INFORMED CONSENT FOR
ELECTRO-CHEMO-THERAPY (ECT)

Protocol Number:	**Patient Name**: more space here to attach an adhesive label

Nature and duration of procedures

Electrochemotherapy is a well-characterised process by which cancer cells can be made more permeable to allow anti-cancer drugs to enter them more easily. A large number of preclinical and clinical phase I and I/II studies have demonstrated the efficiency and safety of electrochemotherapy. These studies have included patients affected by melanoma, head and neck squamous cell carcinoma, basal cell carcinoma, adenocarcinoma and Kaposi Sarcoma nodules. Case series and case reports concerning other primary tumours have also been reported.

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Potential Benefits and Risks

This therapy is not being offered as an alternative to chemotherapy. 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.

Risks and side effects: There may be an initial tingling as well as muscle contractions associated with the electrical pulses.

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 and you would normally be assessed with a lung function test before being treated. 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. 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.

Hyperpigmentation of the skin

 Minimal skin or mucosal sloughing.

 Rare complications, depending on the treatment site, include osteomyelitis, dysphagia, pharyngocutaneous fistulas, and ulceration.

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..

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 o 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.

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

You are being asked to participate in a research study 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 special treatment. Once you understand the study, you will be asked to sign this form if you wish to participate.

Title of the Registry: **InspECT**
International Network for Sharing Practice in ElectroChemoTherapy

InspECT database, patient data collection

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 size with a calliper.
- Photographic documentation
- Anaesthesia.
- Type of Electrochemotherapy carried out

You will be asked to return to the clinic every 4-6 weeks for at least 16 weeks. At each of these visits, you will be asked the following:

- 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

Confidentiality

The information that we collect from this research registry study will be kept confidential. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is. All the data that is entered in the database is continuously monitored according to the International Conference on Harmonization of Good Clinical Practise (ICH- GCP) guidelines. The

knowledge that we get from doing this research will be published in order that other interested people may learn from our research. In all cases confidential information will not be shared.

AGREEMENT TO CONSENT

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

The research study and the treatment procedures associated with it have been fully explained to me. All experimental procedures have been identified and 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 creation of pictures for documentation of progress. Confidentiality of records concerning my involvement in this project will be maintained at all time.
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)	