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PRINCIPLE FOR DATA PRIVACY

FOR OPIC CHARACTER

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The Personal Data Protection Authority met upon invitation

of its President in a regular meeting at its headquarters on 16-01-2018, in order to

decide on the process of issuing a license for the processing of sensitive data

health for the purposes of scientific research. Konstantinos Menoudakos appeared,

President of the Authority and regular members Konstantinos Christodoulou, Pyridon

Vlachopoulos, Antonios ymbonis, Konstantinos Lambrinoudakis, Charalambos

Anthopoulos and Eleni Martsoukou as well as the alternate member Grigorios

Tsolias who had been assigned the duties of rapporteur. the meeting, without right

vote, the Head of the Department also attended, by order of the President

Auditor Philippos Mitletton, and auditor Hariklia Latsiu, specialist scientists –

lawyers, as assistant rapporteurs, and Irini Papageorgopoulou, his employee

Administrative-Financial Department, as secretary.

The Authority took into account the following:

1. In recent years, the number of applications, especially large ones, has increased significantly

public nurses

individual researchers

institutions of the country, which forward requests

(undergraduate or postgraduate students, candidates

PhDs or health professionals in general), who in the context of preparation

research papers wish to gain access to their records. Indicative

it is stated that according to the statistics of the Authority's report

in 2016, a total of 196 new cases were submitted, which concerned the sector

of health and of which a large number had as their object the granting of a license for

conducting research on data controllers who provide health services, and

number of licenses granted by the Authority for health sector affairs

amounts to 69% of the total issued licenses of the same year (see charts 7

and 15, p. 35 and 41 of the 2016 Annual Report).

2. During the examination of the relevant applications, the Authority requests from the applicant nursing

institution (clinic, diagnostic center and health service provider in general),

after prior consultation with the interested (individual) researcher, to

clarify essential elements of scientific research and, in particular: 1) what is the

subject of the research (title), 2) how the specific research will be carried out (e.g.

on-site study of Hospital records and which or distribution of questionnaires to

patients), 3) certificate of the relevant institution for the status of the applicant researcher

(undergraduate or postgraduate student, PhD candidate). the last two

cases requests to find out who is the appointed three-member committee and mainly the

designated professor, as supervisor of the specific research, 4) the complete data

address of the researcher (home address and telephone), 5) if the Scientific

board or the Ethics Committee of the Hospital has approved the specific one

request of the researcher, sending a copy of the relevant decision.

3. The Authority with its series of decisions (see in particular decisions 46/2004, 47/2004, 32/2006,

54/2008, 63/2009, 10/2011 and 121/2011) has prescribed the legality conditions

processing of personal data, both simple and sensitive, for

research purposes and in particular for the preparation of a postgraduate study or

doctoral thesis. this context, as the Authority consistently judges, the implementation

scientific research constitutes a legal purpose of processing, in the sense of article 4

of Law 2472/1997, among others due to the fact that according to Article 16 par. 1 of

by statute, the development and promotion of research is an obligation of the State.

3. In particular, the Authority has the authority to take over relevant cases,

in principle, pursuant to article 7 par. 2 item f of Law 2472/1997, which provides

that exceptionally it is legitimate to process sensitive data after its permission

Authority, when the processing is carried out for research and scientific purposes

purposes only and on the condition that anonymity is maintained and that everything is received

the necessary measures to protect the rights of the persons in which

are mentioned. specifically, the Authority considers that the processing of personal data for

the purpose of conducting scientific research must be carried out, in particular, under

the following conditions: a) the researchers' access to the premises

keeping the record, so that no personal data escapes the sphere

influence of the controller-owner of the file, b) the researcher puts under

processing from the archive only those elements that are according to his scientific judgment

necessary for the completion of his specific research project and c) against

completion of research and prior to publication or in any other way

use of its results, the researcher shall anonymize them

personal data it has collected and to destroy any existing

named file it has collected. often, it is found in practice that the research

is conducted with the consent of the interested subjects-patients

nursing institutions. in the latter case, its provision applies

article 7 par. 2 item a' of Law 2472/1997.

4. Furthermore, the Authority, by decision 31/2013, ruled that in the case of "third parties"-

researchers who wish to gain access to the controller's records

processing, the issuance of two licenses is required: one to the controller-

file owner to extract sensitive data from his file and a

second to the researcher for the sensitive data he will collect. the last

case he himself becomes responsible for the processing of this data for him

purpose of conducting scientific research1.

