

Study Identification

Brief Title: Intranasal Inhalations of Bioactive Factors Produced by M2 Macrophages in Patients With Organic Brain Syndrome

October 11, 2015

Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Institute of Fundamental and Clinical Immunology (IFCI) Institutional Review Board (IRB) has reviewed and approved (approval no 92, 11/10/2015). This form is designed to provide you - as a human subject - with information about this study. The Investigator will describe this study to you and answer any of your questions. You are entitled to a copy of this form. If you have any questions or complaints about the informed consent process of this research study or your rights as a subject, please contact the IRB at the IFCI Office of Institutional Research at (383) 228-54-21 or cke@ngs.ru.

Thank you for agreeing to participate in this research project.

Project Title: Safety/Efficacy of Intranasally-Administered Bioactive Factors Produced by Autologous M2 Macrophages in Patients With Organic Brain Syndrome

Principal Investigator: Alexander A Ostanin, PhD, MD, Head of Clinical Department, (383) 236-03-29

I, the undersigned, confirm that (please tick box as appropriate):

1.	I have read and understood the information about the project, as provided in the Information Sheet	<input type="checkbox"/>
2.	I have been given the opportunity to ask questions about the project and my participation.	<input type="checkbox"/>
3.	I voluntarily agree to participate in the project.	<input type="checkbox"/>
4.	I understand I can withdraw at any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.	<input type="checkbox"/>
5.	The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, etc.) to me.	<input type="checkbox"/>
6.	If applicable, separate terms of consent for interviews, audio, video or other forms of data collection have been explained and provided to me.	<input type="checkbox"/>
7.	The use of the data in research, publications, sharing and archiving has been explained to me.	<input type="checkbox"/>
8.	I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form.	<input type="checkbox"/>
9.	Select only one of the following:	
	<ul style="list-style-type: none">I would like my name used and understand what I have said or written as part of this study will be used in reports, publications and other research outputs so that anything I have contributed to this project can be recognised.I do not want my name used in this project.	<input type="checkbox"/> <input type="checkbox"/>
10.	I, along with the Researcher, agree to sign and date this informed consent form.	<input type="checkbox"/>

Participant:

Name of Participant

Signature

Date

Researcher:

Name of Researcher

Signature

Date