Kinetics of physiological and symptomatic responses to CardioPulmonary Exercise Testing (CPET) in subjects with persistent exercise intolerance after COVID-19: an Open-Source Exercise Network

Informed Consent Form

June 9, 2023

Dear Madam, Dear Sir,

Dr. _____ (LAST NAME, First name), practicing at the hospital/clinic _____,

offers you to participate in a research study to better understand persistent exercise intolerance after Covid. By analyzing information from a large cohort, it is possible to identify subgroups of people with common clinical characteristics that will allow a more detailed understanding of the mechanism and determinants of persistent symptoms, and consequently to propose more adapted treatments.

The physician with whom you have performed a cardiopulmonary exercise test (CPET) is participating in this study which is organized under the aegis of a scientific committee composed of pulmonologists, cardiologists and physiologists.

Study data manager:	aCCPP Association 1901 **A**ssociation pour la **C**omplémentarité des **C**onnaisances et des **P**ratiques de la **P**neumologie
Coordinator:	Pr Bernard Aguilaniu (Grenoble Alpes University Hospital)
Principal investigators:	Pr PierAntonio Laveneziana (La Pitié Salpétrière Paris University Hospital) Pr Frédéric Costes (Clermont-Ferrand University Hospital)

Information collected - Regulations - Publication

This is an observational study that consists of collecting physiological information from your exercise test and clinical information about your health. This information will be collected on an electronic medium that will allow statistical analysis of all 600 records that we wish to collect. The main data on your health status are:

Age - weight, height, sex

History of chronic disease (e.g. cardiovascular, respiratory or metabolic diseases, etc.),

Date of COVID and initial and persistent symptoms

This observational study, which complies with the French MR-004 reference methodology, is published in the French Health Data Hub national directory. The Declaration of conformity to the reference methodology MR-004 was made to the National Commission for Information Technology and Civil Liberties (CNIL) on April 25, 2022 and bears the reference n°2226149 v 0.

Therefore, your voluntary participation does not require any additional visit or examination compared to your usual care. If you do not want your data to be analyzed, this will not influence in any way the care provided by your doctor. At any time, you may revoke your decision to participate in the study and this decision will not affect your medical follow-up.

All data collected are pseudonymized, i.e., identifying information does not appear at any time in the study documents and publications. They are saved under the responsibility of the aCCPP, data manager of the research.

The aCCPP is responsible for processing your personal data for scientific research purposes in the context of this study (art. 9.2(j) of Regulation (EU) No. 679/2016 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, hereinafter referred to as the "GDPR" or "Regulation"). This processing is implemented on the basis of the legitimate interest of the aCCPP to undertake scientific research in the field of pulmonology (Art. 6.1(f) GDPR).

The data of this research will be kept in the information system of the controller until 2 years after the last publication or in the absence of publication, until the signature of the final report of the research. They will then be archived on paper or digital storage medium for a maximum period of 20 years.

In addition, all research projects carried out by the aCCPP are published on the website: https://colibri.semaphore-sante.fr/. From this site, you can consult the projects in progress, ask questions and also oppose that your personal data contribute to a specific research project. The data collected during this study, aggregated and thus strictly anonymized, will be published in scientific medical journals by the scientific committee. You will be informed of the results through the investigating physician of the medical department in which you are being treated, if you wish, as soon as they are available.

Rights of data subjects

In accordance with Article 13 of the GDPR, we inform you that your data will be processed in accordance with the Regulation and with the rules of confidentiality to which the aCCPP association attaches particular importance. You have several rights regarding the information about you:

- You can ask to have access to the information concerning you in order to obtain a copy of it and the indication of the uses which are made of it (right of access);
- You can ask to correct and update information about you (right to rectification);
- You may object to the use of this information for research (right to object). This opposition prevents any use or conservation of these data;
- You can obtain the erasure of this data (right to erasure);

You can exercise these rights at any time with the aCCPP, for the attention of the Data Protection Officer (DPO), 19 avenue Marcelin Berthelot, 38 100 Grenoble - FRANCE, dpo@colibri-pneumo.fr, which undertakes to act on them as soon as possible or within a maximum period of one month (article 12.3 of the RGPD). You can also exercise these rights with the doctor who is following you in the study and who alone knows your identity.

- If you consider that the processing of your personal information constitutes a violation of the General Data Protection Regulation, you may lodge a complaint with the CNIL (right to lodge a complaint with a supervisory authority).

Consent

I freely consent to participate in the study entitled:

"Kinetics of physiological and symptomatic responses to CardioPulmonary Exercise Testing (CPET) in subjects with persistent exercise intolerance after COVID-19: an Open-Source Exercise Network"

- I have read the informed consent form explaining the purpose of this study, how it will be conducted and what my participation will entail,
- I have received appropriate answers to all my questions,
- I have understood that my participation is free and that I can interrupt it at any time without incurring any responsibility or any prejudice to the quality of the care I will receive. I will then indicate to the doctor who is treating me whether or not I wish the data collected up to the moment of my decision to be used,
- My consent does not relieve the physician who is following me in the study of any of his responsibilities and I retain all my rights guaranteed by law.

Patient's signature	**Investigating physician's signature**
LAST NAME First name :	LAST NAME First name :
Date:	Date:
Signature:	Signature: