

1. OBJECTIVE

To guarantee the handling, treatment and confidentiality of the information provided in the monitoring of the investigation and claims related to personal and sensitive data of COLTRIALS SAS collaborators, customers and suppliers, holders of such information, collected by COLTRIALS within the ordinary course of business and in the development of its corporate purpose.

2. SCOPE

This policy applies to personal information obtained by COLTRIALS in the development of research activities, monitoring, in the different phases of clinical studies in the Research centers and in work, commercial and academic activities.

3. DEFINITIONS

Authorization: prior, express and informed consent of the holder to carry out the processing of personal data.

Database: organized set of personal data that is to processing.

Personal data: any information linked or that can be associated to one or several determined or determinable natural persons.

Privacy notice: verbal or written communication generated by the responsible party, addressed to the Data Subject for the processing of his/her personal data, by means of which he/she is informed about the existence of the information processing policies that will be applicable, the way to access them and the purposes of the processing that is intended to be given to the personal data.

Public data: data that is not semi-private, private or sensitive. Public data includes, among others, data relating to the marital status of individuals, their profession or trade, and their status as merchants or public servants. By their nature, public data may be contained, among others, in public records, public documents, official gazettes and bulletins and duly executed court judgments that are not subject to confidentiality.

Sensitive data: sensitive data are understood as those that affect the privacy of the holder or whose improper use may generate discrimination, such as those that reveal racial or ethnic origin, political orientation, religious or philosophical convictions, membership in trade unions, social organizations, human rights or that promote the interests of any political party or that guarantee the rights and guarantees of opposition political parties, as well as data related to health, sex life, and biometric data.

Data processor: natural or legal person, public or private, that by itself or in association with others, carries out the processing of personal data on behalf of the data controller.

Data controller: natural or legal person, public or private, who alone or in association with others, decides on the database and/or the processing of data.

Data subject: for the purposes of this Policy, personal data subjects shall be understood as natural or legal persons, among them: users of health services, research subjects, suppliers, clients, benefactors, students, health professionals and collaborators in general.

Processing: any operation or set of operations on personal data, such as collection, storage, use, circulation or deletion.

Transfer: the transfer of data takes place when the person responsible and/or in charge of the processing of personal data, located in Colombia, sends the information or personal data to a recipient, which in turn is the Data Controller and is located inside or outside the country.

Transmission: processing of personal data that involves the communication of such data within or outside the Colombian territory when its purpose is to carry out a medical treatment on behalf of the responsible party.

4. STATEMENT AND GUIDELINES

COLTRIALS ensures the confidentiality and proper handling of the information obtained, recorded, used, transmitted and updated by prior, express and voluntary authorization of the owner of the information. The above is developed in strict compliance with the Statutory Law 1581 of 2012 and its Regulatory Decree 1377 of 2013. "COLTRIALS SAS, in compliance with law 1581 of 2012, Regulatory Decree 1377 of 2013 and our personal data protection policy, informs you that the personal data you provide under the procedures that you forward with the Contract Research Organization (CRO), will be treated through the use and maintenance of measures that ensure technical and physical security in order to prevent unauthorized third parties from accessing them."

4.1. Authorization

COLTRIALS requires the prior informed and express authorization of the Data Subject, which will be obtained by written means, either physical or electronic, in such a way that it may be subject to subsequent consultation.

When requesting information to the Holder, the purpose for which personal data is collected, the treatment to which personal data may be subjected, their rights and the means by which they can exercise them and the power to authorize or not the treatment in case of sensitive data must be clearly informed.

Authorization of the Data Subject is not required when it is about:

- Responding to a court order or when requested by a public or administrative entity in the exercise of its legal functions.
- Personal data of a public nature.

4.2. Data of Minors

COLTRIALS does not handle information about minors.

4.3 Rights of the Holder

The Holder shall have the right to know, rectify and update their personal data, request proof of authorization except in exceptional cases provided by law, be informed about the use given to their personal data, submit queries and file complaints, request revocation to COLTRIALS for non-compliance with the regulations and access to personal data that have been processed without their authorization.

4.4. Duties of the Holder

The Holder must ensure the accuracy of the information provided to COLTRIALS and update it in a timely manner. In case of falsehood in the information provided, COLTRIALS disclaims any liability.

4.5. Responsible for the processing of personal data.

The identification data of the data controller are:

- Name: COLTRIALS SAS
- Head office address: Cra 19 calle 32 norte esquina parte baja Armenia, Quindío, Colombia
- Telephone: 57- 3104237890
- E-mail: contacto@coltrials.com
- Tax Identification Number in Colombia: Nit 901.503.032-3
- Office hours: main office: Monday to Friday from 7:00 am to 5:00 pm.
- **Service channels:**
- In person: you can approach COLTRIALS at the main office.
- Virtual: through the web page <http://www.coltrials.com>
- Telephonic: Through the line 57-3104237890

4.6. Duties of the person responsible for the processing of personal data

The controller undertakes to proceed within the framework of the regulatory guidelines to ensure to the extent that it is entitled to, the exercise of the rights of the Data Subjects with respect to their personal data, obtained in the course of COLTRIALS' activities.

4.7. Source and type of information recorded

In order to facilitate contact with the Registrants, we keep personal data or any linked information that can be associated with the person. COLTRIALS obtains information from the following sources:

- In the procedures of commercial activities
- In the development of educational activities

- In the exercise of labor procedures

Personal information collected may include, but is not limited to:

- Name, addresses and telephone numbers
- Date and place of birth, as well as your sex and gender
- E-mail addresses
- Information necessary to facilitate contact or other services, including family or employment information
- Identity card number, passport number, nationality and country of residence
- Identification, representation and existence in case of juridical persons
- Use of services.
- Personal information provided through surveys or other research methods.
- Personal information provided to the person in charge of Customer Service.

