PATVIRTINTA
Lietuvos bioetikos komiteto direktoriaus
2016 m. sausio 25 d. įsakymu Nr. V-7
(Lietuvos bioetikos komiteto
direktoriaus 2020 m. lapkričio 11 d.
įsakymo Nr. V-26 redakcija)

BIOMEDICAL INVESTIGATION PROT

1.	**About the study:** By requesting the completion of this questionnaire, we aim to assess the nature, duration, and course of residual symptoms following COVID-19, their impact on the patient's daily life, physical ability, and ability to work. We also want to assess the need for rehabilitation after the onset of COVID-19 disease and the persistence of residual symptoms of the disease after recovery, which in one way or another have an adverse effect on human life. Respondents take 10-20 minutes to complete the questionnaire. Questions marked with * must be answered if the question * is not marked can be left unanswered. All people over the age of 18 with COVID-19 are invited to participate in the study on a voluntary basis. The observation study is ongoing, currently 1717 (12/20/2021) respondents from different websites answered the questionnaire. The anonymous questionnaire is regularly published on the social network Facebook (closed groups of patients with covid-19), on hospital websites, and in the media. It is planned to continue the study in order to collect as many respondents' answers as possible in order to be able to assess, analyze and describe the post -covid syndrome in the Lithuanian population as accurately as possible.

2.	**Link to clinicaltrials.gov (if study is registered):** https://clinicaltrials.gov/ct2/results?cond=&term=NCT05000229&cntry=&state=&city=&dist= **ClinicalTrials.gov Identifier**: NCT05000229
3.	**Links to the website where the survey questionnaire was / is distributed:** https://www.kaunoklinikos.lt/apie-mus/naujienos/covid-19-liga-kokie-pozymiai-ir-liekamieji-reiskiniai-labiausiai-vargina-lietuvius.html https://www.facebook.com/groups/Virusas/?multi_permalinks=648288256333847 https://www.facebook.com/groups/1994091020875362/?multi_permalinks=3124472811170505 https://www.facebook.com/groups/159021887526863 https://www.facebook.com/groups/412929278885515/?multi_permalinks=2097940567051036 https://www.facebook.com/groups/3495414077220547 https://www.facebook.com/groups/lietuvos.mamyciu.turgelis https://www.facebook.com/groups/1312138168987450 https://www.facebook.com/groups/371615077313631

4.	**Biomedical research identification marks:**

	• **Title of the biomedical study:** Residual symptoms in patients with coronavirus disease (COVID-19) and their implications for biopsychosocial function (Post-Povidial Syndrome). • **Protocol number:** 001; • **Version:** 1 • **Date:** 2021-03-15
5.	**Hypothesis of biomedical research:** Post-dysfunction syndrome with persistent dysfunction also develops in patients with a milder form of COVID-19 infection.
6.	**The purpose of biomedical research:** Describe the nature, duration, and course of symptoms in patients with COVID-19, assessing their impact on daily life, physical activity, work, and return to baseline (prior to COVID-19).
7.	**Tasks of biomedical research:** 1. To evaluate the nature, duration and course of residual symptoms after COVID-19 disease. 2. To evaluate the impact of residual symptoms after COVID-19 on daily life, physical capacity / activity, work, and clinical outcome. 3. To evaluate the expediency of rehabilitation, the need for COVID-19 and the persistence of "post-covid syndrome".
8.	**Detailed description of the outcome of the biomedical study (indicating what will be evaluated during the study):** 1. To study and describe the post-covid syndrome and its prevalence in Lithuania. 2. To compare the prevalence and severity of post-covid syndrome with other countries (eg using a similar Swedish questionnaire). 3. To assess the functional condition and working capacity of the participants in order to prepare rehabilitation measures and interventions.
9.	**Description of subjects:** • **Criteria for inclusion of subjects:** • over 18 years of age. age patients; • those who voluntarily agree to take part in the study; • a history of COVID-19 infection that was and was not positive for SARS-CoV-2 diagnostic or antibody testing; • The duration of symptoms in acute COVID-19 infection is longer than 28 days. • **Exclusion criteria for biomedical research:** ➢ Individuals who remain hospitalized after an acute COVID-19 infection due to complications, treatment, or rehabilitation. ➢ Individuals who have contracted another illness during the same period that requires

