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Measure containing the provisions relating to the processing of special categories of data, pursuant to art. 21, paragraph 1 of Legislative Decree 10 August 2018, n. 101 [9124510]

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Measure containing the provisions relating to the processing of special categories of data, pursuant to art. 21, paragraph 1 of Legislative Decree 10 August 2018, n. 101
(Published in the Official Gazette General Series No. 176 of 29 July 2019)

Register of provisions
n. 146 of June 5, 2019

THE GUARANTEE FOR THE PROTECTION OF PERSONAL DATA

Today, with the participation of dr. Antonello Soro, president, of Dr. Augusta Iannini, vice-president, of Dr. Giovanna Bianchi Clerici and of Professor Licia Califano, members, and of Dr. Giuseppe Busia, general secretary;

GIVEN the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 concerning the protection of natural persons with regard to the processing of personal data, as well as the free circulation of such data and repealing Directive 95/46 / EC (hereinafter "Regulation");

CONSIDERING the Legislative Decree of June 30, 2003, n. 196 (Code regarding the protection of personal data, hereinafter the "Code") as amended by Legislative Decree 10 August 2018, n. 101 bearing "Provisions for the adaptation of the national legislation to the provisions of the regulation (EU) 2016/679";

GIVEN the general authorizations adopted pursuant to articles 26 and 40 of the Code;

CONSIDERED that the articles 26 and 40 of the Code have been repealed by art. 27, paragraph 1, lett. a), n. 2) of the aforementioned Legislative Decree no. 101/2018;

WHEREAS the art. 21 of Legislative Decree no. 101/2018, in implementation of the provisions of the Regulation, has delegated to the Guarantor the task of identifying, with its own general provision, the provisions contained in the general authorizations already adopted, relating to the treatment situations pursuant to arts. 6, par. 1, lett. c) and e), 9, par. 2, lett. b) and 4, as well as in Chapter IX, of the Regulation, which are compatible with the Community provisions and the decree that amended the Code, also providing for their updating where necessary;

CONSIDERED to implement the aforementioned art. 21 of Legislative Decree no. 101/2018 by means of this provision, which produces effects up to the adoption, for the pertinent parts, of the deontological rules and the guarantee measures referred to in art. 2-quater and 2-septies of the Code;

NOTING that the general authorization for the processing of judicial data by private individuals, economic public bodies and public subjects n. 7/2016, in light of the regulations applicable to the same data contained in the Regulation and the Code (Article 10 of the Regulation; 2-octies of the Code and Article 21 of Legislative Decree No. 101/2018), has ceased to have effect legal entities as of September 19, in accordance with paragraph 3 of the aforementioned provision;

CONSIDERED that from May 25, 2018 the expression "sensitive data" refers to the special categories of data referred to in the aforementioned art. 9 of the Regulation (Article 22, paragraph 2, of Legislative Decree No. 101/2018);

GIVEN the art. 9 of the Regulation, which identifies the conditions for the processing of personal data that reveal racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, as well as genetic data, biometric data intended to identify in unambiguously a natural person and data relating to health or sexual life or sexual

SEE ALSO (10)

Opinion on a draft Agreement between the Minister of Labor and Social Policies, the Regions and Autonomous Provinces of Trento and Bolzano and the local autonomies for the start of experimentation in the field of evaluation data bases and customized designs - 22 February 2018 [8145482]

Opinion on a draft regulation on the updating and integration of the types of sensitive and judicial data processed and the related transactions carried out by the Ministry of the Interior - 11 December 2014 [3708655]

Publication on an institutional website of identification data of physical persons receiving economic benefits from which it is possible to obtain information relating

to health status and the situation of economic and social hardship - 12 April 2018 [8576011]

JUDGMENT OF THE COURT - Lindqvist

Authorization No. 6/2014 Concerning Processing of Sensitive Data by Private Detectives

Renew general authorizations for sensitive and judicial data

Opinion on a draft regulation on the updating and integration of the types of sensitive and judicial data processed by the Ministry of the Interior and identified with the ministerial decree 21 June 2006, n. 244 - 11 December 2014 [3718295]

Newsletter of 22 December 2014 - Right to oblivion: first rulings of the Guarantor after Google's no

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Opinion on an agreement between INPS, Confindustria, CGIL, CISL and UIL and a related scheme for appointing the INPS as external data processor - December 18, 2014

orientation of the person (so-called "special categories of personal data", paragraph 1) and which allows Member States to introduce additional conditions, including limitations, with regard to the processing of genetic, biometric or health-related data (section 4);

NOTING that in any case the obligations provided for by law or regulation or by the EU legislation that establish prohibitions or more restrictive limits regarding the processing of personal data remain in place;

GIVEN the art. 2-decies, of the Code, according to which the data processed in violation of the relevant regulations concerning the processing of personal data cannot be used, except as provided by the art. 160-bis of the same Code;

CONSIDERED that, based on art. 21, paragraph 5, of Legislative Decree no. 101/2018, the violation of the provisions contained in this general provision are subject to the administrative sanction pursuant to art. 83, par. 5, of the Regulation;

GIVEN the **general provision of December 13, 2018, n. 497** with which the Guarantor has identified the provisions contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the Regulation and Legislative Decree no. 101/2018 for the adaptation of the Code;

CONSIDERING that with the same provision the Guarantor has resolved, as required by art. 21, paragraph 1, d. lgs. 101/2018, to launch a **public consultation** aimed at acquiring observations and proposals regarding the aforementioned provisions which ended after 60 days from the publication of the relative notice (GU n. 9 of 11 January 2019);

GIVEN the observations and proposals received by the Guarantor concerning the application implications of the aforementioned prescriptive provision by interested parties, trade associations and organizations representing the reference sectors;

CONSIDERED to make specific modifications and additions, in the light of the most significant and pertinent contributions sent by the participants to the consultation, also in order to make the indicated provisions more clear and precise as well as to harmonize them in the current regulatory context;

GIVEN the art. 170 of the Code as replaced by art. 15, paragraph 1, lett. e) of Legislative Decree no. 101/2018;

CONSIDERED the articles 21, paragraph 5, of the legislative decree n. 101/2018 and 83, par. 5 of the Regulation;

After considering the official records;

GIVEN the comments made by the general secretary pursuant to art. 15 of the Guarantor Regulation n. 1/2000;

Rapporteur Augusta Iannini;

EVERYTHING HAS GIVEN THE GUARANTEE

pursuant to art. 21, paragraph 1 of Legislative Decree 10 August 2018, n. 101, adopts this provision containing the provisions relating to the processing situations referred to in Articles 6, par. 1, lett. c) and e), 9, par. 2, lett. b) and 4, as well as in Chapter IX of the Regulation reported in Annex 1 making it an integral part of the same provision, and arranges for its publication in the Official Journal of the Italian Republic pursuant to art. 21, paragraph 2, of Legislative Decree no. 101/2018.

