FORM 5.1: PATIENT INFORMATION NOTE - SHORT VERSION

INFORMATION NOTE PURSUANT TO ART. 13 AND 14 OF EU REGULATION GDPR 2016/679

Dear patient,

we would like to provide you with some information on articles 13 and 14 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 ("Regulation") on data processing carried out at Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione ("**ISMETT**"). You will receive documents that concern your involvement in activities such as drug trials or generic data collection.

ISMETT is a center of excellence in the field of transplantation and highly specialized therapies, accredited by JCI (Joint Commission International), an international body that certifies excellence of health care organizations, and compliance with high standards of quality and safety recognized by the international scientific community and by the WHO. ISMETT provides state-of-the-art health services thanks to its partnership with the UPMC Group headquartered in Pittsburgh, U.S.A. In order to ensure a close collaboration with these top international facilities, ISMETT's management was entrusted to UPMC Italy ("**UPMCI**"), the Italian subsidiary of the UPMC Group.

The information on your health status provided by you or by third parties (e.g. your family doctor) will be collected on paper or electronic means. This is required in order for you to access **treatment, diagnosis, rehabilitation, and prevention services**, and for communications and related administrative and accounting fulfillments. The legal basis for data processing is art. 6.1.b of the Regulation ("*processing is necessary for the performance of a contract to which the data subject is party*') and, as regards the exemption from the prohibition on the processing of special categories of personal data, of art. 9.2.h of the Regulation ("*processing is necessary for the purposes of medical diagnosis, the provision of health or social care systems and services pursuant to contract with a health professional*").

For training purposes, clinical care may be carried out in the presence of medical students. In this event, all necessary precautions shall be taken to limit any potential inconvenience, and your will to not abide by this procedure will be respected.

In addition, ISMETT being a government-approved research hospital (**IRCCS**), carries out research in the areas listed on its website under the "Research" page, in order to contribute to the general development of medical knowledge in the interest of public health ("**Current Research**"). This activity is financed by the Italian Ministry of Health on the basis of a law (art. 12-bis of legislative decree 502 of 30 December 1992) and, therefore, can be carried out without obtaining the consent of patients.

Furthermore, if you consent, as the legal basis for the processing, art. 6.1.a of the Regulation and, as regards the exemption from the prohibition on the processing of special categories of

personal data, art. 9.2.a of the Regulation ("*explicit consent of the data subject to processing*") your personal data may be used:

1. to create your electronic file [a.k.a. "dossier sanitario"] (also incorporating any previous clinical event) and allow ISMETT's staff to access updated and complete information on your health status, and provide better care.
2. **scientific research** : your data collected during treatment (except for genetic data) will be entered in encoded form (i.e., marked only with a code consisting of numbers and letters and not with your first and last name) in a database used by ISMETT to conduct retrospective studies (which do not affect the treatment given to it or require further examination or treatment). This data will be used anonymously to conduct research and, if anonymization is not possible, your specific consent will be collected (art. 6.1.a and 9.2.a of the Regulation).
3. to verify the **quality of care** and medical treatment received, and for planning care;
4. to receive e-mails, mail or texts containing **informational material** on ISMETT's initiatives.

With reference to the foregoing (consents from #2 to #4), you may provide or deny consent. Failure to provide informed consent shall in no way affect your medical care. Without prejudice to your freedom to provide or deny consent, failure to sign consent #1 may negatively affect the medical care you will in any case receive, with a release of liability of physicians and health care providers of ISMETT. Please note you may withdraw your consents at any time.

Your data shall be processed by a member of the clinical and administrative staff of ISMETT and UPMCI, acting in compliance with specific instructions on the objects and purposes of the data processing, and notified to third parties, appointed data processors, and providing ancillary services to ISMETT (e.g. professionals asked to provide specific consults, external laboratories, etc.) or to independent data controllers, in fulfillment of governing law or for the protection of their rights (e.g., NHS, institutions, municipalities, social security institutions, national and regional transplant center, disease registers, insurance companies). An updated list of all appointed parties can be requested to the Data Protection Officer or the Data controller, at the addresses listed below.

The information concerning your state of health will be kept according to the Italian Ministry of Health circular letter No. 61 of 19 December 1986. In particular, data contained in medical records and reports will be kept indefinitely, while radiology images will be stored for a period of no less than ten years. Data and samples, on the other hand, processed for research purposes will be kept for the duration of the research project and for at least 7 years following its conclusion (or longer in accordance with the applicable regulations or agreements between the participating centers), which are then anonymized.

