

[doc. web no. 9299150]

Injunction order against Tuscany Center Local Health Unit - February 6, 2020

Register of measures

no. 26 of 6 February 2020

#### GUARANTOR FOR THE PROTECTION OF PERSONAL DATA

IN today's meeting, in the presence of Dr. Antonello Soro, president, of dott.ssa Augusta Iannini, vice president, of dott.ssa Giovanna Bianchi Clerici and of prof.ssa Licia Califano, members and of dott. Giuseppe Busia, general secretary;

HAVING REGARD TO Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, as well as on the free circulation of such data and repealing Directive 95/46 /CE, "General Data Protection Regulation" (hereinafter "Regulation");

HAVING REGARD TO Legislative Decree 30 June 2003, n. 196 containing the "Code regarding the protection of personal data, containing provisions for the adaptation of the national legal system to Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of natural persons with regard to the processing of personal data, as well as to the free movement of such data and which repeals Directive 95/46/EC (hereinafter the "Code");

CONSIDERING the Regulation n. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor for the protection of personal data, approved with resolution no. 98 of 4/4/2019, published in the Official Gazette no. 106 of 8/5/2019 and in [www.gpdp.it](http://www.gpdp.it), doc. web no. 9107633 (hereinafter "Regulation of the Guarantor n. 1/2019");

Given the documentation in the deeds;

Given the observations made by the Secretary General pursuant to art. 15 of the Regulation of the Guarantor n. 1/2000 on the organization and functioning of the Guarantor's office for the protection of personal data, doc. web no. 1098801;

Supervisor Prof. Licia Califano;

#### WHEREAS

##### 1. The personal data breach

It has been reported to the Authority that at the outpatient clinics of Badia a Ripoli Impresa Sociale S.r.l. (alias Misericordia Badia a Ripoli, hereinafter Service Company) a refrigerator was placed for the custody of biological samples and the related

documentation of patients who had joined the campaign for the early prevention of intestinal cancer. The whistleblower complained about the ways in which the patients were called to deposit the biological sample and the forms they filled in, inside the aforesaid refrigerator, complaining about the absence of personnel responsible for the custody of the aforementioned finds and documents.

## 2. The preliminary investigation

In relation to what was reported, the Office proceeded to request information from the subjects involved in the aforementioned prevention campaign and, in particular, from the Institute for the Study, Prevention and the Oncological Network (ISPRO), the aforementioned service company and to the USL Toscana centro (hereinafter Company) (notes of 11.19.2018, prot. n. 33653 and of 01.15.2019, prot. n. 1488) regarding the processing of personal data carried out in the context of the aforementioned early prevention of intestinal cancers.

In response to the request for information from the Office, the Company, ISPRO and the service company provided elements of confirmation (note from the Company dated 25/02/2019, prot. no. 23303; notes from Ispro dated 12.14.2018, prot. n.3074 and of 02/25/2019, prot. n. 522 and note of the Service Company dated 12.14.2018, prot. n. 9) and have sent documentation relating to the application of the regulations on the data processing carried out as part of the aforementioned prevention campaign (Ispro invitation to the prevention campaign containing the personal data sheet of the patient and the "Privacy information and request for consent for data processing (Regulation (EU) 2016/ 679"; deed of designation of the Local Health Authority Toscana Centro as ISPRO data processor of 24 September 2018; Resolution of the Director General of the Local Health Authority no. 10 of Florence no. 56 of 02.03.2005, containing "Approval of the new text of the agreement with the CSPO, period 2004/2006, for the performance d in oncological screening, epidemiology and diagnostic consultancy activities"; Resolution of the Director General of ISPRO n. 175 of 25.6.2018, containing "Identification of personal data manager (DPO) pursuant to European Regulation 2016/679 and contract approval).