Rome, 5 June 2019

THE PRESIDENT
Soro

THE RELATOR
Iannini

THE SECRETARY GENERAL
Busia

Attachment n. 1

1. Requirements relating to the processing of special categories of data in labor relations (aut. Gen. No. 1/2016);
2. Requirements relating to the processing of special categories of data by associations, foundations, churches and religious associations or communities (aut. Gen. No. 3/2016);
3. Requirements relating to the processing of special categories of data by private investigators (aut. Gen. No. 6/2016);
4. Requirements relating to the processing of genetic data (aut. Gen. No. 8/2016);
5. Requirements relating to the processing of personal data carried out for scientific research purposes (aut. Gen. No. 9/2016).

1. Requirements relating to the processing of special categories of data in labor relations (aut. Gen. No. 1/2016)

The processing of personal data in the workplace, in the light of the regulatory framework outlined by Regulation (EU) 2016/679, is considered if carried out by both public and private employers (see art. 88 and 9, par. 2, lett. b), EU Regulation 2016/679); this, differently from the installation of the Code prior to the modifications of the legislative decree n. 101/2018.

1.1 Scope of application

This provision applies to all those who, for various reasons (data controller / controller), carry out processing for the purpose of establishing, managing and terminating the employment relationship, in particular:

- a) employment agencies and other subjects that, in compliance with the law, carry out, in the interests of third parties, intermediation activities, research and selection of personnel or support for professional relocation including accredited training institutions;

b) natural and legal persons, companies, even social bodies, organizations, associations and organizations that are part of an employment relationship or that use atypical, partial or temporary work, or that in any case confer a professional role on the figures indicated in the following point 1.2, letters c) and d);

c) joint bodies or bodies that manage labor observatories, as required by European Union legislation, laws, regulations or even collective agreements;

d) representative of workers for security, including territorial and site;

e) subjects who take care of the obligations regarding work, social security and social and fiscal assistance in the interest of other subjects who are part of an employment or self-employed relationship, pursuant to the law of 11 January 1979, n. 12, which governs the profession of labor consultant;

f) associations, organizations, federations or confederations representing categories of employers, for the sole purpose of pursuing specific and legitimate goals identified by the statutes of associations, organizations, federations or confederations representing employers' categories or collective agreements in the field of trade union assistance to employers;

g) a doctor who is competent in matters of health and safety at work, who works as a freelancer or as an employee of the employer or of affiliated facilities.

1.2 Interested parties to whom the data relate

This provision applies to the processing of special categories of personal data, usually acquired directly from the person concerned, related to:

a) candidates for the establishment of employment relationships, also in the case of curricula spontaneously transmitted by the interested parties for the purpose of establishing an employment relationship (Article 111-bis of the Code);

b) subordinate workers, even if they are part of an apprenticeship contract, training, temporary work, intermittent work, occasional work or practitioners for professional qualification, or workers in the context of a work administration contract, or in an internship relationship, or to associates also in partnership;

c) consultants and freelancers, agents, representatives and agents;

d) subjects that carry out collaborations organized by the client, or other self-employed workers in collaboration relationship, also in the form of ancillary work services, with the subjects indicated in the previous point 1.1 .;

e) natural persons who hold corporate offices or other positions in legal persons, institutions, associations and bodies indicated in the previous point 1.1 .;

f) third parties damaged in the performance of their work or professional activity;

g) third parties (family members or cohabitants of the subjects referred to in the previous letter b) and d) for the issue of benefits and permits.

1.3 Purpose of the processing

The processing of special categories of personal data is carried out only if necessary (art.9, par. 2 of EU Regulation 2016/679):

a) to fulfill or to demand the fulfillment of specific obligations or to perform specific tasks foreseen by European Union legislation, by laws, regulations or collective agreements, including company ones, pursuant to domestic law, in particular for the purposes of establishment, management and termination of the employment relationship (Article 88 of EU Regulation 2016/679), as well as the recognition of benefits or the provision of contributions, the application of legislation on social security and assistance, including supplementary, or on the subject occupational hygiene and safety, as well as tax and trade union matters;

b) even outside the cases referred to in letter a), in compliance with the law and for determined and legitimate purposes, for the purposes of keeping the accounts or paying salaries, checks, prizes, other emoluments, donations or ancillary benefits;

c) to pursue the purpose of safeguarding the life or physical safety of the worker or a third party;

d) to assert or defend a right, even by a third party, in a court of law, as well as in an administrative or arbitration and conciliation procedure, in the cases provided for by law, by European Union legislation, by regulations or by collective agreements, provided that the data are processed exclusively for these purposes and for the period strictly necessary for their pursuit; the processing of personal data for the purpose of protecting one's rights in court must refer to disputes in progress or to pre-litigation situations; remains without prejudice to the provisions of art. 60 of the Code;

e) to fulfill obligations deriving from insurance contracts aimed at covering the risks connected with the employer's liability in matters of occupational health and safety and occupational diseases or for damage caused to third parties in the performance of work or professional;

f) to guarantee equal employment opportunities;

g) to pursue specific and legitimate goals identified by the statutes of associations, organizations, federations or confederations representing employers' categories or collective agreements, concerning trade union assistance to employers.

