



TIMBRO DELLA S.O.

To be filled by the patient

CONSENT TO THE PROCESSING OF PERSONAL DATA IN THE HEALTH CONTEXT AND ARRANGEMENTS FOR THE EXCHANGE OF INFORMATION ABOUT HEALTH STATUS (EU Regulation 679/2016)

I, the undersigned, Surname _____ Name _____ born in _____, on the _____ Tel. _____.

DECLARE

That I have received and read the note on the processing of personal data in the health context;

- 1) That I expressly grant my consent to the Azienda Ospedaliero – Universitaria delle Marche to process my personal data by means of medical Apps or Services/Applications used on devices, for purposes other than telemedicine;
2) That I expressly grant my consent to the Azienda Ospedaliero – Universitaria delle Marche to process my personal data for the purpose of subsequent and possible scientific and/or statistical research (also in medical/biomedical/epidemiological context) exclusively for retrospective studies (that is, studies based on data contained in the medical records produced at the time of your hospitalization/treatment/examination and originally collected for treatment purpose) and in case it is not possible to get in contact with you and in compliance with the laws on scientific (also in medical/biomedical/epidemiological context) and/or statistical research, on the following:

- type of research (to be filled out by the health professional)

(please note: state the type of research exactly according to its known state and in particular state the context in which the research is carried out and its goals):

- 3) That I am aware that consent, after being granted, can be changed or withdrawn, at any time, in whole or in part;

That I give my consent to disclose information on the location of my current hospitalization

- YES
NO

(choose one only if you have been hospitalized)

That I grant my consent to sharing information about my health status with the following persons:

- Spouse Tel Children Tel
Parents Tel Other Tel
No one Anyone

- YES
NO

Ancona, (date) SIGNATURE OF THE DECLARANT

If the patient (whether an adult or a minor) is incapacitated, the person authorized to grant consent signs the following:

SELF-CERTIFICATION

I, the undersigned, _____ born in _____ on the _____,

pursuant to Articles 46 and 47 of Presidential Decree No. 445 of December 28, 2000, aware of the criminal penalties prescribed in the event of a false statement, or the creation or use of false documents, as established by Article 76 of the same Presidential Decree No. 445/2000, concerning

patient _____ born in _____ on the _____

declare under my own responsibility:

- that I have parental authority over the minor named above
- that I am the guardian
- that I have limited guardianship
- that I have power of attorney
- other (specify how you are legitimized to sign in the name and interest of the patient)

SIGNATURE OF THE DECLARANT _____

1) Find attached a copy of the declarant's valid ID



INFORMATION NOTE AND CONSENT FOR THE ELECTRONIC HEALTH DOSSIER (EHD)

Dear Madam/Sir,

the Azienda Ospedaliero-Universitaria Ospedali Riuniti “Umberto I- G.M. Lancisi- G. Salesi” of Ancona (hereinafter referred to as Azienda), as controller, informs you that it makes use of a new information system called Dossier Sanitario Elettronico (Electronic Health Dossier, hereinafter referred to as EHD), in order to improve the health care process.

EHD is the totality of health data stored in an electronic format about your health status and gathered during current and past health care services provided by both the National Health System and private specialists (e.g.: E.R. report, hospital discharge report, medical exam report, etc.) used to document your clinical history.

PURPOSE OF THE PROCESSING USING THE HEALTH DOSSIER AND ITS CONSULTATION

The EHD can only be created with your consent and the information it contains or processes is available only to the health care professionals that take care of you.

The Dossier allows our hospital’s health care staff to know your clinical situation as completely as possible and to make use of the information on your health to provide you with an ever more tailored care.

We also inform you that the dossier can be accessed, by authorized individuals only, when this is deemed necessary in order to protect the health of a third party individual and/or of the collectivity.

The access to your dossier is protected and limited to authorized individuals by means of identification procedures that allow to identify and track the identity of the health care professional who has access to the information included in the EHD.

