ISMETT Istituto di Ricovero e Cura a Carattere Scientifico

MODULO 12.2.: PATIENT INFORMATION (FULL VERSION – WITHOUT ON-LINE REPORTS)

Information pursuant to Sec. 13 of the Privacy Code (Legislative Decree No. 196 of June 30, 2003)

Dear Patient,

Please find enclosed some information on how ISMETT will collect and process your data. You will receive a number of dedicated documents that concern your involvement in activities such as drug trials or general data collection.

WHAT IS ISMETT AND WHY WILL MY DATA BE TRANSFERRED ABROAD?

ISMETT is an authorized and accredited organ transplant and high specialty therapy center created by a partnership between the Region of Sicily and the University of Pittsburgh Medical Center (UPMC) in Pittsburgh, Pennsylvania, U.S.A. This collaboration was created to provide state-of-the-art clinical services using the experience and know-how of UPMC and of the hospitals of its network ("**UPMC network**"). To ensure the collaboration of these top international clinical facilities, the management of ISMETT was entrusted to UPMC Italy S.r.l. ("**UPMCI**"), the Italian subsidiary of the UPMC network. In carrying out its day-to-day operations, ISMETT utilizes data networks and information technology systems shared with UPMC. As a consequence, patients referring to ISMETT are requested to authorize the transfer of their personal data, including sensitive data, to UPMC's network in the United States. According to EU regulations, the laws currently in force in the United States fail to guarantee an adequate level of personal data protection. UPMC is therefore under contractual commitment to adopt the necessary security measures to protect the data of its patients.

WHAT KIND OF DATA WILL BE COLLECTED AND HOW?

ISMETT will ask you or other third parties (e.g., your family doctor) to provide personal data (e.g., name, address, *etc.*), information on your health status (diseases, laboratory results, diagnostic tests, ongoing therapies) and, when required, on your sexual life and social and psychological sphere. During your treatment it may become necessary to collect images of you for consults, also by means of telemedicine, with external experts to assess your health status.

WHY WILL MY DATA BE PROCESSED?

1. To receive medical treatment and for related administrative and accounting purposes

Your personal data will be collected and processed in order for you to receive the required clinical services (outpatient services, admissions, and, generally speaking, patient care, diagnosis, rehabilitation and prevention) and to perform the related administrative and accounting purposes. Thus your data could be shared with the following:

- family doctors and paediatricians;
- social security institutions, insurance companies covering ISMETT's third-party liability or offering additional patient care services, and legal consultants to ISMETT and to its staff;
- National Health Service, for reimbursement of medical services provided; institutions and local municipalities for verification of social services; diplomatic seats or other medical institutions monitoring medical service provision;
- public and private hospitals (for tests and exams that cannot be performed at ISMETT), the national and regional transplant centres, diseases registries, public and private research centres, and for any other legal obligation.

For purpose of identification you will be asked to wear an ID bracelet that contains personal information (name, surname, date of birth, patient code and visit code) using RFID (radio frequency identification) technology. This device allows to associate you in a safe and reliable way to your lab tests, test tubes, blood units, and other information.

In order for ISMETT to provide these services it is necessary you give your consent. Failure to sign your consent will only allow to perform the emergency clinical treatments necessary to safeguard your life or your physical safety or those of a third party.

2. To perform scientific studies and research in the medical field

In order to continuously improve its clinical services and contribute to general medical knowledge, ISMETT is involved in many research studies (internal projects and projects in collaboration with other EU and non-EU facilities). In particular, ISMETT performs research in the following areas: organ transplantation and end-stage organ failure; surgical and diagnostic and interventional radiology/endoscopy; regenerative medicine; clinical immunology and immunotherapy; infectious diseases and molecular medicine; health care information and communication technology.

Many of such studies can be performed using information already collected during **(i)** regular patient care activity; **(ii)** previous clinical studies; as well as **(iii)** from biological samples collected during treatment and stored in the biological material storage systems of the Pathology Lab and by the Department of Laboratory Medicine and Advanced Biotechnologies. Participating to these research projects does not influence in any way the normal patient care and requires no additional tests or treatments for the patients. In order to protect their privacy, the patients' ID data is removed from the information, clinical data and biological samples used for these studies, and replaced with alphanumerical codes that do not allow to trace the patient's identity. The list that allows to match such alphanumerical codes with the patient's identity will be kept by the Principal Investigator and stored as a confidential information.

Key–Coded data is used during information processing and storage, and when forwarding data to the other subjects involved in the study (the list of the centers involved in the studies can be accessed at the Office of Research at responsabileprivacyufficioricerca@ismett.edu). Access to data directly related to a patient can only take place when information is extracted from the original clinical documents and during monitoring activities (when correspondence is checked between data used for research and data contained in the medical records), and to when research data must be updated. Data and specimens are transformed in anonymous form ten years after the conclusion of the research projects. Encryption techniques are adopted for data storage and transfer thus preventing access to unauthorized parties. Research results are disseminated only in aggregate form, i.e. in a manner that makes it impossible to identify the patient.

In order to use a patient's biological samples and clinic information for research purposes, the patient must express his/her consent. Therefore, to allow ISMETT (also in collaboration with centers located in non-EU countries where an adequate level of personal data protection may not be guaranteed as per EU regulations) to use your clinical information and samples collected in the scope of patient care (or during other research projects you were involved in) please express your consent ticking the boxes at the bottom of this document. Please note you may withdraw your consent to data and sample processing at any time, and that this will not affect your treatment. In this case, the biological sample, if still traceable to you, will be destroyed (unless stored solely for purposes of care).

