National reGistry of hypeRtrophic cArDIomyopathy: regional fEatures, geNeTics and course (GRADIENT) Russian Multicenter Open-label Observational Clinical Trial

(Project of the Central State Medical Academy of the Department of Presidential Affairs, Almazov National Medical Research Center, and the ESC Working Group on Myocardial and Pericardial Diseases) Informed Consent Form ReGistry of hypeRtrophic cArDIomyopathy: Regional fEatures, geNeTics and Course (GRADIENT) Multicenter Prospective Registry of Patients With Hypertrophic Cardiomyopathy

PATIENT INFORMATION SHEET

Dear _____, You are being offered participation in an observational scientific study «ReGistry of hypeRtrophic cArDIomyopathy: Regional fEatures, geNeTics and Course (GRADIENT)» (Registry) for patients with hypertrophic cardiomyopathy (HCM). You have been offered participation in this study because you have been diagnosed with hypertrophy (thickening) of the heart walls, most likely of hereditary (genetic) origin. The genetic nature of the disease is assumed when there are no other apparent causes that could explain the existing changes in the heart. Please carefully review this document and ask any questions you may have. You may also consult with individuals you consider knowledgeable. Your participation in the study is voluntary, and you may choose not to participate or change your decision and withdraw your consent at any time without explaining the reasons. In this case, your relationship with your doctor and your treatment strategy will not change in any way. The purpose of this study is to identify genetic and external factors responsible for significant differences in the quality and duration of life among patients with HCM. The information collected in this registry will help improve observation and treatment protocols for this condition and contribute to further advancements. This project is initiated by a national working group, supported by the European working group on inherited cardiac diseases, and will be conducted in various regions of the Russian Federation. If you agree to participate in this study, clinical data about you will be collected by the research physicians. You will not be subjected to any additional examinations other than those necessary for diagnosing and monitoring your heart disease. All changes to your drug therapy, decisions about surgical treatment, or the installation of additional intracardiac devices will be made according to current Russian guidelines. No new treatments will be prescribed to you. The clinical data that will be collected includes: prior diagnoses and treatments, symptoms, data from electrocardiography, echocardiography, cardiac magnetic resonance imaging, and any other heart-related tests. During the study, a research physician will contact you (by phone or during follow-up visits to the clinic) to gather information about your health status. The duration of the study for you will be at least one year from the moment of signing this informed consent form. By signing this informed consent form, you also agree to a one-time blood sample collection of no more than 10 mL for genetic analysis. Please be informed that during the blood draw, you may experience pain, and redness or bruising may form at the puncture site after the procedure. This study aims to analyze the structure of genes, the mutations in which may explain the development of HCM in your case. Understanding hereditary pathology (mutations) can be helpful for establishing an accurate diagnosis, screening family members, and, in some cases, taking preventive measures against sudden death. You will be informed of the results of the genetic analysis. A negative result does not rule out a diagnosis of hereditary heart disease, as not all genetic mutations can be detected at this time. Additionally, the

cause of your condition may be a mutation in a gene that is not included in the analysis. Sometimes, interpreting the pathogenicity (harmfulness) of an identified mutation can be challenging due to insufficient or contradictory data. In such cases, the diagnosis will be confirmed with varying degrees of certainty but not definitively. The likelihood of technical (laboratory) error is minimal, as confirmatory tests are always conducted, although it still exists. The results of the genetic test will be strictly confidential and only accessible to laboratory staff, your research physician, and yourself. For the purposes of the study, your biological sample may be transferred to another medical, research, or educational institution, with confidentiality of personal data maintained. Considering the hereditary nature of the disease, information about your relatives for three generations will be requested, including details that may constitute their medical confidentiality. There is no direct benefit expected from your participation in this study. However, the knowledge gained from the research may help many other patients and contribute to medical progress. You will not receive any financial compensation for allowing the use of your fully anonymized clinical data. This consent also applies to the processing of the following types of personal data: full name, residential address, phone number, and education. No organizations or third parties will have access to information about your health or any other details constituting medical confidentiality. This consent extends to actions regarding the processing of the patient's personal data, including collection, systematization, accumulation, storage, and updating (modification, change). Medical personnel and other participants in this study are required to act in accordance with the laws of the Russian Federation and implement technical and organizational measures to protect personal data (including the use of information security tools) aimed at preventing information leaks and unauthorized use of data. By signing this informed consent form, I confirm my agreement to: • Participate in the Hypertrophic Cardiomyopathy (HCM) Patient Registry; • The storage of my biological material; • The use of research results for investigative or educational purposes (including scientific publications) provided that it does not lead to the disclosure of personal information about me; • The processing and use of my personal medical data in anonymized form.

Patient _____
(Full name)

_____
(Patient's signature)

"_____" _____ 20_____
(Date of signing)

Doctor

_____
(Full name of the doctor conducting the discussion of informed consent)

"_____" _____ 20_____

(Date of signing)

_____(
Doctor's signature)