Therefore, access to the dossier is allowed and reserved exclusively to the staff of the Azienda and the dossier is only used in the hospital: it is not visible nor available to the staff of other health care facilities, to your family doctor nor to your family pediatrician.

CONSENT TO THE CREATION OF AND ACCESS TO THE EHD

Creating the EHD and accessing the information it contains can only happen with a specific and express consent of the data subject.

Please be advised that consenting to the creation of the dossier is voluntary and optional, and any refusal to create the EHD will not have any negative consequences on your ability to receive the requested health care services.

Consent to the creation of the EHD is obtained by the health care staff in written form, while simultaneously electronically recording the patient’s statement at the time of admission.

On the matter of using past clinical data, or data gathered before consent was granted, please note that the data subject must express specific consent for the inclusion of such data in the EHD and for its consultation by health care personnel. This consent pertains to the possibility of accessing past data that was created and stored in the IT system of the Azienda, for which the Azienda is the data controller; however please be aware that completeness of the clinical information is not guaranteed, since consideration must be given to the data format and its availability.

In order to ensure the privacy and dignity of patients, some information of particularly sensitive nature (e.g. data on people who have been victims of sexual assaults or pedophilia, addiction to drugs, abuse of psychotropic substances and alcohol, abortion and anonymous delivery) can be processed by EHD only with express and specific consent, which is granted with a specific additional statement.

In the case of past clinical events, consent expressed for access through the dossier may concern such kind of information, for which the data subject has the right to have data on any individual episode blocked or to withdraw consent to access it.

WITHDRAWAL OR MISSING CONSENT TO DATA PROCESSING THROUGH EHD

Data subjects can withdraw consent to the creation of the EHD and to processing data through the Dossier at any time by sending a specific signed request to the Public Relation Office.

In case of withdrawal of the creation of the EHD, viewing the dossier and the information it contains will not be possible until consent is granted again.

The possible partial or total refusal of access to the health dossier does not affect your ability to receive the required health care services.

Please be aware of the usefulness of this tool to ensure the easy use of available data, allowing to provide a health care service tailored to the information received. In case of withdrawal or refusal of consent, your data will still be available to the staff of the Operational Unit that generated them for treatment and care purposes and for storage as required by law, but will not be visible to professionals at other operational units.

RIGHT TO DATA BLOCKING

After granting consent to processing data through the EHD, it is possible to make data pertaining individual health care episodes (e.g. an E.R. treatment or a specialized health care service) not visible and not accessible.

This ability is an additional form of privacy protection and is called “right to data blocking”.

The right to data blocking can be exercised:

- immediately, by informing the Operational Unit providing the health care service that you want the data pertaining the service to be blocked;
- at a later time, by making a specific signed request to the same Operational Unit where your consent was granted.

The blocking of the clinical episode, that can be revoked at any time, is done by means of technical procedures which ensure that individuals who have access to the health dossier cannot view the blocked episode nor can be automatically informed, not even temporarily, that the data subject has so chosen. Such condition is called “obscured blocking”.

YOUR RIGHTS

Please be informed that at any time the data subject can exercise the rights defined in articles 12 through 23 of EU Regulation 2016/679, which state, in summary, that you can obtain information on the processing of your data, on the modes, purposes, and working logic, and on the use of data through the dossier.

The data subject can also request to update, rectify or complete their data processed by EHD and, as stated above, can request to block their data, also temporarily.

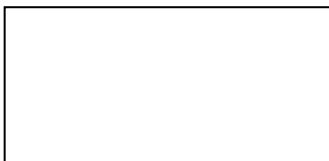
Finally, any data subject has the right to request to erase, block or anonymize data that are processed in violation of the law; they can also withdraw their consent to the creation of the EHD and object to the processing of their personal data for legitimate reasons.

Controller: Azienda Ospedaliero-Universitaria Ospedali Riuniti “Umberto I”, “G.M. Lancisi”, “G. Salesi” – Via Conca, 71 60020 Torrette – Ancona – represented by the Director General.

Processors: Directors of the Wards (S.O.D. and S.O.S.D.).