1.4 Specific requirements relating to the different categories of data

1.4.1 Treatments carried out in the preliminary phase to recruitment

a) employment agencies and other subjects who, in compliance with the law, carry out, in their own interest or in the interest of third parties, intermediation activities, research and selection of personnel or support for professional relocation may process data suitable for disclosing the state of health and the racial and ethnic origin of candidates for the establishment of a working relationship or collaboration, only if their collection is justified by determined and legitimate purposes and is necessary to establish such relationship;

b) the processing carried out for the purpose of establishing the employment relationship, both through questionnaires also sent electronically on the basis of predefined models, and in the case in which the candidates provide data on their own initiative, in particular by sending resumes , must concern, within the limits established by the provisions referred to in art. 113 of the Code, the only information strictly pertinent and limited to what is necessary for these purposes, also taking into account the particular tasks and / or specificities of the professional profiles required;

c) if in the curricula sent by the candidates there are data that are not pertinent to the purpose pursued by the subjects referred to in letter a) or the employers who make the selection must refrain from using this information;

d) genetic data cannot be processed in order to establish the professional suitability of a candidate for employment, even with the consent of the interested party.

1.4.2 Treatments carried out during the employment relationship

a) the employer treats data that reveal religious or philosophical beliefs or membership in associations or organizations of a religious or philosophical nature only in the event of use of permits on religious holidays or for the provision of canteen services or, in the cases provided for by the law, for the exercise of conscientious objection;

b) the employer treats data that reveal political opinions or trade union membership, or the exercise of public functions and political offices, activities or union positions exclusively for the purposes of the use of permits or periods of leave recognized by the law or, possibly, by collective agreements, including company ones, as well as to allow the exercise of trade union rights including the processing of data relating to deductions for the payment of registration fees to associations or trade union organizations;

c) the employer, in the case of participation of employees in electoral operations as representatives of the list, in application of the principle of necessity, must not treat within the scope of the documentation to be presented for the purpose of recognition of legal benefits, data which disclose political opinions (for example, the document designating the list representative should not be required, as the certification of the seat chairman is sufficient for this purpose);

d) the employer cannot process genetic data in order to establish the professional suitability of an employee, even with the consent of the interested party.

1.5 Specific requirements relating to the methods of treatment

With reference to the methods of treatment, the following is represented:

a) the data must be collected, as a rule, from the interested party;

b) in all communications to the interested party that contain particular categories of data, forms of communication, including electronic forms, must be used with regard to the latter or his delegate, including through authorized personnel. In the event that the paper document is transmitted, this will have to be transmitted, as a rule, in a closed envelope, except for the need to acquire, even by signing for receipt, the proof of receipt of the document;

c) documents that contain particular categories of data, where they must be transmitted to other offices or functions of the same organizational structure due to their respective competences, must contain exclusively the information necessary for the performance of the function without attaching, if not strictly necessary, complete documentation or bring back excerpts within the text. To this end, documentation transmission methods must be selected and used to ensure that they are received and processed by only the competent offices or organizational structures and only authorized personnel;

d) when, for work organization reasons, and in the context of the preparation of service shifts, data relating to attendance and absence from the service are made available to subjects other than the interested party (for example, other colleagues) employer must not make explicit, even through acronyms or acronyms, the reasons for the absence from which it is possible to infer the knowability of particular categories of personal data (eg trade union permits or health data).

2. Requirements relating to the processing of special categories of data by associations, foundations, churches and religious associations or communities (aut. Gen. No. 3/2016)

2.1 Scope of application

The following provisions apply:

a) associations, including those not recognized, political parties and movements, associations and trade unions, employers' associations and trade associations, pension funds, welfare or voluntary organizations and, more generally, third sector organizations, as well as to the federations and confederations in which these subjects are brought together in conformity, where existing, with the statute, the memorandum of association or a collective contract;

b) foundations, committees and any other non-profit organization, consortium or organization, with or without legal personality, including non-profit organizations of social utility (Onlus);

c) to social cooperatives and mutual aid societies referred to, respectively, to the laws of 8 November 1991, n. 381 and 15 April 1886, n. 3818;

d) schools, limited to the processing of data revealing religious convictions and for operations strictly necessary for the application of articles 310 and 311 of the legislative decree 16th April 1994, n. 297 and of the art. 3 and 10 of the legislative decree 19 February 2004, n. 59;

e) to churches, associations or religious communities.

2.2 Data subjects to whom the data refer

The processing may relate to the specific details relating to:

a) to members, members and, if strictly necessary for the pursuit of the aims pursued, to their relatives and cohabitants;

b) to the members, supporters or subscribers, as well as to those who apply for admission or membership or who have regular contacts with associations and organizations, associations, foundations, churches and religious communities;

c) subjects who hold corporate or honorary positions;

d) beneficiaries, clients and users of the activities or services provided by the association or associations and organizations, foundations, churches and associations or religious communities, limited to subjects that can be identified on the basis of the statute or the deed of incorporation, where existing, or in any case to those in whose interest the persons mentioned in point 2.1. they can operate on the basis of a regulatory provision;

e) to students enrolled or who have applied for enrollment in the institutions referred to in point 2.1 lett. d) and, in the case of minors, their parents or the person exercising parental authority;

f) to the employees of the associates and members, limited to the data suitable to reveal the adhesion to trade unions, associations or organizations of a trade union nature and to the operations necessary to fulfill specific obligations deriving from collective agreements, including corporate ones.

2.3 Purpose of the processing

The processing of particular data may be carried out for the pursuit of specific and legitimate purposes identified by the law, the deed of incorporation, the statute or the collective contract, where existing, and in particular for the pursuit of cultural, religious, political, union aims, sporting or competitive non-professional type, education also with regard to freedom of choice in religious education, training, advocacy, environmental protection and works of artistic and historical interest, of safeguarding civil rights, of charity, social assistance or social-health care.

The processing of the aforementioned data may also take place to assert or defend a right also by a third party in a court of law, as well as in an administrative or arbitration and conciliation procedure in the cases provided for by the EU legislation, by laws, by regulations or collective agreements.

The same treatment can also be carried out for the exercise of the right of access to data and administrative documents, within the limits established by the laws and regulations on the subject, except for the provisions of art. 60 of the Code, as amended by Legislative Decree no. 101/2018.

For the aforementioned purposes, the aforementioned data processing may also concern the keeping of accounting records and records, lists, mailing lists and other documents necessary for the administrative management of associations and organizations, foundations, churches and associations or religious communities as well as for the fulfillment of tax obligations or for the dissemination of magazines, newsletters and the like.

If the subjects indicated in point 2.1 make use of legal entities or other profit-making bodies or freelancers to pursue the aforementioned purposes, or require them to supply goods, services or services, they may perform the processing of data in question.

