

STATE BUDGETARY EDUCATIONAL INSTITUTION
FOR HIGHER PROFESSIONAL EDUCATION
“KUBAN STATE MEDICAL UNIVERSITY”

OF THE MINISTRY OF HEALTH CARE AND SOCIAL DEVELOPMENT
OF THE RUSSIAN FEDERATION

ETHICAL COMMISSION

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RESOLUTION OF THE ETHICAL COMMISSION

PROTOCOL №8

Date of the meeting: December 21, 2011

Chairman – M.D., Professor E.V.Bolotova (vice-chairman of the Ethical Commission)

Meeting attendants: M.D., Professor E.I.Kondratieva (chairman of the Ethical Commission), M.D., Professor E.V.Bolotova (vice-chairman of the Ethical Commission), M.D., Professor A.H.Kade, candidate of medical sciences, associate professor O.G.Kompaniec, M.D., Professor A.M.Sampiev, M.D., Professor A.A.Slavinskiy, candidate of medical sciences, associate professor G.I.Gurbich, M.D., Professor S.E.Gumenuck, M.D., Professor T.V.Gayvoroskaya, lawyer J.A.Chuiko, president of social organization of medical workers of Krasnodar Region G.A.Pihovkina, M.D., T.F.Shamraeva (secretary).

Professor E.I.Kondratieva didn't vote.

Reported: The protocol of clinical trial “Trachea transplantation: the use of synthetic bioengineered scaffold, manufactured on the basis of polymeric fiber and seeded with autologous mononuclear cells”, carried out in the context of the Agreement from October 19, 2011 №11.G34.31.0065 between the Ministry of Education and Science of the Russian Federation, and State Budgetary Educational Institution For Higher Education “**Kuban State Medical University**” Of The Ministry Of Health Care And Social Development Of The Russian Federation, and the leading Scientist Paolo Macchiarini, providing the guidance for the scientific research, on the on the provision of a monetary grant of the Government of the Russian Federation designed to support research projects implemented by leading scientists at Russian institutions of higher education.

Leading Scientist: Paolo Macchiarini.

Research team:

Professor, corresponding member of the Russian Academy of medical sciences, head of the department of oncology with the course of thoracic surgery, head doctor of the state budgetary institution for healthcare “Regional Clinical Hospital №1 named after Professor S.V. Ochapovsky – Centre of the thoracic surgery” of the Healthcare Department of Krasnodar Region, M.D. professor V.A. Porkhanov.

Associate professor of the department of oncology with the course of thoracic surgery, the first deputy of the head doctor, candidate of medical sciences I.S.Polyakov.

The head of the regional coordination centre of organ donorship of the state budgetary institution for healthcare “Regional Clinical Hospital №1 named after Professor S.V. Ochapovsky, candidate of medical sciences I.A.Pashkova.

Implementing organization: State Budgetary Educational Institution For Higher Education “Kuban State Medical University” Of The Ministry Of Health Care And Social Development Of The Russian Federation.

Clinical base: State budgetary institution for healthcare “Regional Clinical Hospital №1 named after Professor S.V. Ochapovsky – Centre of the thoracic surgery” of the Healthcare Department of Krasnodar Region.

Dates of implementation: 29.10.2011 – 21.12.2013

Reviewer: M.D., Professor E.V.Bolotova

Reviewer: M.D., Professor A.A.Slavinskiy

Examined: The protocol of clinical trial “Trachea transplantation: the use of synthetic bioengineered scaffold, manufactured on the basis of polymeric fiber and seeded with autologous mononuclear cells” from 29.11.2011; informed voluntary consent of the patient from 29.11.2011; The number and type of patients: will be chosen from the database of State budgetary institution for healthcare “Regional Clinical Hospital №1 named after Professor S.V. Ochapovsky; criteria of entry/elimination are specified. Complications are fully described. Transplantation profit exceeds risks. Informed voluntary consent meets the principles of the protection of rights of trial subjects.

Resolved: The protocol of clinical trial “Trachea transplantation: the use of synthetic bioengineered scaffold, manufactured on the basis of polymeric fiber and seeded with autologous mononuclear cells”, carried out in the context of the Agreement from October 19, 2011 №11.G34.31.0065 between the Ministry of Education and Science of the Russian Federation, and State Budgetary Educational Institution For Higher Education “**Kuban State Medical University**” Of The Ministry Of Health Care And Social Development Of The Russian Federation, and the leading Scientist Paolo Macchiarini, providing the guidance for the scientific research, on the on the provision of a monetary grant of the Government of the Russian Federation designed to support research projects implemented by leading scientists at Russian institutions of higher education does not contradict the ethical standards. Documentation is represented in full and contain all the necessary information, the rights of the potential patients to the research entry are not violated.

Vice-chairman of the Ethical Commission
M.D., Professor

E.V.Bolotova