INFORMED CONSENT FOR

ELECTRO-CHEMO-THERAPY (ECT)

Patient Name and Last Name:

Nature of procedures

Electrochemotherapy (ECT) is a treatment by which cancer cells can be made more permeable to allow anti-cancer drugs to enter them more easily. ECT is a localised targeted treatment used for patients with cutaneous and subcutaneous tumours such as basal cell carcinomas, squamous cell carcinomas, breast cancer, head and neck cancers and melanomas with cutaneous metastases. ECT combines short electrical pulses with chemotherapeutic drugs such as bleomycin or cisplatin, both of which can be administered intra-tumourally or intravenously. An electrical pulse is delivered to the affected area through a needle probe which opens the cells and allows bleomycin or cisplatin to enter (electroporation). These chemotherapeutic drugs would normally find it difficult to cross the cell membrane

Potential Benefits

Treatment: The treatment comprises the administration of the drug followed by the local delivery of the membrane-permeabilising electric pulses. The treatment may be carried out under general anaesthesia, under intravenous sedation with local anaesthetic, or using local anaesthetic alone. The type of anaesthetic used depends on the anatomical location and number of lesions to be treated. There may be an initial tingling as well as muscle contractions associated with the electrical pulses.

For treatment with intravenous bleomycin, the drug is given as a slow intravenous bolus. Electric pulses are then applied to each tumour nodule to be treated and to the surrounding skin. These are delivered across electrodes attached to the Cliniporator. When all the area to be treated have received the electric pulses the treatment is completed. The patient is then recovered from anaesthesia and will remain under observation in hospital for a number of hours until considered fit for discharge home. Following treatment you may or may not have a dressing on the treated area. If required a nurse will follow up with you and your homecare providers to assist with this if needed. You may also be asked to provide progress photographs of the treated area. This is to assess how your wound is progressing before you return for follow- up appointment.

Side effects of the intravenous bleomycin are less likely to occur in electrochemotherapy than when this drug is used in systemic chemotherapy treatment. This is because electrochemotherapy is usually a one-off treatment, whereas in systemic chemotherapy, the drug is administered several times weekly for a number of weeks, depending on the specific treatment regime.

Potential Risks

Side effects and possible complications are related to the administration of high voltage pulses and include:

- Involuntary muscle contraction at the instant of the electric pulse, which stops at the end of the pulse, generally painless but uncomfortable.
- Burning of the skin. Sometimes observed when patients were treated with plate electrodes. Not seen when needle electrodes were used.
- Post procedural pain
- Hyperpigmentation of the skin
- Minimal skin or mucosal sloughing.
- Rare complications, depending on the treatment site may include fistulas and ulceration.
- Lung fibrosis

Bleomycin has been reported to cause a number of side effects. Fever on the day of injection, loss of appetite, tiredness or nausea may also occur. When bleomycin is directly injected into tumour nodules, the area around the injection may become inflamed for a few days. Bleomycin is not used in patients with acute pulmonary infection or greatly reduced lung function. As in accordance with the most recent guidelines if patients have symptomatic lung disease they will require a Pulmonary Function Test (PFT's) before receiving intravenous Bleomycin. If you have previously been treated with bleomycin, you should inform your physician.

The apparatus used to deliver the electrical pulses is called Cliniporator. It has been certified by European electrical safety bodies and is compliant with current security rules for electrical devices.

Patient's signature:	Date
Name (PRINT)	
Doctor's signature:	Date
Name (PRINT)	

INFORMED CONSENT FOR PARTECIPATION IN THE INSPECT DATABASE

Title of the Registry: **InspECT**
International **N**etwork for **S**haring **P**ractice in **E**lectro**C**hemo**T**herapy

InspECT database and patient data collection

You are being asked to participate in a registry investigating whether this novel therapy will prove effective in the treatment of certain cancers. The objective of this study registry is to evaluate the short and long term effect of electrochemotherapy in the management primary tumours and metastases originating from different type of cancers.

A study registry is a collection of information on patients who have a particular disease or condition, and/or receive specialised treatment. You will be asked to sign this form if you wish to participate.

In the case of InspECT registry the patients data is collected and uploaded in a specific database.

The potential **benefits** of studying innovative treatments in general include the development of new alternatives to conventional or existing therapies for certain cancers. In particular, the widespread availability of the innovative therapy being tested here may lessen the requirement for more invasive procedures.

The information we will collect is based on:

- Clinical examination.
- Measurement of your tumour.
- Photographic documentation
- Anaesthesia.
- Type of electrochemotherapy carried out

On your return to clinic the following information will be obtained:

- Clinical evaluation of your health.
- Measurement of your tumour size and response to the treatment
- Clinical photos

If clinically appropriate, you may be offered to undergo the same treatment again

AGREEMENT TO CONSENT

Participation in this study registry is voluntary and you may withdraw at any time for any reason

Collecting data for the registry and the treatment procedures associated with it have been fully explained to me. No guarantee has been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved.

I am aware that participation is voluntary and that I may withdraw my consent at any time.

I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me.

I agree with the anonymous collection of all data concerning my course of treatment by electrochemotherapy and to the upload of this data to database administered by the INSPECT-registry group and to its dissemination. In addition I agree to the holding of images for documentation of progress.

