Local Ethics Committee under State Budget Institution of Public Health Department Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky

1st May 167, Krasnodar 350086 Tel. +7 (8612) 52- 73- 90

Abstract from Protocol No 49

Meeting of Local Ethics Committee under State Budget Institution of
Public Health Department Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
Healthcare Department of Krasnodar Region

Dated May 31, 2012

Participants:

- Tsukurova Larisa Alexandrovna – Chairwoman of Ethics Committee, head of neurology department under Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
- Zubareva Natalia Alexandrovna – Secretary of Ethics Committee, clinical pharmacologist in Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
- Arepieva Olga Vladislavovna – head of anaesthesiology and reanimation department No 7 under Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
- Baryshev Alexander Gennadievich – associate professor of oncology department with thoracic surgery course in Kuban State Medical University, Candidate of Medical Science.
- Butaeva Svetlana Vasilievna – head of endocrinology department under Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
- Perebeinos Alexey Nikolaevich, head of law department under Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky
- Kurilenko Olga Vladimirovna – head of clinical pharmacology study in “Krasnodar Clinical Hospital of emergency call service”.

The meeting took place in the study of Chairwoman of Ethics Committee, head of neurology department under Regional Clinical Hospital # 1 after Prof. S.V. Ochapovsky Tsukurova L.A.

31.05.2012 11.00 a.m., 1st May 167, Krasnodar

ISSUE:

Discussion of changes in tracheal transplant protocol and Addendum: investigator's brochure, registration card, informed written consent for research protocol, informed written consent of the patient regarding replacement of trachea, using a synthetic

bioengineered scaffold seeded with autologous mononuclear cells on the clinical base of Regional Clinical Hospital No 1 after prof. Ochapovsky according to tracheal transplant protocol under the Agreement dated October, 19, 2011 No 11.G34.31.0065 between Ministry of Education and Science of the Russian Federation and State Educational institution of Higher Professional Education “Kuban State Medical University” of Ministry of Health and Social Development of the Russian Federation and leading scientist Paolo Macchiarini, head of scientific research regarding grant of the Government of the Russian Federation for the state support of scientific researches under the guidance of leading scientists in Russian educational institutions of higher professional education.

Documents presented:

1. Investigator's brochure
2. Registration card
3. Informed consent for research protocol
4. Informed written consent of a patient

TAKEN THE DECISION:

To accept positive ethical confirmation and approve changes in tracheal transplant protocol and Addendum:

investigator's brochure, registration card, informed written consent for research protocol, informed written consent of the patient regarding **replacement of trachea, using a synthetic bioengineered scaffold seeded with autologous mononuclear cells** on the clinical base of Regional Clinical Hospital No 1 after prof. Ochapovsky according to tracheal transplant protocol under the Agreement dated October, 19, 2011 No 11.G34.31.0065 between Ministry of Education and Science of the Russian Federation and State Educational institution of Higher Professional Education “Kuban State Medical University” of Ministry of Health and Social Development of the Russian Federation and leading scientist Paolo Macchiarini, head of scientific research regarding grant of the Government of the Russian Federation for the state support of scientific researches under the guidance of leading scientists in Russian educational institutions of higher professional education.

Chairwoman of Ethics Committee under Tsukurova L.A.

Regional Clinical Hospital # 1

after Prof. S.V. Ochapovsky