Having seen, file No. 17-060743-001 containing Report No. 026-2017-ESC-OARH-OGGRH/MINSA dated July 7, 2017, from the General Office of
Human resources management;

CONSIDERING:

That, Law No. 30057, Civil Service Law, published in the official newspaper El Peruano on July 4, 2013, is intended for public entities of the State to achieve higher levels of effectiveness and efficiency, and effectively provide quality services to through a better Civil Service, as well as promoting the development of the people who comprise it;

That, the General Regulations of Law No. 30057, Law of the Civil Service, approved by Supreme Decree No. 040-2014-PCM, defines for the Administrative Management System Human Resources, a Type A public entity, as an organization that has legal status under public law, whose activities are carried out by virtue of administrative powers and, therefore, are subject to the common rules of public law, a condition that is met by the Ministry of Health; and is considered a public entity

Type B to those deconcentrated bodies, projects, programs or executing units in accordance with Law No. 28411 of a Type A public entity that, in accordance with its operations manual or equivalent document, comply with having the authority to hire, sanction and dismiss, have a human resources office or the one that acts in its place, an owner, understood as the highest administrative authority and/or senior management or the one that acts in its place, and have a resolution from the head of the public entity to which it belongs defining it as Type B Entity;

That, with Supreme Decree No. 008-2017-SA, modified by Supreme Decree No. 011-2017-SA, the Regulation of Organization and Functions of the Ministry of Health is approved, incorporating into its organizational structure the Directorates of Integrated Health Networks.

Health;
That, in accordance with the current Organization and Function Regulations, the Directorates of Integrated Health Networks are deconcentrated bodies of the Ministry of Health.
Health, which depend on and exercise by deconcentration the functions of the General Directorate of Operations in
Health, in the area of Metropolitan Lima;
That, through Ministerial Resolution No. 450-2017/MINSA, the Guidelines for the preparation and approval of the Operations Manuals of the decentralized bodies of the Ministry of Health are approved:

Directorates of Integrated Health Networks;
That, through Ministerial Resolution No. 467-2017/MINSA approved the Operations Manual of the Directorates of Integrated Health Networks;
That, the Operations Manual of the Directorates of Integrated Health Networks, establishes in its organic structure a General Directorate, as the highest level body, which directs and supervises the operation of the organization; Likewise, among the functions of the

Administrative Management, is responsible for managing and administering the human resources of the bodies and organic units of the entity, within the scope of its competence;

That, according to the seen document, the Addresses of Integrated Health Networks meet the criteria a) and b) established by literal a) of article IV of the General Regulations of Law No. 30057,
Civil Service Law to be defined by the Ministry of Health as Type B entities for the purposes of the System
Administrative of Human Resources Management, being necessary the issuance of the resolution act that formalizes it;
With the approval of the General Director of the General Office of Human Resources Management, the General Director of the General Planning Office,
Budget and Modernization, of the General Director of the General Legal Advice Office, the
Secretary General, and the Vice Minister of Benefits and Health Insurance, and;
In accordance with the provisions of the Legislative Decree No. 1161, Law of Organization and Functions of the Ministry of Health and the Regulation of Organization Functions of the
Ministry of Health, approved by Supreme Decree No. 008-2017-SA and its amendment; and Law No. 30057, Service Law Civil and its General Regulations, approved by Supreme Decree Nº 040-2014-PCM;

IT IS RESOLVED:

Article 1.- Define the following deconcentrated bodies as Type B public entities:

a) Directorate of Integrated Health Networks Lima Norte
b) Directorate of Integrated Health Networks Lima center
c) Directorate of Integrated Health Networks Lima South
d) Directorate of Integrated Health Networks East Lima

Article 2.- Instruct the General Office of Human Resources Management to send a certified copy of this Ministerial Resolution to the National Civil Service Authority – SERVIR and to the deconcentrated bodies referred to in the preceding article.

Article 3.- Instruct the Transparency and Anti-Corruption Office of the General Secretariat to publish this Ministerial Resolution on the Institutional Portal of the Ministry of Health.

Register, communicate and publish.

PATRICIA J. GARCÍA FUNEGRA
Minister of Health

1542989-1

ERRATA

SUPREME DECREE
N° 021-2017-SA

Clinical Trials Regulations

Through Official Letter No. 891-2017-DP/SCM, the Secretariat of the Council of Ministers requests the publication of the Errata of the Clinical Trials Regulation, approved by Supreme Decree No. 021-2017-SA, published in the June 30 edition. of 2017.

- In the Clinical Trials Regulations

In section 16 of section 2.1 of article 2;

DICE:

"16. **Serious adverse event.-** Any adverse event that causes death, threatens the life of the research subject, makes hospitalization or its prolongation necessary, produces permanent or significant disability or disability, or gives rise to a congenital anomaly or malformation. For the purposes of notification, those events that, from a medical point of view, may endanger the research subject or require intervention to prevent one of the results initially indicated in this definition, will also be treated as serious."