I understand that the collected data may be used for evaluating the efficacy of electrochemotherapy treatment. No identifying characteristics of mine will be employed in the use of this data.

I, the undersigned, hereby consent to participate as a patient in the above described project conducted at…… I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the doctor(s) listed above.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

Patient's signature:	Date
Name (PRINT)	
Doctor's signature:	Date
Name (PRINT)	

Information on the processing of personal data

In accordance with the 2016/679 European Regulations we are here to inform you that:

Data Controller	…… (HOSPITAL/CLINIC RESEARCH CENTER NAME) …….. (HOSPITAL/CLINIC RESEARCH CENTER ADDRESS)
Data Processor	…… *(Name and last name of the designated person and contact details, at least one address and one-email address)*
Data Protection Officer (DPO)	…… *(Name and last name of the designated person and contact details, at least one address and one-mail address)*

In accordance with art. 13 of the EU Regulation n. 2016/679 (hereafter "GDPR 2016/679"), laying down provisions for the protection of natural persons and third parties regarding the processing of personal data, we wish to inform you that the personal data you provide will be processed in compliance with the aforementioned law and confidentiality obligations.

Purpose of processing of personal data

You have been asked to participate in a registry that aims at investigating whether this new therapy will prove to be effective in treating certain types of cancer.

Title of the registry study: InspECT - International Network for Sharing Practice in ElectroChemoTherapy

The aim of this research register is to evaluate the short- and long-term effect of electrochemotherapy in the management of primary tumors and metastases of different origins.

A research register is a collection of information about patients who have a particular disease or condition, and / or receive special treatment.

Once you understand the study, if you wish to participate, you will be asked to sign this form.

Procedure of personal data processing and storage of personal data

Data processing will be carried out in an automated and / or manual manner, in compliance with the provisions of art. 32 of the GDPR 2016/679 regarding security measures, by persons specifically appointed and in compliance with the provisions of art. 29 GDPR 2016/679.

Please note that, in compliance with the principles of lawfulness, purpose limitation and data minimization, in accordance with art. 5 GDPR 2016/679, subject to your free and explicit consent expressed at the bottom of this information, your personal data will be kept for the period of time necessary to achieve the purposes for which they are collected and processed.

Scope of communication and dissemination

All information about you will be identified with a code instead of your name. Only the doctor and authorized persons can link this code to your name. All data that will be collected will be continuously monitored in accordance with the guidelines established by the International Conference on the harmonization of good clinical practice (ICH-GCP). This clinical monitoring is entrusted to a third company: IGEA spa.

The check and maintenance of the automated data collection is entrusted to a third company: IGEA spa

The knowledge that we will acquire from this research will be published so that other interested people can learn from our study. In all cases, confidential information will not be shared. We also inform you that the data collected will never be disclosed and will not be communicated without your explicit consent.

Transfer of personal data

Your personal data will not be transferred to third countries that are not belonging to the European Union.

During the clinical monitoring of the collected data, the HOSPITAL (Data Controller) may transfer the data to IGEA S.p.A. The processing of personal data by IGEA SpA will be carried out for the sole purposes mentioned above **(Scope of communication and dissemination)**

Special categories of personal data

In accordance with articles 9 and 10 of EU Regulation no. 2016/679, you may give to the Data Controller data qualifying as "special categories of personal data" that is data that reveals information on physical and mental status of an individual or “data concerning health" (ex articles 9 and 10 GDPR). These categories of personal data may be processed by the Data Controller only upon your free and explicit consent, expressed in writing at the bottom of this information.

Existence of an automated decision-making process, including profiling

‘Profiling’ means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.

The Data Controller does not adopt any automated decision making process, including profiling, referred to, in Article 22, paragraphs 1 and 4, of EU Regulation no. 679/2016, for this specific processing of personal data.

Rights of the interested party

At any time, you can exercise, in accordance with art. 7 of Legislative Decree 196/2003 and articles from 15 to 22 of EU Regulation no. 2016/679, the right to:

a) request confirmation of the existence or not existence of personal data;
b) obtain information about the purposes of the processing, the categories of personal data, recipients or categories of recipients to whom the personal

data have been or will be communicated and, where possible, the retention period;

c) obtain data correction and deletion;
d) obtain treatment limitation;
e) obtain data portability, ie receive the personal data from a data controller, in a structured format, commonly used and readable by automatic device, and transmit it to another data controller without impediments;
f) oppose the processing at any time and also in the case of treatment for direct marketing purposes;
g) oppose an automated decision-making process concerning individuals, including profiling.
h) ask the data controller to access personal data and to rectify or cancel them or limit their processing or to oppose their processing, in addition to the right to data portability;
i) revoke the consent at any time without prejudice to the lawfulness of the personal data processing based on the consent given prior to the revocation;
j) propose a complaint to a supervisory authority.
k) you can exercise your rights by contacting the Data Controller or the Data Processor in charge

Consent to the processing of personal data

I, the undersigned ……..declare:
(NAME and LAST NAME)

• to have received the information aforesaid (Place and Date)

• in light of the information received:

☐ **I give my consent** ☐ **I DO NOT give my consent** to the processing of my personal data including those considered as special categories of personal data.

☐ **I give my consent** ☐ **I DO NOT give my consent** to the communication of my personal data to private companies for the purposes indicated in the information.

Date Signature ……