INFORMED PATIENT CONSENT
for participation in the study

Me: patient / my care recipient (Name):

_____

(underline applicable)

Staying in the department _____ of the National Research Cardiac Surgery Center Non-Commercial JSC I give my consent to participate in Study on the topic **"Development of innovative technologies for the treatment of pulmonary and heart failure to prolong human's life" (hereinafter - Study))** of myself, care recipient.

Dear patient,

This informed consent form is intended for patients suffering from end-stage heart and / or respiratory failure who have been invited to participate in a study on the use of adjunctive therapy in patients with elevated levels of cytokines (harmful substances in the blood) in conditions of systemic inflammatory response syndrome (body defense reaction).

Despite significant advances in perfusion technologies and the use of biocompatible materials used in cardiopulmonary bypass, patients undergoing complex procedures in cardiac surgery still have a significantly high risk of complications ranging from transient organ dysfunction to multiple organ failure and death.

In this regard, during the treatment, an extracorporeal cytokine adsorber (hemoadsorbent - a filter for blood purification) will be used to reduce the effect of cytokines (harmful substances) on the patient's body.

Your doctor will ask you to participate in this study, and this document will provide you with study-related information. Your doctor will answer any questions you may have about your participation.

Purpose of the study

To improve the results of treatment of heart and respiratory failure in the terminal stage using organ replacement technologies. In this study, methods will be developed to restore the function of affected organs before and/or after mechanical support of blood circulation in combination with the use of an extracorporeal cytokine adsorber, which will improve the results of surgical treatment of patients with end-stage heart and respiratory failure.

Method

In the process of hemoadsorption, the blood is purified outside the body using a special filter called hemoadsorbent. During the procedure, it is required to cleanse a large volume of blood from toxins in a relatively short period of time. Ordinary blood vessels cannot provide sufficient blood flow, therefore, a special vascular access is required, which is the only way to ensure sufficient blood flow for the hemoadsorption procedure: passing blood through a filter and returning back to the patient's vascular bed through a system of tubules (highways).

Procedure

During the procedure, blood is removed from your body, filtered through hemoadsorbent and returned to the body. Hemoadsorption is also called extracorporeal blood cleansing, since cleansing is carried out outside the human body using a special apparatus called "artificial kidney". In the filter, blood passes through hundreds of small tubes. These tubes are made of

special membranes with thousands of small holes that allow certain toxins and chemicals to pass through and be removed from your bloodstream. Then these chemicals and toxins that could harm your body are trapped in the filter.

Tubes for blood are attached to the access (a catheter that will be installed for you during the study), and the pump of the hemoadsorption machine pumps blood out of your body, passes it through a filter and returns it back. You will notice that your blood circulates in a continuous circuit: from your body to the hemoadsorbent and vice versa. This means that at any given time, only a small amount of blood is outside your body.

This research will be carried out with cyclic replacement of the sorption column depending on the duration of operation. At each stage, your doctor will inform you about your condition and describe all the options that are acceptable to you. Any procedure or data collection will not commence until your written consent has been obtained.

Blood samples

Blood samples taken before and after implantation will be sent to the hematology laboratory, where they will be stored for special tests. Material for laboratory tests will be collected daily throughout the duration of the ICU stay. Peak values will be compared with those measured 24 hours after starting CytoSorb therapy. Samples obtained in the course of research will be used only for the purpose of this research and must be destroyed after completion of the research. The volume of one blood sample is 20 ml, and the total number of blood samples collected in 1 year of research is about 100 ml.

Risks

- Possible risks and inconveniences that you may face:
- Intraoperative bleeding, which can lead to blood transfusion;
- The need for re-intervention;
- Ischemia or bleeding in the gastrointestinal tract;
- Local infection or septicemia;
- Increase or decrease in blood pressure;
- Blood disorders such as anemia (lack of red blood cells in your blood), hemolysis (destruction of red blood cells);
- Pain / local infection at the catheter site;
- Allergy to anesthetic or drugs;
- Systemic inflammatory response to extracorporeal circulation;
- Disseminated intravascular coagulation syndrome, ischemia-reperfusion injury;
- Increase in the concentration of free hemoglobin in blood plasma.

Volitional participation

Your participation in the study is voluntary. If you do not want to participate in the study, your decision will not affect the quality of your care or your relationship with your doctor.

If you decide to take part in the study, you agree to fulfill its requirements as described in the informed consent form. You will be provided with any new information that emerges during the research that concerns you or may change your consent.

If you wish, you can exit the study at any time and by mistake. You can tell your doctor about your decision. Your data will no longer be collected. Likewise, your doctor is responsible for your follow-up. If the study stops, you will continue to be monitored in accordance with your health condition.

Contacting persons

If you have any questions, you can ask them now or later, even after the start of the study. If you want to ask a question, you can contact the co-head of the Research - Timur Dostaevich Lesbekov, Head of the Department of Cardiac Surgery, National Research Cardiac Surgery Center Non-Commercial JSC, mobile phone +77019659151**.**

Data protection

Specific data about you and your health condition that your doctor collects (for example, age, gender, patient data, underlying medical condition) will be collected and stored encrypted (i.e. anonymous). Your data will be stored in the Research for 5 years, and then will be completely anonymized, so that since then the data cannot be identified as yours.

If you would like to participate in the Study, please sign this informed consent.

✓ **I confirm with my signature that I have read and understood all of the above:**

Patient / Representative (Name, Signature):

_____

Date and time: ___ / ___ / 20___ __ h. ___ min.

Instruction conducted by (Name, Signature):

_____

Date and time: ___ / ___ / 20___ __ h. ___ min.