TIMBRO DELLA U.O.



to be filled
by the patient

CONSENT TO DATA PROCESSING THROUGH ELECTRONIC HEALTH DOSSIER (EHD)

I, the undersigned, Surname Name
born in, on the Tel

DECLARE

That I have received and read the note on the processing of personal data through Electronic Health Dossier (EHD).

And

That I expressly grant my consent to the creation of my Electronic Health Dossier (EHD).

That I expressly grant my consent to the inclusion in my EHD of clinical data prior to the date of this document.

Or:

That I refuse to grant my consent to the creation of my Electronic Health Dossier (EHD).

Ancona, (date)

SIGNATURE OF THE DECLARANT

If the patient is a minor or is under interdiction or consent is granted by a person other than the data subject, then the person with parental authority, the person authorized to grant consent or the person, other than the patient, requested to grant consent to processing health data through EHD, signs the following:

SELF-CERTIFICATION

I, the undersigned, _____ born in _____ on the _____,
pursuant to Articles 46 and 47 of Presidential Decree No. 445 of December 28, 2000, aware of the criminal penalties prescribed in the event of a false statement, or the creation or use of false documents, as established by Article 76 of the same Presidential Decree No. 445/2000, concerning patient _____ born in _____ on the _____

declare under my own responsibility:

- that I have parental authority over the minor named above (1)
- that I am the guardian (1)
- that I have limited guardianship (1)
- that I have power of attorney (1)

SIGNATURE OF THE DECLARANT

(1) Consent is given by a person other than the data subject in cases where the patient is unable to grant their own consent. If the patient is a minor, after they reach the age of majority, their informed consent must be acquired again at the first available opportunity.

CONSENT FORM FOR CONSULTATION OF PERSONAL AND SENSITIVE DATA THROUGH THE ELECTRONIC HEALTH RECORD (EHR) AND SUBSTITUTE DECLARATION

EU Regulation 2016/679 and Presidential Decree 445/2000, art. 46

I, the undersigned (name and surname) _____ Born in _____ _____ on ____/____/____ Tax Code _____ Resident in (_____ municipality, province) _____ street/square _____ postcode _____ -on his own

That is, as - Legal representative of (in this case attach a copy of the declarant's identity document) (name and surname) _____ Born in _____ _____ on ____/____/____ Tax Code _____ Resident in (_____ municipality, province) _____ street/square _____ postcode _____
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Aware of the criminal liability for false or misleading statements pursuant to art. 76 of Presidential Decree 445/2000

a) I declare that I have received and understood the information pursuant to Articles 13 and 14 of EU Regulation 2016/679 on the processing of personal data carried out with the Electronic Health Record (EHR) also published on the website **<https://fse.sanita.marche.it>** regarding the processing of my personal data for the following reasons:

- filling in my name of the Electronic Health Record (EHR) with my personal and sensitive data suitable for revealing my past and future health status (hereinafter for brevity health and social-health data);
- consultation of the ESF by authorized persons;

and aware that:

- the processing concerns in particular personal and sensitive data and data capable of revealing the state of health;
- Consent to consultation, once given, may be modified or revoked at any time, in whole or in part;
- I will be able to decide at any time to black out any single document or information already present in the FSE, provided that the blacked out data will always be visible to the owner who generated them;

b) I declare, on my own behalf or in the interest of the person represented as per the self-certification provided above, that I freely and knowingly consent to the consultation of my personal and sensitive health and social-health data as indicated below:

I AGREE TO CONSULTATION OF THE ELECTRONIC HEALTH RECORD BY AUTHORISED OPERATORS

-YES

-NO

This consent to data access is valid indefinitely unless revoked and/or modified. The minor interested party, upon reaching the age of majority, must provide a new consent form. If this form is being delivered by a third party, the authorized person, with their own identification document, must present a proxy and a photocopy of the front and back of a valid identification document of the person delegating the consent.

