

INFORMATION NOTE IN ACCORDANCE WITH ART. 13 OF REGULATION (EU) 2016/679 (General Data Protection Regulation – GDPR)

1. Giannina Gaslini Children’s Hospital (hereinafter referred to as “Istituto”), as Data Controller (hereinafter referred to as “Controller”), is in control of the processing of personal and sensitive data of its patients in compliance with Regulation (EU) 2016/679 (hereinafter referred to as “Regulation”) and with the obligation of confidentiality, which it must fulfil and has always fulfilled. In particular, sensitive data, including specifically health data, will be processed only after obtaining a valid consent, for the purpose of health care, in compliance with the health law in force and, in particular, the provision of services established by the National Health Service (NHS).

2.

PURPOSE OF PERSONAL DATA PROCESSING

Personal and sensitive data will be processed for the following purposes:

- Prevention, diagnosis, treatment, rehabilitation and, ultimately, for the primary purpose of protecting the health of the person receiving health care;
- Administrative activities related to the above-mentioned health care services as well as other activities provided by the NHS such as planning, management, control, and evaluation of health, care, drug surveillance and authorization of marketing of medicinal products, certification activity, management and control of accredited legal persons or legal persons having an agreement with the NHS, etc.
- Scientific research and statistics in medicine, biomedicine, and epidemiology;
- Legal protection of the rights and interests of the Institute, its employees and similar persons, patients, and/or third parties.

It could be necessary to process the personal data of patients for reasons of public interest in the domain of public health, such as the protection against cross-border severe health threats or the assurance of high quality and safety levels of health care services as well as of medications and medical devices.

Health data of family members of the patients will be processed only when strictly necessary according to the attending physician.

When expressly authorized, data processing could also be aimed at informing the data subject about the activities and services of the Institute and the events concerning him/her.

RELEASE OF PERSONAL DATA

Release of personal and health data is necessary to achieve the above-mentioned objectives and it is compulsory for the administrative purposes

detailed above. Except for health urgencies and emergencies, when release of personal data for the above-mentioned purposes is refused, patients could be unadmitted to health care and the required services and, as a consequence, the Institute could be unauthorized to provide these services and to carry out the activities established by law. Release of personal data for scientific research and statistical purposes in the field of medicine, biomedicine, and epidemiology is optional and refusal to release personal data does not restrict access to and provision of the required health care services, even though the use of data for research purposes can contribute considerably to the improvement of disease prevention, diagnosis, and treatment.

In these cases, the Controller adopts technical and organizational safety measures aimed at guaranteeing data minimization.

CONSENT

Acquisition of consent to processing of health data is necessary for access to and provision of health care services. Except for emergencies/urgencies, refusal to give consent, by using the appropriate form, makes it impossible for the Institute to process the data and can block the provision of the required health care services. Consent is not required when processing of personal data is necessary for administrative purposes related to the provision of health care services and for compliance with National Health Service obligations and/or health regulations. Consent is not required even when data are processed for reasons of public interest in the domain of public health. Release of consent for the above-mentioned scientific research and statistical purposes remains optional.

Consent can be withdrawn at any time, without affecting the lawfulness of processing based on consent before its withdrawal.

RETENTION PERIOD

Personal data will be processed as long as necessary for the complete and correct provision of the required services, for purposes of prevention, diagnosis, treatment, and rehabilitation aimed at the protection of the health status and safety of the data subject and/or of third parties and/or of the community, for administrative purposes related to the provision of prevention, diagnosis, treatment, and rehabilitation services, and subsequently for compliance with specific legal requirements as well as with the Institute's procedures.

COMMUNICATION AND DISCLOSURE OF DATA

Data to be processed can be disclosed to the Institute's health care professionals and administrative personnel previously authorized and informed by the Controller or to appointed external providers in compliance with art. 28 of the Regulation.

The Institute also pursues education and training objectives (Leg. Decree 517/1999); for this, reason, in occasion of the provision of some health care services, personal data of patients can be processed also by students, previously authorized and informed, except for non-consent expressed by the patients' parents or guardians.

In compliance with the law in force and insofar as each is concerned, data can be communicated to the following third parties:

- Public hospitals and accredited health care facilities, local health authorities, national and regional health services;
- Social security bodies for relevant purposes;
- Insurance companies, agents, and brokers, insurance company associations and consortia, attorneys, translators, insurance company medical consultants, experts, car dismantling centres, service companies in charge of claim management and settlement aimed at the protection of the Institute and its employees; these legal entities can in turn disclose the data to specialized consultants and companies for the same purposes;
- Judicial Authority and Public Security in cases expressly established by law;
- Other third parties appointed by law or by the Regulation.

When expressly authorized, personal and sensitive patient data can be disclosed to the family doctor or other persons expressly authorized and appointed by parents/guardians.