Specifically, the Director General of the USL Toscana Centro, Dr. XX, with the aforementioned note dated 02/25/2019, represented that:

- "The Local Health Authority Toscana Centro is the data controller pursuant to art. 4 no. 7 of the GDPR and, in application of the aforementioned regulations, pursues in the specific case the purpose of carrying out screening for the early prevention of intestinal cancer using (...) Ispro";

- «Ispro (...) is identified as responsible for the treatment (...) (the relative appointment) was ordered by the Local Health Authority 10 of Florence, today Local Health Authority Toscana Centro, in the agreement referred to in resolution no. 56 of 02/03/2005»;

- «La Misericordia di Badia a Ripoli, in direct relations with the Local Health Authority Toscana Centro was appointed by the latter as data processor pursuant to art. 28 of the GDPR»;

- "with reference to the relationship between the Local Health Authority Toscana Centro and Ispro, in consideration of the fundamental role that the latter is called to play by law, (...) a new Convention is being defined within which detailed (...) also the roles and responsibilities related to the protection of natural persons with regard to the processing of personal data. In the present case, in fact, the USL Toscana Centro company delegates the management of the project to Ispro and would authorize the appointment of the Misericordia di Badia a Ripoli as "sub-manager" of the treatment in compliance with the obligations pursuant to art. 28 of the GDPR»;

- "the new organizational structure of the Local Health Authority Toscana Centro, defined with reference to the processing of personal data by the General Manager's Resolution no. 179/2019, will lead the company Representatives (former internal data processors) to exercise control activities and functions towards external subjects formally appointed as Data Processors".

The person in charge of the protection of personal data of Ispro, dott. XX, with the note dated 02/25/2019, declared that:

- «in the context of the processing in question, Ispro exclusively assumes the role of Data Processor pursuant to article 28 of the GDPR (...) which is therefore called to carry out processing in the name and on behalf of the Local Health Authority Toscana Centro»;

- "Ispro is not aware (...) of the custody and conservation of the biological samples delivered by the members, since these are aspects that the USL TC company deals with".

In this regard, the Medical Director of the Service Company, Dr. XX, with the note of 12.14.2018, stated that:

- "the commitment of this structure refers only to the custody of the sample (...) of the user who independently deposits his documentation in an anonymous sealed envelope»;

- the refrigerator where the sample is kept «is located in continuity with the reception counter about one meter from the last assigned operator who is present throughout the opening hours. An anti-intrusion alarm system is activated during closing hours. "Throughout the 24 hours a video surveillance service is active (...) aimed (...) at the reception counters, therefore also

the aforementioned refrigerator is included in the control";

- "in about six years of activity, no problems have arisen and (...) that even in the case reported, no violation of privacy has occurred, understood as the dissemination of user data to third parties or entities".

In relation to the results of the aforementioned preliminary investigation, the Office, with deed no. 8762 of 12 March 2019, notified the Local Health Authority Toscana Centro, pursuant to art. 166, paragraph 5, of the Code, the initiation of the procedure for the adoption of the measures referred to in article 58, paragraph 2, of the Regulation, inviting the aforesaid holder to produce defense writings or documents to the Guarantor or to ask to be heard by the Authority (art. 166, paragraphs 6 and 7, of the Code; as well as art. 18, paragraph 1, of law n. 689 of 11/24/1981).

In particular, the Office, in the aforementioned deed, represented that

- the model of "Privacy information and request for consent for data processing (Regulation (EU) 2016/679)", attached to the invitation letter sent by ISPRO, does not contain some of the information elements required by articles 13 and 14 of the Regulation, such as: the retention period of personal data, the right to lodge a complaint with the supervisory authority and the contact details of the data controller and data protection officer. Furthermore, the aforementioned disclosure model does not clearly provide adequate information regarding the processing carried out "for medical-scientific research study activities", with specific reference to the person in charge of the aforementioned activities and the characteristics of the processing;

- with reference to the designation of data controller, pursuant to art. 28 of the Regulation, the legal act with which they must be carried out must include, among other things, the documented instructions of the data controller, the assurances regarding the commitment of confidentiality of the persons authorized to process personal data and the adoption of the security measures of the treatment, as well as the indications regarding the cancellation or return of all personal data after the provision of services relating to the treatment has ended. The designation made by the Local Health Authority Toscana Centro all'Ispro as External Data Processor (deed of 24.9.2018) and the Resolution of the Director General of the Local Health Authority n. 10 of Florence n. 56 of 02/03/2005 containing "Approval of the new text of the agreement with the CSPO, period 2004/2006, for the performance of oncological screening, epidemiology and diagnostic consultancy activities" are instead completely devoid of the aforementioned elements expressly required by the 'art. 28 of the Regulation.

