

Translated from Russian:

DECISION № 17/16_14.03.2018
MOSCOW MUNICIPAL INDEPENDENT
ETHICS COMMITTEE

Moscow, Russia

March 14 2018

Moscow Municipal Independent Ethics Committee, having considered at the meeting on March 14 2018 the application by Lev Vadimovich Brylev, submitted on March 12 2018, for the ethics expertise of non-interventional research protocol “Measuring the effects of a music therapy protocol on respiratory and bulbar functions in patients with early and mid-stage amyotrophic lateral sclerosis: mixed methods single case study series” at the research centre Autonomous Non-Commercial Organization «St. Alexis Central Clinical Hospital», taking into account that:

<input type="checkbox"/> YES N/A	<input type="checkbox"/> NO	the authorization to conduct a clinical study of a medicinal product with the participation of a person as a subject, not issued by the authorized body
<input type="checkbox"/> YES N/A	<input type="checkbox"/> NO	permission to conduct a clinical study of a medicinal product with the participation of a person as a subject, issued by the authorized body
<input type="checkbox"/> YES N/A	<input type="checkbox"/> NO	the authorization to conduct a clinical trial of a drug with human participation as a subject has a positive decision from the Ethics Board of the Ministry of Health of the Russian Federation
<input type="checkbox"/> YES N/A	<input type="checkbox"/> NO	the authorization to conduct a clinical trial of a medicinal product with human participation as a subject does not have a decision from the Ethics Board of the Ministry of Health of the Russian Federation

DECIDED

- To approve the clinical research
- To approve the clinical research. The decision comes into force after obtaining permission to conduct a clinical study from the Ministry of Health of the Russian Federation.
- To conditionally approve the clinical trial (with a recommendation to amend the submitted documents with the subsequent submission of documents to the Moscow Municipal Independent Ethics Committee in a time period of no more than 10 business days for the subsequent issuance of an opinion on the approval of the clinical trial)
- Deny approval of a clinical trial (indicate the reasons for the denial)
- To cancel or suspend a previously issued opinion on the approval of the clinical trial

Vice Chairman of MMIEC
Executive Secretary of MMIEC

Khachanova N.V.
Koval O.M.