Apart from the above-mentioned cases, disclosure of personal data retained by the Institute to third parties after extraction from the Institute's files (right of access to administrative acts or generalized data access) occurs according to the modalities and forms established by law n.241 of August 7, 1990 and related modifications and by legislative decree n. 33/2013 and related modifications, whose application is an activity of relevant public interest. Except for compliance with administrative transparency obligations, personal data processed by the Institute will not be disclosed nor transmitted abroad. For scientific research and statistical purposes, data can be disclosed and transmitted abroad only in an anonymous form. When expressly authorized, patient data can be used to e-mail the medical report to parents/guardians/legal representatives of patients.

RIGHTS OF THE DATA SUBJECT

As regards their personal data processed by the Institute, data subjects can exercise all the rights expressed in art. 15 and subsequent articles of the Regulation. In particular, at any moment they can request from the Controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as to exert the right to data portability in the cases established by law. Appropriate application must be sent to "Istituto Giannina Gaslini, Data Controller, Via

Gerolamo Gaslini 5, 16100 Genova, Italy” or to the Data Protection Officer, available at the Institute, at the following e-mail address: dpo@gaslini.org.

When data subjects believe that processing of their personal data by the Institute breaches the provisions of the Regulation, they have the right to lodge a complaint with the Data Protection Authority, as established in art. 77 of the Regulation, or to an effective judicial remedy (art. 79 of the Regulation).

INFORMATION NOTE ON PROCESSING OF DATA STORED IN AN ELECTRONIC HEALTH RECORD

The Institute has an electronic health record containing the patients’ medical history aimed at improving the process of care.

1. The Electronic Health Record (EHR) is an instrument for the collection of health data in electronic format. The EHR contains information on the patient’s health status, present and past clinical events treated at the Institute (e.g. documents related to hospitalizations, outpatient care, admissions to emergency room). Aim of the EHR is to document the clinical history of the patient, which can be consulted only after previous consent by the patient’s parents or guardians.
2. The goal of health data processing through the electronic health record is to guarantee the improvement of the processes of prevention, diagnosis, treatment, and rehabilitation, and to allow the Institute’s health care professionals attending the patient at different moments in time to access information produced throughout the hospital and not only in single wards. The EHR is also used by the Institute for processing only those data that are essential to administrative management of the process of care.
3. Consent to processing of health data through the EHR is free and optional and can be expressed using the privacy consent form. Therefore, the EHR intended as an instrument for data consultation can be created only after obtaining the consent of patient’s parents or guardians.
4. Only the Institute’s persons, specifically authorized, can access the EHR for purposes related to the process of care and for the other purposes described above. Furthermore, time of each access to the EHR is recorded, and the person accessing it is identified.
5. Consent to processing of health data through the EHR can be modified or withdrawn at any time by applying directly to the Controller.
In case of withdrawal, the EHR can no longer be visualized until the expression of a new consent. If consent is denied, EHR visualization is not allowed. In case of denial, either full or partial, it is still possible to receive the required healthcare services, however it should be underlined that the possibility to access the EHR is important to guarantee the easy use of available data and to optimize the processes of prevention, diagnosis, treatment, and rehabilitation.

In case of withdrawal or denial of consent, patient health data remain available to the health care professionals of the unit where they have been produced and are maintained in compliance with legal requirements, but they cannot be visualized by professionals from other units.

6. After the expression of consent to data processing, it is possible to block the visualization of single episodes of the process of care recorded in the EHR. This possibility, which has been established as a further measure for protection of confidentiality, is defined as the “right to data anonymization”. This right can be exercised, even after the provision of a healthcare service, by emailing the Data Protection Officer at the following e-mail address: dpo@gaslini.it. The anonymization of single clinical events, which can be reversed at any time, is obtained with specific technical modalities in a way that subjects authorized to access the EHR cannot visualize these single events nor learn automatically or even temporarily about the choice of data anonymization made by the data subject. This circumstance is defined “anonymization of anonymization”.

It is always possible to reverse anonymization of data, that is to allow again their visualization, by applying to the Data Protection Officer.

7. Processing of personal data through the EHR for purposes of prevention, diagnosis, and treatment by experts, insurance companies, employers, scientific associations or organizations, or other healthcare administrative bodies is not allowed.
8. In addition to the rights established in art. 15 and subsequent articles of the Regulation, according to the guidelines on the EHR established by the Data Protection Authority, the data subject has also the right to visualize accesses to his/her EHR, their time and date, as well as the Institute’s units that had access to the EHR, by formally applying to the Controller.

The Controller is the “Istituto Giannina Gaslini”, Via Gerolamo Gaslini 5, 16148 Genova. The Data Protection Officer can be contacted at the following e-mail address: dpo@gaslini.org.

Istituto di Ricovero e Cura a Carattere Scientifico “GIANNINA GASLINI”

Via Gerolamo Gaslini 5, 16147 Genova – Italia

Tel. +39 010 56361 – www.gaslini.org