INFORMED CONSENT

PROPEL – Prospective Registry of Parenteral Prostanoids

Dear Sir or Madam,

You have been invited to take part in a research study PROPEL that regards the treatment of Pulmonary hypertension with parenteral prostanoids. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, and what the goal of your participation is and what it means for you. This consent form explains the study. Please read this carefully.

PROPEL is an international registry that collects clinical data of patients diagnosed with Pulmonary hypertension and data about therapeutic effects and safety of parenteral prostanoids. The aim of the study is collection of clinical data of patients with Pulmonary hypertension treated with parenteral prostanoids and the assessment of efficacy of this treatment in European countries (Austria, Czech Republic, Luxembourg, Poland and Slovakia).

The data collection in PROPEL project is non-interventional, so there is no effect on the treatment you are undergoing whether you participate in PROPEL or not and you will be treated in accordance with the usual clinical practise and in order with your physician’s decision. There will be no extra laboratory or any other examination besides those necessary in the usual clinical practise. There will be no necessity to see your physician more often, than the usual checkups.

PROPEL project collects data about the examinations and treatment you are going through during your Pulmonary hypertension treatment.

Only your physician decides on the therapy of your disease. His or her decision about the type of the treatment is not influenced in any way by the PROPEL project.

The statistical analysis of anonymous data is provided by Institute of Biostatistics and Analysis Masaryk University Brno.

Protecting your privacy is an important part of this study. A copy of this consent will be put in your health record.

To protect your information, we will not keep your name or other information that may identify you with the sample; only a code number. No one other than your physician and the staff of medical facility you are treated in will ever be able to link your name to your sample or to any test results.

The project will collect data from the enrolment of the patient for the whole duration of the project (January 2011 – December 2015).

You can withdraw your consent at any time without the reason. Your treatment will not be affected by the withdrawal in any way. However the data collected up to that moment will be utilized in the analysis.

If you have any other question regarding the PROPEL project, please contact your physician:

Dr............................................................... , phone:........................................
PATIENT’S INFORMED CONSENT

WITH PROVIDING THE INFORMATION FROM HEALTH RECORD TO THE PROPEL STUDY

1. I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this project.

2. This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

3. I, signed below, give my consent to processing, collecting and keeping my confidential data and information from health records by Institute of Biostatistics and Analysis, Masaryk University Brno, Kamenice 3, 625 00 Brno, Czech Republic, more precisely my initials, date and country of birth, my ethnicity, sex and health records regarding the treatment of my disease – Pulmonary hypertension, data about my clinical condition, the results of laboratory examination and adverse events occurring during my treatment above all. This consent is valid for PROPEL project only.

4. I was informed and am aware of my rights in accordance with law in Poland.

5. I agree to allow Institute of Biostatistics and Analysis, Masaryk University Brno, Kamenice 3, 625 00 Brno, Czech Republic to have access to my health records.


___________________________ ____________ ____________
Name of the patient       Date                   Signature

___________________________ ____________ ____________
Signature of person conducting
Consent Discussion          Date                   Signature

Thank you for your time and patience!