Information regarding your presence at ISMETT and your health status will only be given to the persons you have listed at the end of this document, without prejudice to the provisions of law. You have the right to request authorization to access, delete, and to limit or deny the processing of your personal data (art. 15 and following of the GDPR). The application must be filed to ISMETT's Data Protection Officer at (ISMETT S.r.l. Via Discesa dei Giudici 4, 90133

Palermo, Italy or to the Data controller - Office of the Director of Health Care Activities available at the locations of the joint controllers or at direzionesanitariaprivacy@ismett.edu. As far as the research activity you may contact the Data Controller - Research Office at the locations of the joint controllers or email direzionescientifica@ismett.edu.
A template of the request is available from the Italian Personal Data Protection Authority ("Garante") https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1089924.
Should you deem your personal data has been processed in breach of the Regulation, you have the right to file a https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/4535524, pursuant to art. 77 of the Regulation.
Joint controllers are Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione (ISMETT) and UPMC Italy, both headquartered in Via Discesa dei Giudici 4, 90133 Palermo, Italy.

Detailed information is contained in the extended Information Note published on ISMETT's website under the "Privacy" page, which we invite you to consult or to request a paper copy at the time your acceptance.

Last updated: March 2024 (Version 4)

INFORMED CONSENT

I, the undersigned, _____ (name and surname)

Date and place of birth / /

in my own right **or in the capacity of***: or Trustee Guardian

having the sole/shared authority with

name and surname of patient

Date and place of birth / /

I HAVE READ THE INFORMATION NOTE AND I AM AWARE THAT ALL STATEMENTS MADE FOR ME OR IN THE ABOVE-MENTIONED CAPACITY, WILL BE DEEMED VALID UNTIL I WITHDRAW AND/OR CHANGE THEM, OR UNTIL THE PATIENT'S STATUS WILL CHANGE.

CONSENT 1- RECEIVE TREATMENT (ELECTRONIC FILE, a.k.a. "dossier sanitario")

I hereby **authorize** the **creation** of my **electronic file, a.k.a. "dossier sanitario"** ☐ y ☐ no

I hereby authorize the inclusion of previous clinical events in my electronic file, a.k.a. "dossier sanitario"] ☐ y ☐ no

PLEASE NOTE: failing to sign your consent to the above items, will allow physicians and health care providers to only have access to selected information regarding a specific treatment, and that them not being informed about specific tests or treatments may negatively affect your treatment, entailing a release of liability for ISMETT and for its health care providers.

CONSENT 2 - SUPPORT RESEARCH

I hereby authorize to inclusion of my personal data (except genetic data) in encoded form **into a database used by ISMETT for anonymously conducting future retrospective studies** in the scope of which ISMETT is an IRCCS. ☐ y ☐ no

You may, at any time, weave such processing, without prejudice to your care, by writing to the addresses indicated in the Information Note.

Consent 3 - IMPROVE PATIENT CARE QUALITY AND APPROPRIATENESS

- I hereby authorize the processing of my data for purpose of verifying the adequacy, appropriateness, effectiveness, and efficacy of patient care and medical treatment received, and to plan care in the scope of projects carried out:
  - - at ISMETT (including data transfer to the UPMC Group in the United States, given the shared information technology systems). ☐ y ☐ no
  - - in collaboration with UPMC Group (i.e. in collaboration with other centers part of the UPMC Group). ☐ y ☐ no
  - in collaboration with centers located in the EU. ☐ y ☐ no

- in collaboration with centers located also in other (non-EU) countries. ☐ Y ☐ no
- I hereby authorize the processing of my personal data (collected during standard clinical practice during my previous admissions at ISMETT, or in the course of my potential participation in clinical trials) for the same purposes and with the subjects listed under **item #1 of this box**. ☐ y ☐ no

CONSENT 4 - RECEIVE INFORMATION MATERIALS

I hereby authorize the mailing of ISMETT information materials, also for fund-raising initiatives. ☐ y ☐ no
To that end, I provide the following contact details:

