INFORMED CONSENT FORM

STUDY TITLE

INCIDENCE OF SARS-CoV-2 RESPIRATORY VIRAL INFECTION IN USERS OF HIV PRE-EXPOSITION PROPHYLAXIS. PROTECTION FACTORS FOR COVID-19 (PJN-BCP -2020-01).

PRINCIPAL INVESTIGATOR

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INTRODUCTION

We are contacting you to inform about a research project, in which we would like to invite you to participate in. The project has been approved by an Institutional Ethics Review Board of l'Hospital Universitari Germans Trias i Pujol, in accordance with current regulation, Biomedical Research Law 14/2007.

Our only intention is that you receive accurate and enough information so that you can evaluate and decide whether or not you want to participate in this study. For this reason, we kindly ask you to read this informative text carefully. We will clarify any doubts that may arise after the explanation. In addition, you can consult with whom you choose.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary and may be withdraw from the study at any time without any need of explanation. You may at any time ask the research team any questions or clarifications that you deem appropriate.

STUDY OVERVIEW

Coronaviruses are a large family of viruses that normally only affect animals. Some have the ability to pass from animals to people. The new coronavirus SARS-CoV-2 is a new type of coronavirus that can affect people and was first detected in December 2019 in Wuhan City, Hubei Province, China. There are still many unknown issues regarding the disease it causes: COVID-19.

Transmission of SARS-CoV-2 occurs through close contact with respiratory secretions generated by the affected person. Transmission depends on the amount of the virus in the airways. These secretions would infect another person if they come into contact with their nose, eyes or mouth. Transmission at distances greater than 1-2 meters seems unlikely.

General measures of individual protection against respiratory diseases include:

- Frequent hand hygiene (washing with soap and water or alcoholic solutions), especially after direct contact with affected people or their environment.
- When coughing or sneezing, cover your mouth and nose with your elbow.
- Use disposable handkerchiefs, and throw them away after one use.
- If respiratory symptoms arise, avoid close contact (keeping a distance of approximately 1-2 meters) with other people.
- Avoid touching your eyes, nose and mouth, as hands make the transmission easier.

No special precautions should be taken with animals, or food, to prevent this infection.

There is no specific treatment for COVID-19, but some antivirals that have shown some efficacy in recent studies are being used. There are many treatments for controlling your symptoms; therefore medical attention can improve the prognosis. As a viral infection, antibiotics should not be used as means of prevention or treatment.

Among the treatments being studied, there are repurposed drugs known to act in the replication of other viruses that are similar to SARS-CoV-2, such as reverse transcriptase inhibitors like emtricitabine and tenofovir disoproxil, active components of PrEP.

Understanding SARS-CoV-2 infection, risk factors of adverse effects, and possible protective factors is important not only for establishing virus transmission patterns and infection risk factors, but also to prevent future infections and to inform and update infection prevention and control measures. This information would be essential for individuals and public health and may help to reduce secondary transmission of SARS-CoV-2.

The NGO Projecte dels NOMS-Hispanosida, the organization managing the community centers BCN Checkpoint and BCN PrEP·Point, intends to evaluate the frequency of occurrence of COVID-19 symptoms among its users, study the extent of person-to-person transmission between them, characterize the signs and symptoms of this infection and its evolution, as well as its possible relationship with the use of PrEP.

WHAT WOULD BE YOUR PARTICIPATION IN THE STUDY?

Your participation in this study will consist of answering the following online questionnaire twice (once now, and once within 30 days). You will be asked questions about PrEP and other medications and your general health.

If you agree to participate in this study you will be asked to sign the informed consent by CLICKING on the terms and conditions checkbox in the survey.

BENEFITS AND RISKS ARISING FROM YOUR PARTICIPATION IN THE STUDY

The benefit of this study for you is the ability to better understand the risk of SARS-CoV-2 infection and the evolution of COVID19 among people using PrEP. There is no potential risk arising from your participation in the study.

CONFIDENTIALITY

Compliance with Organic Law 3/2018, of December 5, On the Protection of Personal Data and guarantee of digital rights will be ensured to protect the right to privacy of all participants. Good Clinical Research Practices will be respected at all times and the anonymity of participating individuals and hospitals or care facilities will be ensured both in the construction of the databases and in any type of external dissemination of the results.

The participant may limit the processing of incorrect data, request a copy of the data or limit data transference to a third party the data provided for the study (portability). To exercise these rights, the principal investigator of the study will be directed.

The data will be collected on a secure server and processed solely and exclusively as part of your participation in this study.

The digital questionnaire has been designed in accordance with the Mobile App Privacy Code of Conduct available at https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-beenfinalised. According to this code, the following issues have been taken into account:

- User consent: in order to respond to the survey, users must sign informed consent (accepting by clicking the terms and conditions specified in the form).
- Objectives limitation and data minimization: the data collected will only be used to assess the frequency of occurrence of COVID-19 cases among BCN Checkpoint and BCN PrEP·Point users. The digital questionnaire will collect the minimum data necessary to achieve the objectives of the study.
- Privacy by design and by default: the digital questionnaire has been created by trying to maximize user privacy by both design and default.
- Right of access to data: users of the digital questionnaire will have the right to access the data they have provided, as well as to correct and object to the processing and/or to delete them at any time.
- Information Requirements: users of the digital questionnaire are clearly informed of the objectives of the study for which the data is collected. They are also informed of who is the team responsible for the study and are offered contact information with the research team to ask questions regarding the study, the information collected and/or to request access to their data. The data will be stored on a secure server. The use of the questionnaire is strictly voluntary and requires your consent to process the data.