5. The General Regulation 2016/679 in the provision of article 89 paragraph 1 prescribes the

rules for processing personal data for the purposes of scientific research with

ensuring guarantees for the non-disclosure of the subject's identity

data (e.g. through pseudonymisation), while paragraph 2 of the same article provides

the possibility for member states to establish restrictions on its rights

access, correction, deletion, opposition and limitation

processing for data processing carried out for research purposes

purposes2. Finally, in recital 156 of the General Regulation it is provided that the

1 Decision 31/2013 SC 3 and 4.

2 Article 89 Safeguards and derogations regarding the processing for archiving purposes to the

public interest or purposes of scientific or historical research or statistical purposes: "1. THE

processing of personal data carried out for research purposes

must comply with other relevant legislation, such as that for clinics

tests. in this regard, Regulation 536/2014 of the European Parliament and

council for clinical trials of medicinal products intended for humans poses

as basic principles for the conduct of clinical studies: a) protection and

ensuring the rights, dignity and well-being of the participants and b)

the production of valid and reliable data (article 3). To ensure the

these principles provide, among other things, that clinical studies are approved in terms of

their scientific and ethical adequacy by an ethics committee (article 4),

as well as that the clinical study is carried out, in principle, with the consent of the interested party

person (Article 28 of Regulation 536/2014)3.

6. the majority of cases examined by the Authority the investigators, who carry

the status of doctors or other health professionals (and whom the Authority, such as

mentioned above, after the decision 31/2013 makes it responsible for processing in respect of

record that they collect and keep), are bound, beyond his general obligation

of article 371 of the Civil Code for the observance of professional confidentiality, by their relatives

codes of conduct regarding privacy and confidentiality. For example,

processing for archiving purposes in the public interest or for scientific or historical purposes

research or statistical purposes is subject to appropriate safeguards, in accordance herewith

regulation, regarding the rights and freedoms of the data subject, in accordance with

this regulation. These guarantees ensure that the technical and organizational measures are in place

measures, in particular to ensure compliance with the data minimization principle. Those in question

measures may include the use of pseudonyms, as long as such purposes may

be fulfilled in this way. As long as said purposes can be fulfilled by further

processing which does not allow or no longer allows the identification of data subjects,

said purposes are thus fulfilled. 2. When personal data

are processed for the purposes of scientific or historical research or for statistical purposes, the

Union or Member State law may provide for derogations from the rights listed

in articles 15, 16, 18 and 21, without prejudice to the conditions and guarantees referred to in

paragraph 1 of this article, since the rights in question are likely to make it impossible or

to seriously hinder the achievement of the specific purposes and since the said deviations are

necessary for the fulfillment of said purposes. 3. When personal data exists

processing for archiving purposes in the public interest, Union or Member State law

may provide for derogations from the rights referred to in articles 15, 16, 18, 19, 20 and 21,

subject to the conditions and guarantees mentioned in paragraph 1 hereof

article, since the said rights are likely to make impossible or to seriously hinder

the achievement of the specific purposes and as long as said deviations are necessary for the fulfillment of said purposes. 4. When the processing referred to in paragraphs 2 and 3 serves the same moment and other purpose, the derogations only apply to the processing for the purposes that provided for in said paragraphs".

3 Corresponding formalities are provided for under no. C5a/59676 joint ministerial decision of the Ministers of Economy and Development and Health regarding provisions for the implementation of Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical tests intended for humans and the repeal of Directive 2001/20/EC (Official Gazette B 4131/22.12.2016), see in particular Articles 8 and 18.

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Article 13 of Law 3418/2005 (Code of Medical Ethics) establishes the medical confidentiality, while respectively in the provisions of articles 11 of Legislative Decree 216/2001 and 25 of Law 3252/2004 establishes nursing confidentiality. In addition, especially for doctors the article 14 par. 5 of Law 3418/2005 provides regarding the investigation that the doctor receives all the necessary measures, so that in the case of scientific publications not the identity of the patient is disclosed in any way, and only if because of it nature of the publication, the disclosure of the patient's identity is necessary or elements that indicate or can lead to the verification of identity of, the specific written consent of the patient is required.

SEVEN E ACCORDING TO THE LAW

In view of the above, and taking into account, in particular: a) the fact that in all cases of examining requests from individual researchers for their access in the records of the nursing institution (medical records) or conducting interviews with patients of nursing institutions, the Authority granted the requested license to nursing institution, making at the same time - by virtue of the Authority's decision 31/2003 - the researcher responsible for processing the file he collects and that in the cases

during which reservations arose as to the risk of weakening it

right of the subject-patient in view of conducting a specific study, the

Authority considered that this risk is prevented in particular due to the approval of the research

protocol from the relevant (university) institutions and from their relevant approval

Scientific councils of the relevant nursing institution, b) of the large number

of the relevant applications submitted to the Authority, c) the possibility of the Authority to

apply simplified processing rules to processing for which it judges

that they do not pose particular risks to privacy and d) perspective

abolition of the obligation to notify and permit sensitive processing

data and their replacement with effective procedures and mechanisms

for the protection of privacy in accordance with the General Regulation 2016/2794, it is judged