Place _____ Date ____/____/____ Signature (in full) _____

Space reserved for the office

<i>module collected by the operator:</i> (name and surname) _____ on date _____ signature _____
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**NEUROPSYCHIATRY
CHILDISH
MARCHE REGION NEONATAL SCREENING
CENTER
DIRECTOR
Dr. Elisabetta Tarsi**



Nurse Coordinator
Loriana Naspini
For any information regarding the
activities: 0721/882419 from 11am to 1pm
Email: Elizabeth Tarsi
@ospedalimarchenord.it

TERRITORIAL HEALTH AUTHORITY

**INFORMED CONSENT FORM FOR THE
NEONATAL SCREENING PROGRAM**

Dear Parents

every child born in the Marche Region is subjected to an examination for the early identification (neonatal screening) of **Phenylketonuria, Congenital Hypothyroidism, Cystic Fibrosis, Galactosemia, Biotinidase Deficiency, Other Aminoacidopathies, Organic Acidurias and Beta-Oxidation Defects.**

Newborn screening has been made mandatory in Italy for the first three diseases with **Law 104 of 1992** while for the others with the **Law 167 of 2016** which regulates extended metabolic screening.

Your baby, like all babies born in this region, undergoes a birth test. **heel sampling**, from which the blood needed to perform the screening is collected.

Early detection (screening), diagnostic confirmation, and early treatment of these pathologies can significantly alter the prognosis, avoiding neurological or organ damage, serious disability or disease, and, in the most severe cases, life-threatening conditions.

If it is necessary to repeat the test due to the presence of altered values in the first determination, you will be contacted by the Birth Unit where your child was born or by the Neonatal Screening Center to repeat the sampling.

The exams of **diagnostic confirmation** are carried out in several laboratories in Italy, more frequently in the laboratory of the Marche Nord Pesaro-Fano Hospital Company where the screening is carried out and at the Analysis laboratory of the Bambino Gesù Pediatric Hospital in Rome/Biochemistry-Metabolic Section.

Given the importance of screening tests, the material collected—while preserved—may be used for research purposes or for other diagnostic tests for genetic and metabolic diseases, while respecting privacy or the right to confidentiality.

Information about newborn screening can be found in the online information brochure on the company website.

The file can be downloaded in various languages at the following links:

<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-italiano>
<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-inglese>
<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-french>
<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-cinese>
<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-albanese>
<https://www.astpu.marche.it/it/organizza/documenti/screening-neonatale-malattie-rare-arabo>

Child Neuropsychiatrist
Dr. Elizabeth Tarsi

Marche Region Health Service
PESARO URBINO TERRITORIAL HEALTH AUTHORITY Registered office:
Piazzale Cinelli 4 - 61121 Pesaro - VAT number 02789340417
PEC: ast.pesarourbino@emarche.it

NEUROPSYCHIATRY
CHILDISH
MARCHE REGION NEONATAL SCREENING
CENTER
DIRECTOR
Dr. Elisabetta Tarsi



Nurse Coordinator
Loriana Naspini
For any information regarding the
activities: 0721/882419 from 11am to 1pm
Email: Elizabeth Tarsi
@ospedalimarchenord.it

TERRITORIAL HEALTH AUTHORITY

INFORMED CONSENT FORM FOR THE
NEONATAL SCREENING PROGRAM

I, the undersigned _____
(last name and first name in capital letters)

Born in _____ on _____

Mother/Father (delete the entry that is not relevant) Of:

_____ Born on _____
(surname and name of the newborn) (baby's date of birth)

I declare that:

- have been adequately informed about the Newborn Screening program in the Marche Region
- to have received the information brochure
- to exercise parental authority over the minor and that the other parent is informed

For this reason:

- I authorize / I do not authorize (delete the entry that is not relevant) the Regional Reference Centre for the Neonatal Screening of the Marche Region to perform genetic testing for cystic fibrosis in the cases provided for by the procedures adopted by the Center

Place and date: _____ Full signature _____

From the interview, it emerged that the parent had received the necessary information, using the information leaflet, and had freely expressed his consent.

Surname, name and qualification (in capital letters)
of the person responsible for the sampling who provided the information: _____

Place and date: _____ Full signature _____