4.8. Use of information

COLTRIALS uses personal information to contact the Holders in order to provide them with information about monitoring services; dissemination of scientific information and technological updating in COLTRIALS; presentation of agreements to provide our services with different entities. In addition to using it to process, confirm and comply with the purpose of operation of COLTRIALS or any other service that the Holder requests, COLTRIALS may use this information for administrative and analytical purposes, such as database management, billing, accounting and auditing, business relationship, processing and verification of means of payment, correspondence related to Customer Service, and for the operation of promotional programs that may be implemented. COLTRIALS does not sell the information of its users or share personal data without authorization of the Holder.

COLTRIALS also uses data Holders information to identify, develop and publicize services that we believe are valuable to our customers and the general public, and may communicate via email, text message or physical mail. Occasionally, they may receive information about new services and expansion of locations among others.

4.9. Transfer and transmission of personal data

COLTRIALS complies with the provisions of Article 26 of the Statutory Law 1581 of 2012 and refrains from transferring personal data of the Data Controllers to other countries that do not have equal or higher standards of protection. However, the following exceptions shall apply. This prohibition shall not apply in the following cases:

- Information with respect to which the Data Subject has given express and unequivocal authorization for the transfer.
- Bank or stock exchange transfers, in accordance with the applicable legislation.

- Transfers agreed under international treaties to which the Republic of Colombia is a party, based on the principle of reciprocity.

- Transfers necessary for the execution of a contract between the Data Subject and the Data Controller, or for the execution of pre-contractual measures, as long as the Data Subject's authorization is obtained.

4.10. Refusal to process information

- If the user considers that COLTRIALS should not use or share his/her personal information for the purposes stated herein, or does not want to receive informative materials related to COLTRIALS, he/she should write to contacto@coltrials.com expressing his/her refusal or write to the COLTRIALS Administrative Manager at Cra 19 calle 32 norte esquina parte baja Armenia, Quindío, Colombia.

4.11 Procedures for the exercise of the policy

Guarantee the right of access to data. COLTRIALS guarantees the right of access to personal data, once the identity of the owner and/or representative has been verified, making the respective personal data available to him/her. For this purpose, COLTRIALS guarantees the establishment of simple electronic and/or face-to-face means and mechanisms with permanent availability, which allow the direct access of the holder to the personal data.

Facilitate consultations. The holders or their representatives may consult the personal information of the holder that is contained in any database, so COLTRIALS as responsible for the treatment, will provide them with all the information contained in the individual record or that is linked to the identification of the holder.

COLTRIALS guarantees the means of communication established for consultation and claims, which will be the same used for the reception and attention of requests, complaints, claims, suggestions, complaints and / or compliments administered by the Administrative Direction of COLTRIALS.

- **Consultations:** the consultations made by the Holder or its assignees will be answered by COLTRIALS within a term of (10) working days from the receipt of the request, extendable for a maximum term of (5) working days.

- **Claims:** the Holder or his assignees who consider that the information contained in the COLTRIALS database should be corrected, updated or deleted, or when they notice the alleged breach of any of the duties contained in the law or in this policy, may file a claim with the Administrative Department of COLTRIALS, which will be processed under the following rules:

The claim shall be formulated by means of a request addressed to the Administrative Direction of COLTRIALS at Cra 19 calle 32 norte esquina parte baja Armenia, Quindío, Colombia or by e-mail to

contacto@coltrials.com with the identification of the Holder, the description of the facts that give rise to the claim, the address of residence, and accompanying the documents that are to be asserted.

The maximum term to address the claim will be fifteen (15) working days from the day following the date of receipt, which may be extended for a maximum term of eight (8) working days.

If the claim is incomplete, the interested party will be required within five (5) business days following receipt of the claim to correct the faults. After two (2) months from the date of the requirement, without the applicant submitting the required information, it will be understood that the claim has been abandoned.

Before going to the entity responsible for monitoring compliance with the rules on protection of personal data, the Holder must initially process your claim with COLTRIALS through the means and channels provided for that purpose.

- **Update and rectify the data.** COLTRIALS as responsible for the processing of data, will rectify and update at the request of the holder, any information that it turns out to be incomplete or inaccurate. For these purposes, the representative holder, indicate the updates and rectifications to which they give rise, with documentation to support your request.
- COLTRIALS will enable the existing means in the organization available to ensure this right, which will be the same used for the receipt and attention of requests, complaints, claims, suggestions, complaints and / or compliments administered by COLTRIALS.

4.12. Confidentiality and Information Security Policies

For COLTRIALS, confidentiality is a fundamental ethical principle immersed in the performance of its organizational processes. Thus, it is responsible for guaranteeing the protection of information against misuse or unjustified access and ensuring its proper handling only by authorized persons. It is for this reason that there is a Confidentiality Policy established within the organization that seeks to direct its actions under this principle, through the mechanisms defined for each type of information within the institution, including the protection and proper use of Personal Data recorded from its employees, suppliers, customers, among others.

Additionally, COLTRIALS provides the necessary resources for the training and education required to comply with this policy.

4.13. Compliance with the Personal Data Protection Law

COLTRIALS ensures the protection of the personal data of the Data Controllers by adopting the necessary technical, human and administrative measures. Likewise, it will prevent adulteration, loss or unauthorized use.

4.14. Modifications and validity

COLTRIALS reserves the right to modify this Policy at any time and will notify the Holders of any changes by updating the content on the website and in the documents that include it.

5. LEGAL FRAMEWORK

- Law 1581 of 2012
- Regulatory Decree 1377 of 2013

6. ANNEXES

Personal Data Protection Data Processing Authorization Form (Personal Data Protection Data Processing Authorization Form)