	special treatment, such as asthma, anxiety syndrome, depression, cardiovascular disease, and so on. Treatment is not yet stabilized. ➢ If stabilization of treatment of other diseases is taking place, e.g. testing for new medications and when side effects of the medication are felt. • **Number of subjects and its justification:** from 1 to 5 thousand participants. The panorama of participants' symptoms will be heterogeneous, so it is important to have a large population sample to ensure statistical reliability of the results.
10.	**Biomedical research methodology:** • **Type of biomedical research:** descriptive and monitoring. • **Description of measures to reduce the influence of subjective factors:** the study does not provide for grouping; the questionnaire questions will be designed in such a way that some parameters / dimensions of the survey will be repeated in order to obtain the most accurate information possible. A detailed informational description of the study will be provided. The questionnaire will unfortunately be based solely on the subjective information of the participants. The study will not use patient-identifiable personal data, except for e-mails of those who wish to be re-interviewed. The collected data will be used, processed and processed in a random order. • **Description of the biomedical research plan and individual stages**: ➢ **Survey Methods and Questionnaires**: The online survey will be conducted using a questionnaire with selected responses or free response text. ➢ Questions: age, gender, socio-demographic status, degree of working capacity, pre-existing co-morbidities, date of COVID-19 disease, acute symptoms of COVID-19 (~ 20), when and what specific COVID-19 tests were performed / not performed, summary question on COVID -19 participation in daily / work activities during treatment with post-infection symptoms (~ 40) and how these symptoms affect functional status. ➢ The questionnaire will be disseminated through social networks and various websites in order to reach as many Lithuanian populations as possible. ➢ The development and publication of the questionnaire, the management of the collected data and the analysis of the research results are planned to be performed at LSMUL KK Rehabilitation Clinic in cooperation with the Karolinska Institute in Sweden (Department of Clinical Sciences, Rehabilitation Medicine). • **Data evaluation and analytical methods used**: Data will be analyzed primarily to describe the population, persistent symptoms, functional status, and need for rehabilitation. An in-depth analysis will be carried out analyzing the distribution of key parameters by gender, age and socio-demographic situation. By collecting a repeated questionnaire with the same participants, it will be possible to follow the course of symptoms.
11.	**Description of the study sites, institutions where the biomedical research activities will be carried out (eg criteria according to which institutions are selected):**

	Online questionnaire. Information about the study will be published on the website. This will reach the widest possible population and increase the aggregation of data.
12.	**Planned duration of the entire biomedical study:** 2021-03-15 - 2022-12-31 (21.5 of the month)
13.	**Duration of research participation in biomedical research:** The patient will only participate in the study until they have completed the questionnaire. It will take up to 20-30 minutes to complete the questionnaire, depending on the side effects and persistent symptoms. Participants who indicate that they will agree to participate in the additional study and leave the e-mail details will be asked in addition to e.g. 6 months to follow the condition.
14.	**Description of the criteria for termination of the biomedical study (description of the subjects' participation in the biomedical study, parts of the biomedical study and the conditions for suspension or termination of the entire biomedical study):** The majority will participate only once in the questionnaire survey, a smaller part will be invited to participate 2 or a maximum of 3 times if the participants express a wish to participate in a further study survey. The time to complete the questionnaire will remain the same and will take up to 20-30 minutes.
15.	**Procedure for inviting individuals to participate in a biomedical study (provide a description of how individuals will be invited to participate in the biomedical study, such as inviting patients to visit the study center, using online or social media advertisements, etc.):** The study will be open on a voluntary basis to all persons over the age of 18 with COVID-19 infection who belong to closed groups formed by social networks in which the questionnaire will be distributed.
16.	**Peculiarities and procedure for obtaining information on a biomedical study and obtaining informed consent for a biomedical study (provide a detailed description of the procedure for inclusion and informed consent, especially when persons are incapable of giving informed consent):** The study will be attended by people who speak Lithuanian and have online knowledge. Incapacitated persons will not participate. Respondents will complete the questionnaire on a voluntary basis and most will be completely anonymous. The questionnaire will be placed in a closed social network, e.g. COVID-19 infection in the relapsed group. By agreeing to complete the form, the participant will automatically leave the consent.
17.	**Potential benefits of biomedical research in subjects:** The group of subjects will benefit indirectly as the group will be described and investigated in terms of symptomatology, level of functional impairment, and rehabilitation needs.