In the aforementioned deed of 12 March 2019, the Office therefore considered that the Company had processed the personal data of the interested parties who joined the campaign for the early prevention of intestinal tumors, also through the activities

carried out, on their own behalf, by the 'ISPRO and by the service company, in violation of the right of the interested parties to receive - at the time of data collection - all the information referred to in art. 13 of the Regulation and the obligations of the data controller regarding the correct designation of the data controller pursuant to art. 28 of the Regulation.

With a note dated 10 April 2019 (prot. n. 43515), the Company asked to be heard by the Authority and sent its defense briefs, in which, in particular, it was represented that:

- a) "the Tuscan regional law of 14 December 2017 n. 74 (Discipline of the Institute for the study, prevention and oncological network (ISPRO) and, in particular, by art. 3, in accordance with which: "I. The purpose of ISPRO, in the context of the health service regional, consists in promoting, measuring and studying primary, secondary and tertiary prevention actions for tumors and in organizing and coordinating, in synergy with the companies and entities of the regional health service, the paths of diagnosis, treatment and rehabilitation, as well as the programs of research in the field of oncology";
- b) the Company has assigned the management of the screening process for the early prevention of intestinal cancer to ISPRO, lending "its collaboration for the collection of samples at the identified collection points";
- c) "the Local Health Authority Toscana Centro, following its establishment by merging the previous territorial companies, has progressively started a process of adaptation aimed at centralizing management; proceeded to appoint the same Institute as Data Processor for the areas included in the district pertaining to the former companies of Pistoia (USL3), Prato (USL4) and Empoli (USLII) for the activities carried out, in this context, by ISPRO (see . resolution no. 1862 of 12.20.2018 as updated with Resolution no. 522/2019) for "the processing and reporting of cytological screening samples to be sent to the Single Regional Laboratory for Oncological Prevention of ISPRO"";
- d) "given the complexity of the relationships and the need for a progressive alignment of the agreements, as already highlighted in the deeds, a new agreement is being studied by the Company and ISPRO concerning the screening process with the clear assumption in head of the latter of any activity inherent to the same";
- e) -"in relation to the elements required pursuant to art. 13 of EU Regulation 2016/679 (...) the indication of the Data Controller (AUSL Toscana Centro for the screening process) allows interested parties to easily and without limitation find information regarding the contact details of the same, of the Head of data protection, the data retention period as well as the right to complain to the Supervisory Authority by accessing the general information published on the institutional website";
- f) "to have provided for the adoption of a text containing the information pursuant to art. 13 of EU Regulation 2016/679 updated

with respect to the contents highlighted in the provision in question, endeavoring, as will be better specified, to send the same to the Data Processor for delivery to the interested parties" and to have also "provided for the preparation of a new and updated deed of appointment as Data Processor for ISPRO".

On 20 January 2020, the hearing of the USL Toscana Centro company took place in which, the Avv. XX, delegate to represent the Company, reiterated "the company's desire to review the agreement currently in force with Ispro, in order to better outline the Institute's tasks also with reference to the profile of the protection of personal data . This revision activity has already led to the drafting of a new draft of the agreement, which, as soon as completed, will be sent to the Office for the part of competence" (minutes of the hearing of the parties, prot. n. 2191 of 20.1.2020) . On the occasion of the hearing, the Company representative also produced the deed of designation as ISPRO manager dated 18.6.2019, of which the new information model to be provided to interested parties drawn up in light of art. 13 of the Regulation and company resolution no. 179/2019 relating to the corporate organization of the data management system, with which it was specified that the relationship with external subjects must be managed by the manager of a simple or complex structure, in order to maintain a more effective supervisory position.