The subjects referred to in the aforementioned point 2.1 can communicate to legal entities and for-profit organizations indicated above (if the latter qualify as holders of autonomous treatment) the only particular data strictly indispensable for the activities effectively supporting the aforementioned purposes, with particular reference to the generality of the interested parties and to address books, on the basis of a written document that precisely identifies the information communicated, the methods of subsequent use and the particular security measures adopted. The disclosure to be made to the interested parties must make this circumstance particularly evident and must bear the precise mention of the data controllers and the purposes they pursue.

2.4 Specific requirements

The personal data referring to the members / members can be communicated to the other members / members even in the absence of the consent of the interested parties, provided that the aforementioned communication is provided - within the private autonomy remitted to each entity - by the memorandum or by the articles of association for the pursuit of specific and legitimate purposes and that the methods of use of the data are made known to those concerned when the information is released pursuant to art. 13 of the Regulation (EU) 2016/679.

In any case, taking into account the respect of the principles of necessity, purpose and minimization and of any internal regulation within the entity, where exclusively personal profiles referring to the members / members are considered, forms of individualized consultation with the same must be used, taking all appropriate measures aimed at preventing the undue disclosure of personal data to subjects other than the recipient.

The communication of personal data relating to the members / members outside the organization and their dissemination can be carried out with the consent of the interested parties, after informing them about the type of recipients and the purposes of the transmission and provided that the data is strictly relevant to the purposes and purposes pursued.

Particular data can be communicated to the competent authorities for the purpose of prevention, detection or repression of crimes, with the observance of the rules governing the subject.

3. Requirements relating to the processing of special categories of data by private investigators (aut. Gen. No. 6/2016).

3.1 Scope of application

The present provisions are intended for natural and legal persons, institutions, bodies, associations and organizations that carry out an authorized private investigation activity with a prefectural license (Article 134 of Royal Decree 18 June 1931, No. 773, and subsequent amendments and additions).

3.2 Purpose of the processing

The processing of special categories of personal data referred to in Article 9, paragraph 1, of Regulation (EU) 2016/679 can only be carried out for the purpose of carrying out the task received from the parties referred to in point 3.1 and in particular:

a) to allow those who confer a specific assignment, to have their right ascertained, exercised or defended in a judicial context which, when it concerns genetic data relating to the health, sex life or sexual orientation of the person, must be of rank equal to that of the subject to whom the data refer, or consist of a right of the personality or another right or fundamental freedom;

b) on behalf of a lawyer in reference to a criminal proceeding, to search for and identify elements in favor of the relative client to be used solely for the exercise of the right of proof (Article 190 of the Criminal Procedure Code and Law 7 December 2000, No. 397).

3.3 Specific requirements

Private investigators cannot undertake investigations, research or other forms of data collection on their own initiative. These activities can be performed exclusively on the basis of a specific assignment given in writing, even by a lawyer, for the exclusive purposes referred to in point 3.2.

The act of appointment must specifically mention the right that is intended to be exercised in a judicial context, or the criminal procedure to which the investigation is connected, as well as the main elements of fact that justify the investigation and the reasonable time within which this must be concluded.

The interested party must be provided with the information referred to in articles 13 and 14 of Regulation (EU) 2016/679, except, in the event that personal data has not been obtained from the data subject, that this risks making it impossible or to seriously prejudice the achievement of the purposes of this treatment.

The defender or the person who conferred the assignment must be informed periodically of the progress of the investigation.

The private investigator must personally carry out the assignment received and cannot use other investigators not named by name at the time of the appointment, or subsequently at the bottom of it if this possibility has been provided for in the assignment.

Once the specific investigative activity has been completed, the processing must cease in all its forms, except for the immediate communication to the defender or to the person who conferred the assignment who can allow, also during the mandate, the eventual preservation temporary of strictly personal material of the subjects who took care of the activity carried out, for the sole purpose of the possible demonstration of the legality and correctness of their work. If the treatment has been contested, the defender or the person who conferred the assignment can also provide the investigator with the material necessary to prove the lawfulness and correctness of his work, for the time strictly necessary.

The mere inclination of the proceeding to which the investigation is connected, or the passage to other stages of judgment pending the formation of the *res judicata*, do not constitute, in themselves, a valid justification for the conservation of data by the private investigator .

The data can only be communicated to the person who has given the job.

The data can be communicated to another private investigator only if the latter has been indicated by name in the act of conferring the assignment, or subsequently at the bottom of it if this possibility has been envisaged in the assignment, and the communication is necessary for the performance of the tasks entrusted.

Genetic, biometric and health-related data can be communicated to the competent authorities only for the purpose of prevention, detection or repression of crimes, with compliance with the rules governing the subject.

Without prejudice to the provisions of art. 2-septies, paragraph 8, of the Code, data relating to sexual life or sexual orientation cannot be disclosed.

As far as the processing of genetic data is concerned, the provisions of the relevant provisions are still valid.

4. Requirements relating to the processing of genetic data (aut. Gen. No. 8/2016).

4.1 Definitions

For the purposes of this provision we mean:

- a) genetic data, the personal data relating to the genetic inherited or acquired characteristics of a natural person that provide unequivocal information on the physiology or health of said natural person, and that result in particular from the analysis of a biological sample of the natural person in question ;
- b) biological sample, each sample of biological material from which genetic data characteristic of an individual can be extracted;
- c) genetic test, a clinical analysis of a specific gene or its product or function or other parts of the DNA or of a chromosome, aimed at making a diagnosis or confirming a clinical suspicion in an affected individual (diagnostic test) , or to identify or exclude the presence of a mutation associated with a genetic disease that may develop in an unaffected individual (presymptomatic test) or, again, to assess the greater or lesser susceptibility of an individual to develop multifactorial diseases (predictive test or of susceptibility);
- d) pharmacogenetic test, the genetic test aimed at identifying specific variations in the DNA sequence capable of predicting the "individual" response to drugs in terms of efficacy and relative risk of adverse events;
- e) pharmacogenomic test, the genetic test aimed at the global study of the variations of the genome or its products related to the discovery of new drugs and to the further characterization of drugs authorized for trade;
- f) tests on individual variability, genetic tests that include: kinship tests aimed at defining family relationships; the ancestral test aimed at establishing a person's relations with an ancestor or a specific population or how much of his genome was inherited from ancestors belonging to a particular geographical area or ethnic group; the genetic identification test aimed at determining the probability with which a sample or trace of DNA recovered from an object or other material belongs to a specific person;
- g) genetic screening, the genetic test performed on defined populations or groups, including family analyzes aimed at identifying - through "cascade screening" - people potentially at risk of developing the genetic disease, in order to outline their common genetic characteristics or to identify affected individuals or carriers of genetic pathologies or other inherited characteristics early;
- h) genetic counseling, communication activities aimed at helping the individual or family affected by genetic pathology to understand the medical information that includes the diagnosis and the probable course of the disease, the forms of assistance available, the contribution of heredity to the occurrence of the disease, the risk of recurrence existing for oneself and for other family members and the opportunity to make them aware of them, as well as all the existing options in dealing with the risk of illness and the impact that this risk may have on procreative choices ; in the performance of genetic tests this advice also includes information on the meaning, limits, reliability and specificity of the test as well as the implications of the results; participate in this process,
- i) genetic information, activities aimed at providing information regarding the specific characteristics of genetic screening.