SHOULD SAY:

"16. **Serious adverse event.-** Any adverse event that causes death, threatens the life of the research subject, makes hospitalization or its prolongation necessary, produces permanent or significant disability or incapacity, or gives rise to a congenital anomaly or malformation. For the purposes of their notification, those events that, from a medical point of view, may endanger the research subject or require intervention to prevent one of the results initially indicated in this definition, will also be treated as serious.

In section 41 of section 2.1 of article 2;

DICE:

"41. **Serious adverse reaction.-** It is any adverse reaction that results in death, is potentially fatal,

requires hospitalization or prolongation of hospitalization, produces permanent or significant disability or disability, causes a congenital anomaly or malformation. For the purposes of notification, those events that, from a medical point of view, may endanger the research subject or require intervention to prevent one of the results initially indicated in this definition will also be treated as serious."

SHOULD SAY:

"41. **Serious adverse reaction.-** It is any adverse reaction that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, produces permanent or significant disability or incapacity, causes a congenital anomaly or malformation. For the purposes of notification, events that, from a medical point of view, may endanger the research subject or require intervention to prevent one of the results initially indicated in this definition will also be treated as serious.

In article 19;

DICE:

"The conduct of clinical trials in those who do not
are in a position to give their informed consent and that they have not given it prior to the beginning of their disability, requires in addition to the provisions of the
Title II of this Regulation:

(...)"

SHOULD SAY:

"The conduct of clinical trials in those who do not
are in a position to give informed consent and have not given it prior to the onset of their disability, requires in addition to the provisions of the

Title II of this Regulation:

(…)".

In literal n) of article 40;

DICE:

"n) Notify critical or very serious and major or serious deviations from the clinical trial protocol within a maximum period of fifteen (15) calendar days from when the sponsor or OIC becomes aware of them."

SHOULD SAY:

"n) Notify critical or very serious and major or serious deviations from the clinical trial protocol within a maximum period of seven (7) calendar days from when the sponsor or OIC becomes aware of them."

In literal (b) of Article 105;

DICE:

b) The final national report, within sixty (60) calendar days following the date of presentation of the final report of the last research center. In the case of clinical trials carried out only in Peru, the presentation of the report will take place within a maximum period of six (6) months after the end of the clinical trial. The content of the report must follow the format established in the Clinical Trial Procedures Manual. The OGITT will send the ANM a copy of the national final report of clinical trials carried out only in Peru within thirty (30) business days following its receipt.

SHOULD SAY:

"b) The final national report, within sixty (60) calendar days following the date of presentation of the final report of the last research center. In the case of clinical trials carried out only in Peru, the presentation of the results will take place within a maximum period of six (6) months after the end of the clinical trial. The content of the report must follow the format established in the Clinical Trial Procedures Manual. The OGITT will send the ANM a copy of the national final report of clinical trials carried out only in Peru within thirty (30) business days following its receipt."

In literal (h) of Article 108;

DICE:

"h) Notify the OGITT of the INS, the CIEI and the principal investigators of any finding that could adversely affect the safety of the research subjects, have an impact on the conduct of the study or alter the benefit/risk balance. A report will be prepared independently, without prejudice to the periodicity indicated in Chapter II of this Title and sent to the INS and the corresponding CIEI within a maximum period of seven (7) calendar days."

SHOULD SAY:

"h) Notify the OGITT of the INS, the CIEI and the main investigators of any finding that affects or could adversely affect the safety of the research subjects, has or could have an impact on the conduct of the study or alters or could alter the benefit/risk balance. A report will be prepared independently, without prejudice to the periodicity indicated in Chapter II of this Title and sent to the INS and the corresponding CIEI within a maximum period of seven (7) calendar days."

1542992-1

TRANSPORTATION AND COMMUNICATIONS

They approve total area appraisal values of properties affected by rights of way and the execution of infrastructure works, as well as the corresponding payment

MINISTERIAL RESOLUTION
N° 595-2017 MTC/01.02

Lima, July 7, 2017

SEEN: Elevation Note No. 175-2017-MTC/20 dated April 10, 2017, of the Special Project of
National Transportation Infrastructure – PROVIAS
NATIONAL; and,

CONSIDERING:

That, the Fifth Final Complementary Provision of Law No. 30025, Law that Facilitates the Acquisition,
Expropriation and Possession of Real Estate for Infrastructure Works and Declaration of Public Necessity
Acquisition or Expropriation of Real Estate affected for the Execution of various Infrastructure Works, among others, declares the execution of the Work of public necessity: Road Network No. 6: Section: Pucusana Bridge - Cerro
Azul - Ica, of the South Pan-American Highway and authorizes the expropriation of real estate that is necessary for such purpose;

That, Legislative Decree No. 1192, Decree
Legislative that approves the Acquisition Framework Law and Expropriation of Real Estate, Transfer of Real Estate Property of the State, Release of Interferences and dictates other measures for the Execution of Construction Works.
Infrastructure and its amendments (hereinafter, the Law), establishes the legal regime applicable to the processes of