

Study Identification

ClinicalTrials.gov ID: NCT03119025

Brief Title: Autologous Dendritic Cell Vaccine for Treatment of Patients with Chronic HCV-Infection

April 10, 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 88, 04/10/2015). 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@nqs.ru.

Thank you for agreeing to participate in this research project.

Project Title: Safety/Efficacy of Vaccination With Autologous Dendritic Cells Pulsed With Recombinant HCV-Antigens (Core and NS3) for Treatment of Patients With Chronic HCV-Infection

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any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.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