RESOLUTION OF THE ETHICAL COMMISSION
PROTOCOL №11

Date of the meeting: May 29, 2012

Meeting attendants: M.D., professor A.H.Kade (chairman); M.D., Professor E.I.Kondratiev, candidate of medical sciences, associate professor O.G.Kompaneec, M.D. Professor, head of the pharmacy department A.M.Sampiev, M.D. Professor, head of oral and maxillofacial surgery department T.V.Gaivoronskaya, M.D., Professor A.A.Slavinsky, M.D. professor of the hospital therapy department Kanorsky Sergey Grigoriyevich, O.E.Philippova (secretary). Professor E.I.Kondratieva didn’t vote.

Reported: Appendix 1 from May 25, 2012 to the clinical research protocol “Trachea transplantation” from February 5, 2012 on the direction “Molecular and cellular biology, biotechnology, regenerative medicine” in the frames of the implementation of the Grant of the Russian Federation, designed for state support of scientific research, conducted under the guidance of leading scientists in Russian institutions for higher professional education according to the Agreement № 11.G34.31.0065 October 19, 2011 between the Ministry of Education and Science of the Russian Federation, and 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, and the leading Scientist Paolo Macchiarini, providing the guidance of the scientific research in the period from October 19, 2011 till December 31, 2013. (Alteration of the composition of tracheal matrix (PET and PU 50/50) for better compliance to physical characteristics and measures of human trachea and compatibility with protheses, created for the patient)

Given: Appendix 1 from May 25, 2012 to the clinical research protocol “Trachea transplantation” from February 5, 2012, (Alteration of the composition of tracheal matrix (PET and PU 50/50) for better compliance to physical characteristics and measures of human trachea and compatibility with protheses, created for the patient)

Leading Scientist: Paolo Macchiarini.
Examined: Appendix 1 from May 25, 2012 to the clinical research protocol “Trachea transplantation” from February 5, 2012 on the direction “Molecular and cellular biology, biotechnology, regenerative medicine” in the frames of the implementation of the Grant of the Russian Federation, designed for state support of scientific research, conducted under the guidance of leading scientists in Russian institutions for higher professional education according to the Agreement № 11.G34.31.0065 October 19, 2011 between the Ministry of Education and Science of the Russian Federation, and 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, and the leading Scientist Paolo Macchiarini, providing the guidance of the scientific research in the period from October 19, 2011 till December 31, 2013. (Alteration of the composition of tracheal matrix (PET and PU 50/50) for better compliance to physical characteristics and measures of human trachea and compatibility with protheses, created for the patient)

Resolved:  
To approve the introduction of the Appendix 1 from May 25, 2012 to the clinical research protocol “Trachea transplantation” from February 5, 2012, (Alteration of the composition of tracheal matrix (PET and PU 50/50) for better compliance to physical characteristics and measures of human trachea and compatibility with protheses, created for the patient).

Chairman of the meeting of the  
Ethical Commission  
M.D., Professor

A.H.Kade