During the hearing, the Company representative also specified that "the data subject involved in the processing of the data subject of this proceeding has not currently presented any claim for compensation or other deeds relating to the aforementioned processing against the Company" .

### 3. Outcome of the preliminary investigation

Having taken note of what is represented by the Company, ISPRO and the service company in the documentation in the Company's deeds and defense briefs, it is noted that:

1. the Regulation, in establishing a general prohibition on the processing of particular categories of personal data, provides for a derogation in the event that the processing is necessary for purposes of preventive medicine, diagnosis, assistance or health therapy (Article 9, paragraph 2 , letter h) and par. 3 of the Regulation) and is carried out by (or under the responsibility of) a healthcare professional subject to professional secrecy or by another person also subject to the obligation of secrecy. The processing of personal data carried out as part of the early prevention campaign for intestinal cancer in question can be traced back to the case indicated in art. 9, par. 2, lit. h) Regulation. Therefore, the processing of data relating to health, necessary to pursue the aforementioned prevention purpose, can be carried out, within the limits indicated in the aforementioned provision,

after having provided the interested party with the information required by articles 13 and 14 of the Regulation, without the need to acquire the consent of the interested party;

2. there are no preliminary findings regarding the inadequacy of the methods with which the service company has kept the biological samples and the related documentation relating to the aforementioned prevention campaign;

3. the model of "Privacy information and request for consent for data processing (Regulation (EU) 2016/679)", attached to the invitation letter sent by ISPRO, is, however, lacking in some of the information elements expressly requested by the aforementioned articles 13 and 14 of the Regulation, such as: the retention period of personal data, the right to lodge a complaint with the supervisory authority, the contact details of the data controller and the data protection officer and does not clearly provide information regarding the treatment carried out "for medical-scientific research study activities", with specific reference to the person in charge of the aforementioned activities and the characteristics of the treatment. The fact that the information relating to the contact details of the Data Controller and of the Data Protection Officer, the data retention period as well as the right to complain to the Supervisory Authority are present in the "general information published on the corporate website" does not allow to overcome the findings made by the Office as, in the aforementioned model, there was no reference to the so-called "General information" and the Company's institutional website was not indicated. In any case, it is the precise duty of the data controller to provide complete, clear and exhaustive information in relation to the specific treatment that does not require the interested party to search or retrieve the relevant information elsewhere in relation to the specific treatment to be carried out (see provision of 7.3.2019 - Clarifications on the application of the regulations for the processing of data relating to health in the health sector, web doc. n. 9091942). The "Information on the processing of personal data - cancer screening activity" model, produced by the Company during the hearing of 20.1.2020, has overcome the critical issues raised by the Office with the aforementioned note of 12.3.2019, eliminated by all references to the purposes of scientific research by the Company and reported the information elements which were missing from the model "Privacy information and request for consent for data processing (Regulation (EU) 2016/679)", attached the letter of invitation sent by ISPRO and used at the time of the facts covered by the report;

4. the designation as data processor made by the Local Health Authority Toscana Centro to ISPRO as "External Data Processor" (deed of 24.9.2018) and the Resolution of the Director General of the Local Health Authority n. 10 of Florence n. 56 of 02.03.2005 containing "Approval of the new text of the agreement with the CSPO, period 2004/2006, for the performance of

oncological screening, epidemiology and diagnostic consultancy activities" were lacking the following elements expressly required by art. 28 of the Regulation: documented instructions from the data controller, assurances regarding the commitment to confidentiality of the persons authorized to process personal data and the adoption of processing security measures, as well as indications regarding the cancellation or return of all personal data at the end of the provision of services relating to the treatment. The "deed of appointment as data processor pursuant to article 28 of EU regulation 2016/679" dated 18.6.2019 and produced by the Company during the hearing of 20.1.2020, has overcome the critical issues raised by the 'Office with the aforementioned note of 12.3.2019, reporting the aforementioned missing elements.