4.2 Specific requirements

The following precautions are taken for the safekeeping and security of genetic data and biological samples:

- a) access to the premises must take place in accordance with a documented procedure established by the data controller, which provides for the identification of the persons, previously authorized, who access for any reason after closing time. These checks can also be performed with electronic instruments. The use of biometric data with regard to the aforementioned physical access procedures is permitted, in compliance with the principles regarding the protection of personal data and the specific requirements of the treatment pursuant to art. 9 of the Regulation;
- b) the storage, use and transport of biological samples are implemented in ways that also guarantee their quality, integrity, availability and traceability;
- c) the transfer of genetic data, with electronic messaging systems including mail, is carried out with the following precautions: transmission of the data in the form of an attachment and not as a text included in the body of the message; data encryption taking care to disclose the encryption key to the recipient through communication channels different from those used for data transmission; use of protected communication channels, taking into account the state of the art of the technology used; protection of the attachment with appropriate methods to prevent the illegal or accidental acquisition of the transmitted data, such as a password for opening the file made known to the recipient through communication channels different from those used for data transmission.
- d) the consultation of genetic data processed by electronic means is allowed after the adoption of authentication systems based on the combined use of information known to the designated subjects and devices, even biometric, in their possession;
- e) genetic data and biological samples contained in lists, registers or databases, are treated with encryption or pseudonymisation techniques or other solutions which, given the volume of data and samples processed, make them temporarily unintelligible even to whom he is authorized to access it and allow to identify the interested parties only in case of need, so as to minimize the risk of accidental knowledge and unauthorized or unauthorized access. Where the lists, registers or databases are kept with electronic means and also contain data concerning the genealogy or health status of the persons concerned, the aforementioned techniques must also permit

4.3 Information to interested parties

Information to be provided to interested parties pursuant to articles 13 and 14 Regulation (EU) 2016/679 and also in accordance with articles 77 and 78 of the Code for the general practitioner and for the freely chosen pediatrician, also highlight:

- a) the results achievable also in relation to unexpected news that may be known due to the processing of genetic data;
- b) the faculty or not, for the interested party, to limit the scope of communication of genetic data and the transfer of biological samples, as well as the possible use of such data for further purposes.

After reaching the age of majority, information on the processing of personal data is also provided to the data subject for the purpose of acquiring a new manifestation of consent (with. 38, 58, and Articles 5 and 8 Regulation (EU) 2016 / 679 and articles 82, paragraph 4, of the Code).

4.4 Genetic counseling and information activities

In relation to the treatments carried out by genetic tests for health protection or family reunification purposes, the person concerned is provided with genetic counseling before and after the analysis. Before the introduction of genetic screening aimed at health protection by health organizations, appropriate measures are adopted to guarantee an activity of information to the public regarding the availability and the voluntariness of the tests carried out, the specific purposes and consequences, also in the institutional publications and electronic communication networks.

The genetic counselor helps the interested parties to take the most appropriate decisions independently, taking into account the genetic risk, family aspirations and their ethical-religious principles, helping them to act coherently with the choices made, as well as to achieve the best adaptation possible to the disease and / or the risk of recurrence of the disease itself.

In cases where the test on individual variability is aimed at ascertaining paternity or maternity, the persons concerned are also informed about the laws on filiation, highlighting the possible psychological and social consequences of the examination.

The implementation of scientific research on population blocks is preceded by an information activity among the affected communities, also through appropriate means of communication and public presentations, aimed at illustrating the nature of the research, the aims pursued, the methods of implementation, the sources of financing and the risks or benefits expected for the populations involved. The information activity also highlights the possible risks of discrimination or stigmatization of the communities involved, as well as those inherent to the knowledge of unexpected relationships of consanguinity and the actions undertaken to minimize these risks.

4.5 Consent

Consent to the processing of genetic data is necessary for:

1. purposes of protecting the health of a third party as provided for in the following point 4.7;
2. the carrying out of genetic tests in the field of defensive investigations or for the exercise of a right in court, unless an express provision of law, or a provision of the judicial authority in accordance with the law, provides otherwise (see infra point 4.9);
3. treatments carried out by genetic testing, including screening, for research or family reunification purposes. In these cases, the interested party is required to declare whether he wants to know or not the results of the examination or research, including any unexpected news concerning him, if the latter represent a concrete and direct benefit in terms of therapy for the person concerned. o prevention or awareness of reproductive choices (see infra point 4.10);
4. purposes of scientific research and statistics not provided for by law or other specific requirement pursuant to art. 9 of the Regulation (see infra point 4.11).

4.5.1 Method of collecting and revoking consent

For information relating to unborn children, consent is validly given by the expectant mother. In the event that the treatment carried out by means of a prenatal test can also reveal genetic data relating to the future onset of a pathology of the father, the latter's consent is also previously acquired.

The opinion of the minor, to the extent that his age and degree of maturity allows it, is taken into consideration, where possible, while the minor's interest remains paramount. In other cases of incapacity, processing is permitted if the aims pursued lead to a direct benefit for the data subject and his opinion is taken into consideration, where possible, while the interest of the incapable remains paramount in any case.

In case of revocation of the consent by the interested party, the processing must cease and the data must be deleted or made anonymous even through the destruction of the biological sample taken.

