGITT-041 (Request for Suspension of a Clinical Trial, Edition No. 02); FOR-OGITT-042 (Request for Cancellation of a Clinical Trial, Edition No. 02); FOR-OGITT-043 (Clinical Trial Title Change Request, Issue No. 02); and FOR-OGITT-044 (Request for Authorization of Clinical Trial Amendment Report, Issue No. 02).

- **Directorial Resolution No. 361-2021-OGITT/INS,** which approved FOR-OGITT-025 (Request for Accreditation of the Institutional Committee on Research Ethics, Edition No. 03).
- **Directorial Resolution No. 037-2020-OGITT/INS,** which approved FOR-OGITT-027 (Verifier of Compliance with the Accreditation Standards of the Institutional Research Ethics Committee – CIEI, Edition No. 01).

- **Directorial Resolution No. 302-2021-OGITT/INS,** which approved FOR-OGITT-028 (Authorization Request) from the Clinical Trial, Edition No. 03).
- **Directorial Resolution No. 303-2021-OGITT/INS,** which approved FOR-OGITT-033 (List of Products and Supplies to be Imported in the Clinical Trial, Edition No. 03).
- **Directorial Resolution No. 218-2018-OGITT-OPE/INS,** which approved FOR-OGITT-046 (Report of Serious Adverse Events, Edition No. 02).
- **Directorial Resolution No. 588-2017-OGITT-OPE/INS,** which approved FOR-OGITT-047 (Notification of Pregnant Women and Newborns in Clinical Trials, Edition No. 01); and FOR-OGITT-048 (Summary of the Annual Investigational Product Safety Report, Edition No. 01).
- **Directorial Resolution No. 099-2022-OGITT/INS,** which approved FOR-OGITT-049 (Clinical Trial Inspection Form, Edition No. 02).
- **Directorial Resolution No. 585-2017-OGITT-OPE/INS** approved FOR-OGITT-053 (Notification of Protocol Deviations, Edition No. 01); FOR-OGITT-054 (Clinical Trial Progress Report, Edition No. 01); FOR-OGITT-056 (National Final Report, Edition No. 01); FOR-OGITT-057 (International Final Report, Edition No. 01); FOR-OGITT-058 (Clinical Trial Results Report to be published in the REPEC, Edition No. 01); and FOR-OGITT-059 (Other Relevant Notifications, Edition No. 01).
- **Directorial Resolution No. 586-2017-OGITT-OPE/INS,** which approved FOR-OGITT-055 (Final Report of the Research Center, Edition No. 01).
- **Directorial Resolution No. 688-2017-OGITT-OPE/INS,** which approved FOR-OGITT-060 (Affidavit of Compliance with the Obligations and Requirements established in the Clinical Trials Regulations – Principal Investigator, Issue No. 01).
- **Directorial Resolution No. 225-2021-OGITT/INS,** which approved FOR-OGITT-065 (Confidentiality Declaration of the Research Team of the National Institute of Health, under any employment relationship and of those responsible for collaborating institutions, who are in charge of the planning and execution of a research project, Edition No. 01).

- **Directorial Resolution No. 305-2021-OGITT/INS,** which approved FOR-OGITT-066 (Virtual Supervision of Clinical Trials, Edition No. 01); these will now be known as FOR-DIIS.

Article 3.- ORDER the person responsible for Information Technology at DIIS to update the corresponding information in the Peruvian Registry of Clinical Trials – REPEC, in accordance with the provisions of the preceding articles.

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Article 4.- NOTIFY this Resolution to the Office of Information and Communications Technologies - OTIC, so that within the framework of its institutional powers, it proceeds with the corresponding publication on the institutional portal of the National Institute of Health.

Register and communicate

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Dr. Leda Yamilee Hurtado Roca,
Director
of Health Research and Innovation, National Institute of Health

ANNEX 1

LIST OF FORMS FOR CLINICAL TRIAL PROCEDURES

No.	Procedure	Form
1	Application for Sponsor Registration	FOR-DIIS-020
2	Application for Registration of Organization Contract Research	FOR-DIIS-021
3	Application for Registration of the Center of Investigation	FOR-DIIS-022
4	Affidavit of Compliance with the Minimum Requirements of the CI	FOR-DIIS-023
5	Request for Accreditation of the Committee of Institutional Ethics in Research	FOR-DIIS-025
6	Affidavit of compliance with CIEI accreditation standards	FOR-DIIS-026
7	Verifier of compliance with the Committee's accreditation standards Institutional Ethics in Research – CIEI	FOR-DIIS-027
8	Application for Trial Authorization Clinical	FOR-DIIS-028
9	Affidavit from the sponsor stating that he has a financial fund	FOR-DIIS-029
10	Curriculum Vitae of the Team Investigation	FOR-DIIS-031
11	Detailed National Total Budget of the Clinical Trial	FOR-DIIS-032
12	Request for Extension or Modification of the List of Supplies	FOR-DIIS-033
13	List of Products and Supplies to Import into the Clinical Trial - Annex	FOR-DIIS-033
14	Request for Extension of the Number of Research Centers	FOR-DIIS-036
15	Request for Extension of Time Conducting the Clinical Trial	FOR-DIIS-037
16	Request for Change of Investigator Major	FOR-DIIS-038
17	Request for Change of Sponsor or Contract Research Organization	FOR-DIIS-039
18	Request for Closure of a Center Research for a Clinical Trial	FOR-DIIS-040
19	Request for Suspension of the Clinical Trial	FOR-DIIS-041
20	Trial Cancellation Request Clinical	FOR-DIIS-042
21	Request for Change of Essay Title Clinical	FOR-DIIS-043
22	Request for Authorization of Report Clinical Trial Amendment	FOR-DIIS-044
23	Serious Adverse Event Report	FOR-DIIS-046

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24	Notification of the Pregnant Woman and the Newborn in Clinical Trials	FOR-DIIS-047
25	Summary of the Annual Investigational Product Safety Report	FOR-DIIS-048
26	Clinical Trial Inspection Form	FOR-DIIS-049
27	Inspection Report	FOR-DIIS-050
28	Notification of Deviations to the Protocol	FOR-DIIS-053
29	Clinical Trial Progress Report	FOR-DIIS-054
30	Final Report of the Research Center	FOR-DIIS-055
31	National Final Report	FOR-DIIS-056
32	International Final Report	FOR-DIIS-057
33	Clinical Trial Results Report to be published in REPEC	FOR-DIIS-058
34	Other relevant notifications	FOR-DIIS-059
35	Affidavit of Compliance with the Obligations and Requirements established in the Clinical Trials Regulation – Principal Investigator	FOR-DIIS-060
36	Affidavit of Absence of Financial Conflict of Interest	FOR-DIIS-063
37	Affidavit of the Conditioning of the Research Center	FOR-DIIS-064
38	Confidentiality Statement of the Research Team of the National Institute of Health, under any employment relationship and of those responsible for collaborating institutions, who are in charge of planning and executing a research project	FOR-DIIS-065