18.	**Assessment of potential risks and inconveniences to subjects (describe the inconveniences that may result from participating in a biomedical study (eg time spent, changes in normal life rhythm, risks associated with processing health information, etc.):** Participation in the study does not pose any risks and / or inconveniences. Personal information of those who agree to be invited to the re-application form will only be an online email address and will be stored at the LSMU Clinic in accordance with the level and requirements of personal data protection.
19.	**Procedures for documenting and evaluating adverse events observed in a biomedical study:** **• a description of what is considered an adverse event in the scope of the biomedical research,** **• a description of how this is recorded and evaluated,** **• a description of which authorities have been reported for adverse reactions.** An anonymous online questionnaire is conducted during the study, which is not harmful to health, therefore no adverse events related to the study are expected. Participation time is limited to 30 minutes.
20.	**Processing of personal data, ensuring the confidentiality of subjects and protection of personal data (this section is to be completed on the basis of a questionnaire (question - answer), answering all the questions below):** • **what data about the person will be collected (exhaustive list of data collected from the person and medical documents):** age, sex. • **where the personal data will come from, i. y. only from the subject himself / herself, from his / her medical records or other sources in the healthcare institution (s) (specifying them):** provided on a voluntary basis by filling in an online questionnaire. • **which data collected will be encoded and how:** will not be encoded**.** • **who will have access to the data for direct identification of the subject and for what purpose:** the principal investigator of the study and his / her authorized investigator, investigators of the study center, investigating authorities (such as ethics committees) and authorized supervisors will have access to the questionnaire. • **to whom and for what purpose only coded personal health information will be made available:** the collection of personal / confidential personally identifiable data is not foreseen, except for those who agree to be invited to the repeat questionnaire. In this case, the e-mail addresses will be entered in the USB memory and printed on paper and stored in the LSMU Rehabilitation Clinic in a safe place inaccessible to unauthorized persons. • **how the data will be processed (eg by creating "paper" files, entering them into an electronic system):** entering them into an electronic system. • **data storage at the research center (how, where and for how long the data collected during the study will be stored, who will be responsible for this**

	(researcher, biomedical research center): the main researcher will be responsible for data storage at the research center. • **Provision / transfer of data to the sponsor or third parties (what data will be transferred and to whom, specify the data to be transferred and the recipients):** only a schematic general analysis of all data will be provided, without personal e-mail addresses, names and surnames. • **Name and address of the data controller:** LSMUL Kauno Klinikos, Eivenių str. 2, Kaunas. • **how long the data of the subjects collected during the biomedical research will be stored and who will be responsible for it (eg researcher, biomedical research center):** the data will be stored until the end of the research. The lead researcher will be responsible for data storage**.** • **how will the research subject's right to revoke the informed person's consent to participate in the biomedical research be ensured and what will be the actions of the researchers upon receipt of the person's request to revoke the informed person's consent to participate in the biomedical research:** if the respondent decides not to participate in the survey, he / she will be able to stop answering the questionnaire at any time. Data from an incomplete questionnaire will not be included in the analysis. After filling in the questionnaire, it will not be possible to trace and remove the data from the study, as the respondent / respondent will not leave his / her name or other data that allow to identify the person. Information about this will be published in the study description for participants.
21.	**Description of the criteria for the replacement of a biomedical study:** No discontinuation or modification of the study is planned, and protocol changes and additional analysis are possible if new features of scientific value are observed.
22.	**Person reimbursing the costs and time spent participating in a biomedical study, the procedure and conditions for calculating and paying the compensation:** There will be no compensation or remuneration for participation. Participation is voluntary and anonymous and short.
23.	**Funding of biomedical research (institution or natural persons financing biomedical research, financial or other benefits to the researcher):** LSMU and Karolinska Institutet.
24.	**Procedure for compensation for possible damage caused by participation in a biomedical research (insurance):** The respondent will not be harmed by completing the questionnaire for a limited time.
25.	**Procedure for publishing the results of biomedical research:** The results will be published in scientific publications, the data will be presented at

	conferences, recommendations for doctors will be prepared, and rehabilitation program plans will be prepared. Based on the obtained results, it is planned to plan further scientific work.
26.	**Confirmation that the biomedical research will be performed in accordance with the requirements of the biomedical research protocol and relevant legislation:** We confirm that we are acquainted with the legal acts of the Republic of Lithuania regulating the performance of biomedical research. We will strictly adhere to the conditions set out in the protocol for biomedical research. It is undertaken to notify the Lithuanian Bioethics Committee of any changes in the biomedical research protocol and of the results of the biomedical research.
27.	**An explanation of which documents authorizing the biomedical research will be obtained and confirmation that the researcher (institution) will allow control of the biomedical research, audit, ethical supervision and inspection, giving direct access to the original documents (data sources).** The biomedical research will be performed only after obtaining the permission of the Kaunas Regional Biomedical Research Ethics Committee to conduct the research. The control of biomedical research, audits, ethical oversight and inspection will be facilitated by providing direct access to source data. The application for the biomedical research received the consent signed by the head of the institution where the research will be performed (LSMUL Kaunas Clinic, Rehabilitation Clinic) and permission to carry out the planned research. **Note:** The permission of Kaunas Regional Biomedical Research Ethics Committee to perform the research has been obtained.