4.6 Communication and dissemination of data

Without prejudice to the general rules governing the communication and dissemination of particular categories of data, including genetic data, such processing operations can be carried out in compliance with the following requirements (art. 9, EU Regulation 2016/679 and art. 2 -sexies of the Code).

With the exception of the personal data previously provided by the same interested party, the genetic data must be disclosed to the interested party or to the subjects referred to in article 82, paragraph 2, letter a) of the Code by the operators of the health professions and health organizations only through a doctor designated by the interested party or the owner.

The data controller or data controller may authorize operators in the health professions other than doctors, who in the exercise of their duties have direct relations with patients and are designated to treat genetic data or biological samples, to disclose the same data to the interested party or to the subjects pursuant to art. 82, paragraph 2, letter a) of the Code. In the instructions to the persons authorized to the treatment of the data appropriate modalities and cautions are identified related to the context in which the processing of data is carried out.

Genetic data must be disclosed, as a rule, directly to the person concerned or to persons other than the person concerned solely on the basis of a written proxy from the latter, adopting any means to prevent unauthorized knowledge by even co-present individuals. The communication in the hands of a delegate of the interested party is carried out in a closed envelope.

The results of tests and genetic screening, as well as the results of research if they involve a concrete and direct benefit in terms of therapy, prevention or awareness of reproductive choices for the person concerned, must be communicated to the interested party also in respect of his declaration willingness to know or not such events and, where necessary, together with appropriate genetic counseling.

The results of tests and genetic screening, as well as the results of the research, if they involve a concrete and direct benefit in terms of therapy, prevention or awareness of reproductive choices, even for those belonging to the same genetic line as the person concerned, may be communicated to the latter, at their request, if the interested party has expressly consented to it or if such results are indispensable to avoid prejudice to their health, including the reproductive risk, and the consent of the interested party is not given or cannot be loaned for actual unavailability.

In the case of research conducted on population groups or isolated populations, any research results that have a therapeutic or preventive importance for the protection of the health of people belonging to such communities must be made known to the communities concerned and the local authorities.

4.7 Protection of the health of a third party

Without prejudice to the specific health conditions set forth in art. 75 of the Code, the processing of genetic data for the purpose of protecting the health of a third party can be carried out if it belongs to the same genetic line as the data subject and with the consent of the latter.

In the event that the data subject's consent is not given or cannot be given due to physical impossibility, incapacity to act or incapacity to understand or wish, as well as for actual unavailability, the treatment may be carried out limited to the genetic data available if it is essential to allow the third party to make an informed reproductive choice or is justified by the need, for the third party, for preventive or therapeutic interventions. In the event that the person concerned has died, the treatment may also include genetic data extrapolated from the analysis of biological samples of the deceased person, provided that it is indispensable to allow the third party to make a conscious reproductive choice or be justified by necessity, for the third,

4.8 Presymptomatic tests

The processing of genetic data and the use of biological samples for the execution of presymptomatic and susceptibility tests can be carried out exclusively for the pursuit of health protection purposes, also to make conscious reproductive choices and for research purposes aimed at protection of health.

Data processing connected to the performance of presymptomatic genetic tests can be performed on unaffected minors, but at risk for genetic pathologies only if there are concrete possibilities of therapies or preventive treatments before reaching the age of majority. Individual variability tests cannot be conducted on minors without the consent of both parents, both exercising parental authority.

4.9 Treatment of genetic data for the conduct of defensive investigations pursuant to the law of 7 December 2000, n. 397

The processing of genetic data for defensive investigations pursuant to the law of 7 December 2000, n. 397 also by means of substitutes, technical consultants and authorized private investigators, or, in any case, to assert or defend a right even by a third party in a judicial context, must be carried out with the consent of the interested party only in the event that require genetic testing.

Informed consent is required from the person to whom the biological material necessary for the investigation belongs, unless an express provision of law, or a provision of the judicial authority in accordance with the law, provides otherwise.

This, provided that the right to assert or defend is of equal rank to that of the interested party, or consisting in a right of the personality or in another fundamental or inviolable right or freedom and the data are processed exclusively for these purposes and for the period strictly necessary for their pursuit (Article 60 of the Code).

4.10 Treatment of genetic data for purposes of family reunification and inbreeding restrictions

International bodies deemed suitable by the Ministry of Foreign Affairs and International Cooperation and diplomatic or consular representations for the purpose of issuing certifications (currently governed by Article 52 of Legislative Decree no. 71 of 3 February 2011) may process data genetic to allow family reunification limited to cases in which the interested party cannot document in a certain way his consanguinity constraints through certificates or attestations issued by competent foreign authorities, due to the lack of a recognized authority or in any case when there are well-founded doubts on the authenticity of the aforementioned documentation (see also Legislative Decree of 25 July 1998, No. 286).

In the hypothesis of carrying out tests or genetic screening for family reunification purposes it is necessary to acquire the consent of the interested parties; those interested are asked to declare whether they want to know the results of the examination, including any unexpected news concerning them, if they represent a concrete and direct benefit for the interested parties in terms of therapy or prevention or awareness of reproductive choices .

The genetic data collected for the purpose of family reunification can be communicated only to the diplomatic or consular offices competent for examining the documentation produced by the interested party or to the international body deemed suitable by the Ministry of Foreign Affairs and International Cooperation to which the interested party addressed. Biological samples taken for the same purpose can only be transferred to the laboratory designated to carry out the test on individual variability or to the international body deemed suitable by the Ministry of Foreign Affairs and International Cooperation.

4.11 Treatment of genetic data for purposes of scientific research and statistics

The processing of genetic data and biological samples for purposes of scientific and statistical research is permitted only if it is aimed at protecting the health of the interested party, third parties or the community in the medical, biomedical and epidemiological fields, including in the context of clinical trials or scientific research to develop genetic analysis techniques.

The processing must be carried out on the basis of a project drafted in accordance with the standards of the relevant disciplinary sector, also for the purpose of documenting that the processing of data and the use of biological samples is carried out for suitable and effective scientific purposes.