Email Address City Postal code

Mobile Phone

PLEASE ENTER YOUR CONTACT DETAILS BELOW TO RECEIVE REMINDERS OF UPCOMING APPOINTMENTS, INSTRUCTIONS TO PREPARE FOR TESTS, AND PLANS OF CARE

Communications regarding plans of care, dates of appointments, as well as any indications on how to prepare for tests, can be sent to the following email address (only if not already indicated or different from the previousone)

or the following addresses

INFORMATION ON MY STAY AT ISMETT MAY BE PROVIDED TO:

Family members, relatives and partners
□ yes: (name and kinship, or if partner) □ no

to third parties
□ yes: (name) □ no

INFORMATION ON MY HEALTH STATUS MAY BE PROVIDED TO:

Family members, relatives and partners
□ yes (name and kinship, or if partner) □ no

to third parties

□ yes (name) □ no

Signature/s of the data subject/s(1)

Palermo, _____ / /

(1) If the patient is able to understand the Information Note and express his/her consent, but is unable to physically affix his/her signature, the following section must be completed and signed by two witnesses.

PATIENT UNABLE TO SIGN (patient able to understand the Information Note and express his/her consent, but unable to physically affix his/her signature, such as, for example, a patient who is illiterate or unable to use his/her hands). The patient who received this Information Note has expressed his/her consent but is unable to physically affix his/her signature.

WITNESSES

Name and surname

Date of birth

Signature ID

Name and surname

Date of birth

Signature ID

* If the person concerned is unable to provide his/her consent due to incapacity to contract (underage) or is unable to exercise his/her will (interdicted or assigned to a trustee), the consent must be signed by the parent/parents or guardian/trustee, respectively. In this case, the person providing consent must sign the self-statement on behalf of the data subject pursuant to Decree of the President of the Italian Republic (D.P.R.) 445/2000. The consent may be provided by the patient if he/she is an emancipated underage or disabled person.

I have listened to and understood the translation of this document into English orally made by an interpreter appointed by the hospital.

ITA □	Dichiaro di aver ascoltato e compreso la traduzione del presente documento nella lingua sotto contrassegnata, oralmente resa dall'interprete incaricato dall'ospedale
FRA □	Je déclare que j'ai entendu et compris la traduction orale en française de ce document réalisée par l'interprète de l'hôpital
SPA □	Yo declaro que he escuchado y entendido la traducción oral en español de este documento realizada por el interprete del hospital

ARA □	أنا الموقع أدناه أقر أنني سمعت واستوعبت الترجمة الشفوية إلى اللغة العربية لهذه الوثيقة التي أجراها المترجم المعين من المستشفى
EBR □	אני מצהיר בזאת ששמעתי והבנתי את התרגום בעל פה, בעברית, של המסמך הזה מהמתרגם של בית החולים
BUL □	ТВЪРДЯ, ЧЕ СЪМ ЧУЛ И РАЗБРАЛ ИЗЛОЖЕНОТО В ДОКУМЕНТА, ПРЕВЕДЕН МИ УСТНО НА БЪЛГАРСКИ ЕЗИК ОТ НАРОЧНО ПОСОЧЕНИЯ ЗА СЛУЧАЯ ОТ БОЛНИЦАТА ПРЕВОДАЧ
RUM □	Declar ca am ascultat si am înteles traducerea orala în limba româna a acestui document facuta de traducatorul însarcinat de catre acest spital
GER □	Hiermit erkläre ich, dass ich die deutsche mündliche Übersetzung des vorliegenden Dokumentes angehört und verstanden habe
GRE □	Δηλώνω ότι άκουσα και κατανόησα, από τον αρμόδιο διερμηνέα του νοσοκομείου, την προφορική μετάφραση στα Ελληνικά του παρόντος εγγράφου
ALB □	Deklaroj qe kam ndegjuar e kuptuar perkthimin gojore te ketij dokumenti ne gjuhen shqipe i perkthyer nga perkthyesi pergjgjes nga spitali
SR-CR □	Izjavljujem da sam cuo i razumeo usmeni prevod ovog dokumenta na srpskom - hrvatskom jeziku zaduzen od prevodilaca bolnice
MAL □	Jiena smajt u fhimt it-traduzzjoni għal malti tà dan id-dokument magħmul ha mill-interpretu tà l-isptar
…… □	……

Signature of the person who received the Information Note: _____
Signature of the interpreter: _____
Palermo, _____