ISMETT is committed to participating to research projects governed by laws in the above mentioned areas. In order to use data in the scope of these studies, however, it is not necessary to obtain the patients' consent as this is provided for by law.

3. To verify the quality of care and medical treatment and to draft the plan of care

ISMETT is committed to monitor and assess the effectiveness of the patient care delivered, its appropriateness and quality, as well as clinical risk factors beyond those provided for by law. ISMETT's goal is to assess and compare the appropriateness, efficacy, effectiveness and efficiency of care delivered to different population groups or in different facilities, also with reference to specific diseases or health issues. ISMETT is involved in surveillance systems and registries collecting data on diseases and risks for the patients' health. This involves using data with no direct identification elements (e.g., name, surname, tax code, *etc.*), therefore not allowing to trace the identity of the patient. Data is processed and compared using computer tools with information managed by other clinical facilities. In order to use your personal data for similar purposes it is necessary that you give your consent. If you wish to authorize ISMETT to process your data, also collected in the past, for purpose of conducting these important tests that could provide useful information for your treatment, please give your consent ticking the box at the bottom of this document.

4. To receive information

Please sign your consent to receive news on ISMETT's projects, promotional campaigns and fund raising initiatives.

5. To receive reminders for upcoming appointments, instructions to prepare for scheduled tests, and plans of care

Please sign your consent to receive information concerning your plans of care, reminders of upcoming appointments at ISMETT, and instructions on how to prepare for your scheduled tests.

6. To allow ISMETT clinicians to access data on my procedures at ISMETT

An electronic tool is used at ISMETT, the Electronic health file (**HF**), which allows clinicians to access all the documentation related to the care provided at ISMETT, also in the past. This tool allows clinicians to access more complete information on the patient's health status (so called medical history) thus improving the services provided, and can only be activated with the patient's consent.

Therefore, only after you express your consent to the creation of HF ISMETT's clinicians be able to access information regarding all the treatment you have received at ISMETT, also in the past. You may decide for specific information not be included in your HF asking the chief of staff [*direttore sanitario*] to "blank" that information by contacting the address below or at direzionesanitariaprivacy@ismett.edu. In the same way, you may oppose at any time to adding further data to your HF while

nevertheless continuing to be treated at ISMETT, as well as revoking your decisions at any given time. If you do not sign the consent to the creation of your clinical file, clinicians will only be able to access data relating to that particular treatment. Please note that failure of these clinicians to be informed about specific tests or treatments may negatively affect your treatment, entailing a release of liability for the latter. Finally, please note your HF could be accessed, also without your consent, should this be deemed necessary to protect the physical safety of a third party or of the community.

HOW WILL MY DATA BE PROCESSED?

Data processing is performed with both paper and electronic tools adopting security measures that ensure confidentiality and security of your data.

WHO WILL ACCESS MY DATA?

Your personal data will be processed by a member of the clinical and administrative staff of ISMETT duly appointed "Person in charge of processing" and bound by professional secrecy and confidentiality. For training purposes, clinical treatment may be performed in the presence of medical students. In this event, all necessary precautions will be taken to limit any possible inconvenience. Please note you may ask for medical students not to be present during your treatment.

Your data may be shared with third parties, who, as Autonomous Data Controllers or appointed Data Processors or Person in charge of processing, provide ancillary services to activities of ISMETT, such as:

- professionals consultants,
- voluntary organizations proving support to the patient,
- hospital catering firms,
- maintenance companies,
- other subjects providing services instrumental to ISMETT's operations.

The updated list of hospitals of UPMC's network, to which data is transferred, and of the Data Processors is available on the home page of www.ismett.edu or mailing direzionesanitariaprivacy@ismett.edu

WHO WILL BE INFORMED OF MY PRESENCE AT ISMETT AND OF MY HEALTH STATUS?

Information regarding your stay at ISMETT and on your health status will only be provided to your relatives and friends listed at the end of this document, without prejudice to the provisions of law.

WHAT ARE MY RIGHTS ACCORDING TO LAW?

Section 7 of the Privacy Code (Legislative Decree No. 196 of June 30, 2003) states your right to:

- receive confirmation that ISMETT's (paper and electronic) archives contain personal data that concern you;
- be informed about this data on paper or electronic format;
- be informed about the source from which your data was obtained, of the reason and mode of data processing;
- be informed about the update, correction or integration of data;
- be informed about the cancellation, transformation into anonymous form, or blockage of personal data processed in violation of the law, and to oppose, in whole or in part, to its use.

HOW CAN I EXERCISE MY RIGHTS?

Rights may be exercised mailing a standard request to the chief of staff [*direttore sanitario*] to the address below or mailing direzionesanitariaprivacy@ismett.edu

For data processed in the scope of clinical studies and researches, rights may be exercised contacting the Office of Research at the address below or at responsabileprivacyufficioricerca@ismett.edu.

CO-DATA CONTROLLERS

Co-data controllers are Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione S.r.l. (ISMETT) and UPMC Italy S.r.l., both headquartered in Discesa dei Giudici 4, 90133 Palermo, Italy.

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