The project specifies the measures to be taken in the processing of personal data to ensure compliance with this provision, as well as the legislation on the protection of personal data, also for the profiles concerning the custody and security of biological data and samples, and identifies any data controllers (art. 28 EU Regulation 2016/679). In particular, where the research involves the collection and / or use of biological samples, the project indicates the origin, nature and method of collection and storage of the samples, as well as the measures taken to guarantee the voluntary nature of the conferment of the biological material from the interested party.

The project is kept in a confidential form (since it is possible to consult the project only for the purpose of applying the law on the protection of personal data) for five years from the planned conclusion of the research.

When the purposes of the research can only be achieved through the identification, even temporary, of the interested parties, the data controller adopts specific measures to keep the identification data separate from biological samples and genetic information already at the time of collection, unless this is impossible in because of the particular characteristics of the processing or requires a manifestly disproportionate use of means.

4.11.1 Information to interested parties

In relation to the treatments carried out for scientific research and statistical purposes in the information provided to the interested parties, we also highlight:

- a) the measures adopted to allow the identification of the interested parties only for the time necessary for the purposes of collection or subsequent processing (art. 25 EU Regulation 2016/679);
- b) the ways in which interested parties, upon request, can access the information contained in the research project.

Treatments carried out using genetic tests, including screening, for research purposes require the consent of the interested parties; in these cases the interested parties are required to declare whether they want to know the results of the research or not, including any unexpected news concerning them, if the latter represent a concrete and direct benefit for the interested parties in terms of therapy or prevention or awareness of the reproductive choices.

4.11.2 Consent

Subject to the provisions of point 4.5, genetic data and biological samples of people who cannot give their consent due to incapacity may be processed for scientific research purposes that do not involve a direct benefit to the same interested parties if the following conditions are met simultaneously:

- a) the research is aimed at improving the health of other persons belonging to the same age group or who suffer from the same pathology or who are in the same conditions and the research program is subject to a justified favorable opinion by the competent ethical committee territorial;
- b) a search of a similar purpose cannot be carried out by processing data referring to persons who can give their consent;
- c) the consent to the processing is acquired by the person who legally exercises the authority, or by a neighbor, by a family member, by a cohabitant or, in their absence, by the person in charge of the structure where the person is staying;
- d) the research does not involve significant risks for the dignity, rights and fundamental freedoms of the persons concerned.

In such cases, the aforementioned provisions regarding the need to take into consideration, where possible, the opinion of the minor or of the incapacitated person remain valid.

In the event that the data subject withdraws his consent to the processing of data for research purposes, the biological sample is also destroyed, provided that it has been taken for such purposes, unless, originally or following treatment, the sample can no longer be referring to an identified or identifiable person.

4.11.3 Conservation for research purposes and further processing

In the absence of the consent of the interested parties, the biological samples taken and the genetic data collected for health protection purposes can be stored and used for scientific research or statistical purposes in the following cases:

- a) statistical surveys or scientific research provided for by European Union law, by law or, in the cases provided for by law, by regulation;
- b) limited to the pursuit of further scientific and statistical purposes directly connected with those for which the informed consent of the interested parties was originally obtained.

When, due to particular reasons, it is not possible to inform the interested parties in spite of having made every reasonable effort to achieve them, the conservation and further use of biological samples and genetic data collected for the realization of research projects and statistical surveys, other than the original ones are permitted if a similar search cannot be carried out by processing data referring to persons from whom informed consent may or has been acquired and:

aa) the research program involves the use of biological samples and genetic data that originally do not allow to identify the interested parties, or that, following treatment, do not allow to identify the same interested parties and it does not appear that the latter have in previously provided contrary indications;

bb) or the research program, subject to the prior favorable opinion of the competent ethical committee at the local level, is subject to prior consultation with the Guarantor pursuant to art. 36 of the Regulation (EU) 2016/679.

4.11.4 Communication and dissemination of data

Genetic data and biological samples collected for scientific and statistical research purposes may be communicated or transferred to research institutions and bodies, associations and other public and private research organizations for joint projects and in respect of the 'art. 26 of the Regulation.

Genetic data and biological samples collected for scientific and statistical research purposes may be communicated or transferred to the aforementioned subjects, if they are autonomous data controllers, limited to information without identification data, for scientific purposes directly related to those for which they are been originally collected and clearly determined in writing in the request for data and / or samples. In this case, the requesting party undertakes not to process the data and / or use the samples for purposes other than those indicated in the request and not to communicate them or transfer them further to third parties.

5. Requirements relating to the processing of personal data carried out for scientific research purposes (aut. Gen. No. 9/2016).

5.1 Scope of application

The present provisions concern the processing carried out by:

- a) universities, other institutions or research institutes and scientific societies, as well as researchers operating within the said universities, institutions, research institutes and the members of said scientific societies;
- b) practicing health professions and health organizations;
- c) natural or legal persons, bodies, associations and private bodies, as well as persons specifically responsible for the treatment as designated or responsible for processing (researchers, expert commissions, contract research organizations, analysis laboratories, etc.) (art. 2 -quaterdecies of the Code; 28 of the EU Regulation 2016/679).

5.2 Types of research

The following provisions concern the processing of personal data for medical, biomedical and epidemiological research purposes carried out when:

- the processing is necessary for the conduct of studies carried out with previously collected data for health care purposes or for the execution of previous research projects or obtained from biological samples taken previously for health protection purposes or for the purpose of execution of previous research projects or
- the treatment is necessary for the conduct of studies carried out with data referring to persons who, due to the gravity of their clinical status, are not able to understand the indications given in the disclosure and to validly consent.

In these cases the research must be carried out on the basis of a project, object of a justified favorable opinion of the competent ethical committee at territorial level.

5.3 Consent

The consent of the interested party is not necessary when the search is carried out based on legal or regulatory provisions or European Union law.