4 See Recital 89 of the General Regulation: "Directive 95/46/EC provided for a general obligation

notification of the processing of personal data to the supervisory authorities. Although the

this obligation implies an administrative and financial burden, it did not contribute in all cases to

improving the protection of personal data. Therefore, general obligations

of such disclosure, without variation, should be repealed and replaced

with effective processes and mechanisms focused on those types of transactions

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it is advisable to abolish the issuance of an ad hoc license for the purpose of conducting research

study. For this purpose, the original license of nurses must be amended

institutions for the operation of the file they keep for the purpose of providing the

health services, so as to include a term for the purpose of conducting research

of studies by the controller himself (nursing institution, medical,

nursing and other staff of the controller) and by individuals

researchers. it is reduced that the researchers are either included in the sphere of the person in charge

processing, whether they are "third parties" in terms of the controller, are bound by

the codes of ethics applicable in each case regarding its observance

privacy and security of the processing and are therefore subject to criminal charges (art

371), disciplinary (codes of ethics) and civil liability (Article 57 Civil Code). With the

incorporation of the appropriate term in the operating license of the nursing institution,

the Authority will be exempted from the relevant requests to issue an ad hoc license for its purpose

conducting research studies.

This is tolerable under the current personal data protection regime as the

ratio of the establishment of the obligation to disclose the processing and the

prior permission of the Authority for the processing of sensitive data is recommended

in increasing the guarantees regarding the processing of sensitive data

of the subject. the case of carrying out scientific studies by individuals

researchers, the above conditions are guaranteed by the special condition incorporated in

general permission to process sensitive data granted to the nursing facility

institution. Therefore, there is no need to issue a special permit to the individual researcher,

despite the fact that he holds the position of data controller, he must, however,

be incorporated into nurses' licenses

institutions condition in which the

an individual researcher, who becomes a data controller, is exempted from

the obligations to notify and obtain permission from the Authority in accordance with the provisions

in the provisions of articles 6 and 7 of law 2472/1997, however, carries all the

obligations deriving from this law, especially regarding its observance

privacy and security of processing. the concept of the individual researcher

processing that may result in a high risk to rights and freedoms

of natural persons due to their nature, scope, context and purposes. These

types of processing operations may be those which, in particular, involve the use of new

technologies or which are of a new type and when no impact assessment has previously been carried out in terms of

concerns the protection of data by the data controller or when it becomes necessary due to

of the time that has elapsed since the initial processing".

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including undergraduate and postgraduate students, PhD candidates,

as well as other individual researchers who are bound by the medical or otherwise

professional secrecy.

For those reasons

1. Pursuant to article 7 par. 2 item f of Law 2472/1997 is added to

licenses issued by the Authority to the data controllers-hospital institutions

for the purpose of providing the health services condition according to which it is allowed

the processing of patient health data by its staff

nursing institution and individual researchers for the purpose of the conduct

research studies, under the following conditions:

a) The Scientific Council of the nursing institution has approved the conduct

of the specific research work in its area5.

b) the cases in which the processing of data for research purposes

is not carried out with the consent of the patients concerned (article 7 par. 2

item a' of Law 2472/1997), the controller must inform them

patients, as data subjects, not necessarily during data collection

(according to article 11 par. 1 of Law 2472/1997), but in any case no later than before

processing carried out for research study for this distinct

processing that will be carried out (Article 11 par. 3 of Law 2472/1997). When conducted

retrospective study, for which the researcher cannot obtain the previous one

consent of the patients, in his application to the controller, o

researcher has an obligation to explain the reasons why it is not possible

prior information and obtaining consent of the hospitalized or hospitalized

5 It should be noted that especially in the public sector, article 36 par. 2 of Law 3979/2011 provides for the establishment project management team (PMO) with the following authority: "2. O.D.E. or lives one of its members as internal personal data protection officer. The internal responsible protect us of personal data takes care of receiving all the necessary technical and organizational measures to comply with the principles and obligations described in this law and in the 2472/1997, such as the adoption and implementation of security and personal data protection policies character, the periodic training and the awareness of the employees and operators of the organization regarding the protection of personal data, the proposal to receive internal control procedures and verifying the effective implementation of measures during the operation of systems and services electronic government".

patients.

2. When an application for the grant or renewal is submitted by the nursing institutions permission to keep a record with health data pursuant to article 7 par. 2 item d of Law 2472/1997, the proposed condition will automatically be included in the license. The the same applies when the request concerns access to the records of the nursing institution by the staff of the nursing institution or by individual researchers for him purpose of conducting research studies.

The President of the Authority

The Secretary

Konstantinos Menudakos

Irini Papageorgopoulou