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@nas.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
2. I have been given the opportunity to ask questions about the project and my participation.
3. I voluntarily agree to participate in the project.
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any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.
5. The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymisation of data, etc.) to me.
6. If applicable, separate terms of consent for interviews, audio, video or other forms of data collection have been explained and provided to me.
7. The use of the data in research, publications, sharing and archiving has been explained to me.
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.
9. Select only one of the following:
   - 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.
10. I, along with the Researcher, agree to sign and date this informed consent form.

Participant:

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<th>Name of Participant</th>
<th>Signature</th>
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Researcher:

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<th>Name of Researcher</th>
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