- Data retention: the collected data will only be used to assess the frequency of occurrence of COVID-19 cases among PrEP users. The digital questionnaire will collect the minimum data necessary to achieve the objectives of the study.
- Security measures: security measures will be implemented to ensure the confidentiality, integrity and availability for the user of the data collected through the digital questionnaire. The necessary technical and organizational measures will be implemented to protect personal data from accidental or unlawful destruction, loss, alteration, disclosure, access and other forms of illegal processing.
- Advertising: advertising of any kind will not be included in the digital questionnaire.
- Use of personal data for secondary purposes: data obtained with the digital questionnaire will not be used for purposes other than the objectives of this study.
- Transfer of data to third parties: the collected data will be stored on a secure server. No data will be transferred to third parties.
- Personal data breach: if, despite all efforts made to ensure user privacy and data confidentiality, personal data breaches will be notified Relevant. Measures will also be implemented to minimise the risk of a personal data breach again. Affected users will also be informed, describing the measures taken in this regard.
- Data collected from children: no data will be collected from minors.

WHAT DO RESEARCHERS DO WITH THE DATA THEY COLLECT?

The personal data included in the questionnaire will be sex, date of birth, postal code and email address. It will not include patient name or other personal data.

To facilitate data analysis, a random code will be assigned to each user of the web questionnaire. To guarantee anonymity, two separate databases will be kept in different files, containing the responses and any data that could identify the participant, respectively.

The data will be stored on a secure server. Information will not be collated in hard copy formats.

Statistical analyses will be carried out to obtain the results of the study, which will be published in scientific journals, but will not include data that enables the identification of participants.

You can ask any question in connection with the study. Researchers are at your disposal to answer, now and throughout the study.

ECONOMIC REMUNERATION

Your participation in the study will not incur any expenses. You will NOT receive any economic remuneration for your participation either now or in the future.

OTHER RELEVANT INFORMATION

If you decide to withdraw the consent to participate in this study, no new data will be added to the database and may require the deletion of the data provided.

By signing the attached consent, you agree to comply with the study procedures presented to you.

PARTICIPANT CONSENT

Study Title: **INCIDENCE OF RESPIRATORY VIRAL INFECTION BY SARS-CoV-2 IN USERS OF PROPHYLAXIS PREEXPOSITION AGAINST HIV. COVID-19 PROTECTION FACTORS.**

Protocol code: *PJN-BCP -2020-01*

– I am aware that this digital questionnaire PJN-BCP-2020-01 collects personal data such as gender, age, level of education, employment situation, family situation and country of origin. It does not collect users' names nor other personal data. The digital questionnaire will also collect data on prEP and other drug use habits and general health status.

– I am aware that the data collected will only be used to assess the frequency of occurrence of COVID-19 cases among BCN Checkpoint and BCN PrEP·Point users and that the digital questionnaire will collect the minimum data necessary to achieve the objectives of the study.

– I also know that the digital questionnaire has been created trying to maximize the privacy of users both by design and by default.

– I am aware that as a user of the digital questionnaire I will have the right to access the data I have provided, as well as to correct it and oppose its processing and/or delete it at any time.

– I have been clearly informed of the objectives of the study for which the data is being collected. I have also been informed of who is the team responsible for the study and I have been offered contact information with the research team to ask questions about the study, the information collected and / or to request access to my data.

– I know that the data will be stored on a secure server, that the use of the questionnaire is strictly voluntary and my consent is required to process the data.

– I have been informed that the collected data will be stored on a secure server only for the time necessary to carry out the statistical analysis and process to achieve the study objectives. The data will later be deleted.

– I am aware that security measures will be implemented to ensure the confidentiality, integrity and availability for the user of the data collected through the digital questionnaire. I am aware that the necessary technical and organizational measures will be implemented to protect personal data from accidental or illegal destruction, loss, alteration, disclosure, access and other forms of illegal processing.

– I have been informed that advertising of any kind will not be included in the digital questionnaire.

– I am also aware that the data obtained with the digital questionnaire will not be used for any purposes other than the objectives of this study.

– I have been informed that no data will be transferred onto third parties.

– I have been informed that if, despite all the efforts made to ensure the privacy of users and the confidentiality of the data, any personal data breach occurs, the relevant data protection authorities will be notified. In addition, the necessary measures will be implemented to minimise the risk of a personal data breach again. Affected users will also be informed, describing the measures taken in this regard.

– I have been informed that no data will be collected from underage persons.

– I agree to participate voluntarily in the aforementioned study. I have had the opportunity to ask the appropriate questions, I understand the risks and benefits may arise from the study and that my participation in it is voluntary and that I can withdraw whenever I want from it.

– I understand that I will not receive an economic compensation from my participation in this study; and that I will not receive any economic benefit either now or in the future or in the event that a new study will be developed.

– I understand that the study information will be confidential and that no unauthorized person will have access to the results.

– I know how to get in touch with the study principal investigator if I need to.

– I know that this study has been approved by the Ethical Committee for Clinical Research of the Germans Trias i Pujol University Hospital.

– I have received enough information about the study.

– I understand that my participation is voluntary.

– I understand that I can withdraw from the study:

- Whenever I want.
- Without having to provide any explanation.
- Without this fact affecting my medical care.

– In accordance with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, I declare that I have been informed of the existence of a personal data processing file, of the purpose of their collection and of the recipients of the information.

I FREELY AGREE TO PARTICIPATE IN THE STUDY.