

Clinical Center Niš  
Ethics Committee  
Number: 18280/58  
Date: 02.07.2013.

Pursuant to Article 12 of the Law on Medical Products and Medical Devices and Ethics Committee Rules of Procedure of Clinical Center Niš, Ethics Committee of Clinical Center Niš, consisting of Steva Stanišić, MD, infectologist, president, and members: Radmila Veličković-Radovanović, MD, Assist. Prof., pharmacologist, Zorica Stanojević, MD, PhD, oncologist, Ljiljana Pejčić, MD, PhD, pediatrician, Milan Rančić, MD, PhD, specialist of pneumoftiziology, and Marina Petrović, prim. MD, neuropsychiatrist, on the meeting held on 2.7.2013, reached this

## **DECISION**

### **I**

The request of Stevo Lukić, MD, for the authorization of non-profit clinical study “EpiNet-international register of patients with epilepsy”, act number 14607, 27.5.2013., is hereby approved.

### **II**

The clinical study is to be conducted at the Neurology Clinic, the principal investigator being Stevo Lukić, MD.

### **III**

The decision is made on the basis of the following documentation:

1. Request form for the Ethics Committee of the Clinical Center Niš
2. Approval of the OU director
3. Open clinical study protocol with the publication from the pilot study
4. Information for patients and written consent form
5. Information for parents/caregivers and written consent form
6. Decision and opinion of other (international) Ethics committees where the study is conducted

### **IV**

Ethics Committee works in accordance with ICH-GCP rules.

### **V**

The main investigator, Stevo Lukić, MD, is to submit reports on the course of the study and possible adverse effects to the Ethics Committee of the Clinical Center Niš.

## VI

The main investigator, Stevo Lukić, MD, is to submit regular reports on the beginning of the clinical study with a plan for conducting the study, quarterly reports on all services (hospital days, diagnostic and other services) performed in that period for the purpose of invoicing, and on ending of the clinical study. The reports are to be submitted to the Team for compliance and enforcement of contracts and to the Financial Department.

## VII

Members of the Ethics Committee are:

1. Steva Stanišić, MD, Department for Artificial Ventilation, Vital Function Monitoring and Parenteral Nutrition at the Infectious Diseases Clinic – president
2. Radmila Kovačević-Kuštrimović, full professor at the University of Novi Pazar
3. Marina Petrović, prim. MD, neuropsychiatrist, Special hospital for psychiatric illnesses "Gornja Toponica"
4. Ljiljana Pejčić, MD, PhD, Pediatric Internal Diseases Clinic
5. Radmila Veličković-Radovanović, MD, Assist. Prof., head of the Department for Clinical Pharmacology
6. Zorica Stanojević, MD, PhD, Oncology Clinic
7. Milan Rančić, MD, PhD, Pulmonary Diseases Clinic

**Decision to be delivered to:** Steva Stanišić, MD, president of the Ethics Committee, director of the Clinical Center Niš, Stevo Lukić, MD, and Archives.

President of the Ethics Committee  
Steva Stanišić, MD