#### 4. Conclusions

In the light of the assessments referred to above, taking into account the statements made by the data controller and data processors during the preliminary investigation ☐ and considering that, unless the fact constitutes a more serious crime, whoever, in a proceeding before the Guarantor, declares or falsely certifies news or circumstances or produces false deeds or documents and is liable pursuant to art. 168 of the Code "False declarations to the Guarantor and interruption of the execution of the duties or the exercise of the powers of the Guarantor" ☐ the elements provided by the data controller in the defense briefs do not allow to overcome the findings notified by the Office with the deed of initiation of the proceeding, since none of the cases envisaged by art. 11 of the Regulation of the Guarantor n. 1/2019.

For these reasons, the unlawfulness of the processing of personal data carried out by the Local Health Unit of Tuscany Center is noted, in the terms set out in the justification, in violation of art. 13 and 28 of the Regulation.

In this context, considering, in any case, that the conduct has exhausted its effects, given that the Company has declared that it has adopted a new model "Information on the processing of personal data - cancer screening activity" and that it has taken steps to adopt on 18.6.2019 a new "deed of appointment as data controller pursuant to article 28 of EU regulation 2016/679" (report of the hearing of the parties, prot. n. 2191 of 20.1.2020), the conditions for the adoption of the corrective measures pursuant to art. 58, par. 2, of the Regulation.

In the same way, the proactivity with which the Company has taken steps to amend the aforementioned documents, as well as to review the agreement deed with ISPRO, highlights the maximum and diligent collaboration shown by the same in relations with the Authority, in order to conform the processing to the regulations on the protection of personal data (see the aforementioned report of the hearing of the parties, prot. n. 2191 of 20/01/2020).



5. Adoption of the injunction order for the application of the pecuniary administrative sanction and accessory sanctions (articles 58, paragraph 2, letter i and 83 of the Regulation; article 166, paragraph 7, of the Code)

The violation of the articles 13 and 28 of the Regulation, caused by the conduct put in place by the Toscana Centro Local Health Authority, is subject to the application of the administrative pecuniary sanction pursuant to, respectively, art. 83, par.5, lett. b) and par. 4, lit. a) of the Regulation.

Therefore, the art. 83, par. 3, of the same Regulation, on the basis of which, if, in relation to the same treatment or related treatments, a data controller violates, with willful misconduct or negligence, various provisions of the Regulation, the total amount of the pecuniary administrative sanction does not exceed amount specified for the most serious violation (referred to in Article 83, paragraph 5, of the Regulation) thus absorbing the other less serious violations (see Article 83, paragraph 4, of the Regulation). Therefore, the aforementioned violations concerning, among others, the unsuitable disclosure pursuant to art. 13 of the Regulation, are to be traced back, pursuant to art. 83, par. 3 of the same Regulation, in the context of the sanction envisaged for the aforementioned violation with consequent application of the sanction envisaged in art. 83, par. 5, letter. b), of the Regulation.

Consider that the Guarantor, pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, has the power to "impose a pecuniary administrative sanction pursuant to article 83, in addition to the [other] [corrective] measures referred to in this paragraph, or instead of such measures, according to the circumstances of each single case" and, in this context, "the Board [of the Guarantor] adopts the injunction order, with which it also orders the application of the ancillary administrative sanction of its publication, in whole or in part, on the website of the Guarantor pursuant to article 166, paragraph 7, of the Code" (art. 16, paragraph 1, of the Guarantor's Regulation no. 1/2019).