In other cases, when it is not possible to acquire the consent of the interested parties, the data controllers must document, in the research project, the existence of the reasons, considered to be completely particular or exceptional, for which informing the interested parties is impossible or involves an effort disproportionate, or risks making it impossible or seriously prejudicial to the achievement of the aims of the research, including in particular:

1. the ethical reasons attributable to the circumstance that the person concerned ignores his condition. This category includes research for which the information on the processing of data to be made to the interested parties would entail the disclosure of information concerning the conduct of the study, the knowledge of which could cause material or psychological damage to the interested parties (they can be included in this hypothesis, for example, epidemiological studies on the distribution of a factor that predicts or can predict the development of a morbid state for which there is no treatment);
2. the reasons of organizational impossibility attributable to the fact that the failure to take into account the data referring to the estimated number of interested parties that it is not possible to contact in order to inform them, with respect to the total number of subjects that is intended to be involved in the research, would produce significant consequences for the study in terms of alteration of the relative results; this had regard, in particular, to the inclusion criteria foreseen by the study, to the enrollment methods, to the statistical number of the chosen sample, as well as to the period of time elapsed from the moment in which the data referring to the interested parties were originally collected (for example,

With reference to these reasons of organizational impossibility, the following provisions also concern the processing of the data of those who, upon the conclusion of any reasonable effort made to contact them (also through the verification of the state in life, the consultation of the data reported in the documentation clinical, the use of the telephone numbers eventually supplied, as well as the acquisition of the contact data at the register of the assisted or resident population) are at the time of enrollment in the study:

- deceased or
- not contactable.

The obligation to provide the information to interested parties included in the research remains in all cases in which, during the course of the study, this is possible and, in particular, where these are addressed to the care center, also for control visits, also in order to allow them to exercise the rights provided by the Regulation;

3. health reasons attributable to the seriousness of the clinical condition in which the person concerned is paying due to the fact that he is unable to understand the information given in the information and to validly consent. In such cases, the study must be aimed at improving the same clinical status in which the person

concerned is. Furthermore, it must be proved that the aims of the study cannot be achieved by processing data referring to persons able to understand the information given in the information sheet and to validly give consent or other research methods. This, having regard, in particular, to the inclusion criteria envisaged by the study, to the enrollment methods, to the statistical number of the chosen sample, as well as the reliability of the results achievable in relation to the specific purposes of the study. With reference to these reasons, the consent of the persons indicated in the art. Must be acquired. 82, paragraph 2, lett. a), of the Code as amended by Legislative Decree no. 101/2018. This, without prejudice to the fact that the data subject is informed of the processing of the data as soon as the health conditions allow it, also for the purpose of exercising the rights provided for by the Regulation.

5.4 Processing methods

If the research cannot achieve its aims without the identification, even temporary, of the interested parties, in the treatment subsequent to the retrospective collection of the data, techniques of encryption or pseudonymisation or other solutions are adopted which, considering the volume of data processed, the nature, object, context and purpose of the processing, make them not directly attributable to the interested parties, allowing the identification of the latter only in case of need. In these cases, the codes used cannot be deduced from the personal identification data of the interested parties, unless this proves impossible due to the particular characteristics of the processing or requires the use of manifestly disproportionate means and is also justified, in writing, in the research project .

The combination with the research material of the identification data of the interested party, provided that it is temporary and essential for the result of the research, is also justified in writing.

In application of the principle of minimization, the processing of personal data for purposes of scientific research in the medical, biomedical or epidemiological field may concern the data relating to the health of the interested parties and, only when indispensable for the achievement of the aims of the research, also data together related to sexual life or sexual orientation, as well as racial and ethnic origin (Article 5, paragraph 1, letter c), EU Regulation 2016/679).

5.5 Communication and dissemination

Individuals who act as data controllers for the purposes in question, even together with other data controllers, can communicate with each other the personal data covered by this authorization to the extent that they are promoters, coordinating centers or participating centers. and the communication operation is essential for conducting the study.

In addition to the prohibition of dissemination of data relating to the health of the interested parties (art. 2-septies of the Code), those relating to sexual life, sexual orientation and racial and ethnic origin used for the conduct of the study.

5.6 Storage of data and samples

The biological data and samples used to carry out the research are stored using encryption techniques or the use of identification codes or other solutions which, given the number of data and samples stored, do not make them directly traceable to the interested parties, for a period of time not exceeding that necessary for the purposes for which they were collected or subsequently processed.

To this end, the conservation period is indicated in the research project, following the conclusion of the study, at the end of which the aforementioned data and samples are anonymized.

5.7 Custody and security

Without prejudice to the obligation to adopt technical and organizational measures to guarantee an adequate level of security for the risk, they are employed by the data treatment owner (s), each for the part of his / her competence in relation to the role covered in the processing of data and to the consequent responsibilities, specific measures and technical measures to increase the level of security of the data processed for the execution of the study.

This is in the phase of storing or storing data (and, possibly, collecting and storing biological samples), and in the subsequent phase of processing the same information, as well as in the subsequent phase of data transmission to the promoter or external collaborating subjects with the first for the execution of the study. They are adopted, in particular:

- to. adequate precautions to guarantee the quality of the data and the correct attribution to the interested parties;
- b. appropriate measures to guarantee the protection of the study data from the risks of unauthorized access to data, theft or loss, partial or integral, of portable or fixed storage media or processing systems (for example, through the partial or full application of cryptographic technologies to file systems or databases, or through the adoption of other measures that make the data unintelligible to non-legitimate subjects) in data recording and archiving operations;
- c. protected transmission channels, taking into account the state of the art of the technology, in the cases where it is necessary to communicate the data collected within the study to a centralized database where they are stored and archived or to a promoter or to external subjects of which the promoter uses for conducting the study. Where said transmission is carried out by optical support (CD-ROM), a specific person in charge of reception at the promoter is designated and a transmission channel different from that used for the transmission of the content is used for sharing the data encryption key. ;
- d. tecniche di etichettatura, nella conservazione e nella trasmissione di campioni biologici, mediante codici identificativi, oppure altre soluzioni che, considerato il numero di campioni utilizzati, li rendono non direttamente riconducibili agli interessati, permettendo di identificare questi ultimi solo in caso di necessità;
- e. con specifico riferimento alle operazioni di elaborazione dei dati dello studio memorizzati in una banca dati centralizzata, è necessario adottare:
 - idonei sistemi di autenticazione e di autorizzazione per il personale preposto al trattamento in funzione dei ruoli ricoperti e delle esigenze di accesso e trattamento, avendo cura di utilizzare credenziali di validità limitata alla durata dello studio e di disattivarle al termine dello stesso;
 - procedure per la verifica periodica della qualità e coerenza delle credenziali di autenticazione e dei profili di autorizzazione assegnati ai soggetti designati al trattamento;
 - sistemi di audit log per il controllo degli accessi al database e per il rilevamento di eventuali anomalie.

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