The aforementioned pecuniary administrative sanction imposed, depending on the circumstances of each individual case, must be determined in the amount taking into account the principles of effectiveness, proportionality and dissuasiveness, indicated in art. 83, par. 1, of the Regulation, in the light of the elements provided for in art. 85, par. 2, of the Regulation in relation to which it is observed that:

- the Company immediately demonstrated a high degree of cooperation, by modifying the "Information on the processing of personal data - cancer screening activity" model and adopting a new "Deed of appointment as data processing manager pursuant to art.28 of EU regulation 2016/679" (minutes of the hearing of the parties, prot. n. 2191 of 20.1.2020), as well as to

review the agreement in force with ISPRO, currently being redefined (art. 83, paragraph 2, letters c), d) and f) of the Regulation);

- the Authority received only one report regarding the processing of data carried out through the campaign for the early prevention of intestinal cancer, in relation to which, however, no particular critical issues were found in the deeds (art. 83, paragraph 2, lett. a) and h) of the Regulation);

- the data processing carried out through the early intestinal cancer prevention campaign concerns biological samples and clinical documentation suitable for detecting information on the health of the interested parties and, potentially, the presence of oncological pathologies (Article 4, paragraph 1, no. 15 of the Regulation and Article 83, paragraph 2, letters a) and g) of the Regulation).

Based on the aforementioned elements, evaluated as a whole, also taking into account the phase of first application of the sanctioning provisions pursuant to art. 22, paragraph 13, of Legislative Decree lgs. 10/08/2018, no. 101, it is decided to determine the amount of the pecuniary sanction provided for by art. 83, par. 4, lit. a) and par. 5, letter. b) of the Regulation, to the extent of 10,000 (ten thousand) euros for the violation of articles 13 and 28 of the Regulation as a pecuniary administrative sanction withheld, pursuant to art. 83, par. 1, of the Regulation, effective, proportionate and dissuasive.

It is also believed that the ancillary sanction of publication on the Guarantor's website of this provision should be applied, provided for by art. 166, paragraph 7 of the Code and art. 16 of the Regulation of the Guarantor n. 1/2019, also in consideration of the potential number of interested parties and the type of personal data subject to unlawful processing. Finally, it should be noted that the conditions pursuant to art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

ALL THIS CONSIDERING THE GUARANTOR

declares the illegality of the processing of personal data carried out by the Local Health Unit of Tuscany Center, for the violation of the articles 13 and 28 of the Regulation in the terms referred to in the justification.

ORDER

pursuant to articles 58, par. 2, lit. i) and 83 of the Regulation, as well as art. 166 of the Code, to the Central Tuscany Local Health Authority, with registered office in Florence (FI), Piazza S. Maria Nuova, 1 - C.F./P. 06593810481, in the person of the pro-tempore legal representative, to pay the sum of 10,000 (ten thousand) euros as a pecuniary administrative sanction for the

violations indicated in this provision, according to the methods indicated in the attachment, within 30 days of the notification in the motivation ; it is represented that the offender, pursuant to art. 166, paragraph 8, of the Code, has the right to settle the dispute by paying, within 30 days, an amount equal to half of the fine imposed.

ENJOYS

to the aforementioned Company, in the event of failure to settle the dispute pursuant to art. 166, paragraph 8, of the Code, to pay the sum of 10,000 (ten thousand) euros, according to the methods indicated in the attachment, within 30 days of notification of this provision, under penalty of adopting the consequent executive acts pursuant to art. 27 of the law n. 689/1981.

HAS

pursuant to art. 166, paragraph 7, of the Code, the entire publication of this provision on the website of the Guarantor and believes that the conditions set forth in art. 17 of Regulation no. 1/2019 concerning internal procedures having external relevance, aimed at carrying out the tasks and exercising the powers delegated to the Guarantor.

Pursuant to art. 78 of the Regulation, of the articles 152 of the Code and 10 of Legislative Decree no. 150/2011, against this provision it is possible to lodge an appeal before the ordinary judicial authority, under penalty of inadmissibility, within thirty days from the date of communication of the provision itself or within sixty days if the appellant resides abroad.

Rome, 6 February 2020

PRESIDENT

Soro

THE SPEAKER

Califano

THE SECRETARY GENERAL

Busia