Post COVID-19 restart Informed Generic Post COVID-19 restart clinical activities Consent form



Sponsor:	Pfizer Inc.
Research organisation:	Pfizer Clinical Research Unit (PCRU), Route de Lennik 808, 1070 Brussels
Medical Ethics Committee	: Comité d'Ethique Hospitalo-Facultaire Erasme-ULB.
Contact for questions:	PCRU medical team
Emergency contact:	0800 30 019 / +32(0) 2 556 70 03

I. Information vital to your decision to take part to the post COVID-19 restart clinical activities

Introduction

Following the COVID-19 coronavirus pandemic, the Pfizer Clinical Research Unit ("PCRU") has taken the decision to temporarily suspend certain clinical activities. This measure has been taken in order to limit the propagation of COVID-19 and thus to preserve the health of our participants, their families and loved ones.

We are now pleased to inform you that these activities can resume with some additional precaution to protect our participants and staff, which are as follows:

- We kindly ask you not to come to the PCRU in case you have experienced/are experiencing any COVID-19 like symptoms in the past 2 weeks. Here are some examples of these symptoms: headache, fever, cough, sore throat, shortness of breath, muscle and joint pain, diarrhoea, fatigue, sneezing, runny nose, loss of smell and/or taste, conjunctivitis (pink eye), skin eruption...
- We kindly ask you not to come to the PCRU if you have had close contact with a person who is a confirmed or suspected COVID 19 positive case in the past 2 weeks.
- Staff will be wearing masks, face shields, gowns and gloves.
- We ask you to wear a surgical mask when you are coming to the PCRU and during a stay in the PCRU.
- We will also measure your temperature before you enter the PCRU building in addition to any temperature assessment which is already planned in the study which you are invited to take part in.
- A Nasopharyngeal (NP) swab or an Oropharyngeal (OP) swab will be used for testing any asymptomatic participant before entering the PCRU building (Day Hospital Erasme) and potentially during a stay in the PCRU building.

The swab is used in common medical practice in order to diagnose certain respiratory infections. It allows to collect a sample from the back of the nose or throat. The swab is inserted in each nostril or the mouth. The swab is then rotated to collect secretions, is then removed and placed into a sterile viral transport media, which preserves the sample until the subsequent analysis. The purpose of the swab in these Post COVID-19 restart clinical activities is to analyse the samples for the presence of COVID-19.

• A blood sample may also be collected for COVID-19 testing before entering the PCRU building, potentially during your stay in the PCRU (for instance if you would show COVID-19 symptoms) and at the end of a stay in the PCRU.



Before you agree to take part in this Generic Post COVID-19 restart clinical activities, we invite you to take note of all the implications in terms of organisation and possible risks, to allow you to take a decision with full awareness of all the consequences. This is called giving an "informed consent". Please read these pages of information carefully and ask any questions you may have to the PCRU medical team or their representative. There are 3 parts to this document:

- the information essential to your decision;
- your written informed consent; and
- supplementary information (appendices) detailing certain aspects of the basic information.

Course of the Post COVID-19 restart clinical activities

Obtaining the swab will only last few minutes.

The analysis of the swab would be internally performed by our local laboratory, and even then you would have to wait for its result (less than 1 hour). You would only be allowed to enter the PCRU building if this analysis has a negative result.

It is anticipated that a minimum of three swabs will be required during your participation in a study of interest (at screening visit, at admission, and 96 hours after admission). Additional swabs may be required on a case by case basis.

Obtaining the blood sample will only last few minutes. The total blood volume collected will be maximum 50 mL.

<u>Risks associated with the evaluation procedures or specific to the generic post COVID-19 restart</u> <u>clinical activities</u>

1. SWAB

The NP or the OP swab procedure could be experienced as uncomfortable, especially if you are not cooperating to the procedure. In these instances, it can be followed by pain or by light bleeding from the nose, sneezing or feeling of a need to vomit. These discomforts are only temporary. You are required to disclose any use of anti-inflammatory drugs in the last 7 days, or any previous history of nasal surgery.

2. BLOOD DRAWS

Blood draws may cause faintness, dizziness, inflammation of the vein (blood vessel), pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection.

3. COVID-19

There is a risk of COVID-19 infection when you are in close contact with staff or other study participants during the screening process and during your potential participation in the study of interest. However, safety procedures will be followed during screening and your potential study participation to minimize the risk of COVID-19 transmission.

Outcome of the swab/blood sample

If your COVID-19 test is **positive during an ambulatory visit**, you will be informed about it and you will not be granted access to other premises of the PCRU. You will receive a letter for your general practitioner with a copy of your positive result. You will have to inform your general practitioner about this positive test in application of article 9, paragraph 2 (i) General Data Protection Regulation and the recommendations of the Belgian Authorities. She/he will do the necessary declaration of your case with the competent national authorities and inform you about the isolation measures to adopt. This test needs to be repeated by your general practitioner request, to confirm this positive status and you would have to send us this report before any participation in a study. Your health status follow-up for the occurrence of COVID-19



like symptoms would be done by your general practitioner. You will also have to take all safety and preventive measures to avoid contaminating your relatives and contacts as recommended by the Belgian Authorities.

If your COVID-19 test is **negative**, you will be informed about it and you will be allowed to enter other PCRU buildings. You have to take note that a negative result is not a warranty that you have not been in contact with the virus before, or that you will not turn positive in a subsequent test. Therefore, your full adherence to all safety and preventive measures in application remains very important.

During your stay in the PCRU building, a COVID-19 swab will be performed after 96 hours in house to ensure that you are still free of COVID-19 since your admission. If you develop COVID-19 like symptoms during your stay in the PCRU, we would take additional measures to isolate you from other participants, to closely monitor your health status to ensure your safety, and a PCRU medical team will determine whether you can remain in the study you are participating in. The monitoring of your health status may include additional NP or OP swab tests to determine whether these symptoms are related to COVID-19.

If your COVID-19 test is **positive at any time during your stay** in the PCRU building, you will first be isolated from the other participants and the medical team will discontinue you from the study you are participating in.

The same discharge measures will apply as mentioned here above for a participant positive during an ambulatory visit.

If you take part in these Generic Post COVID-19 restart clinical activities, you should be aware that:

- These Generic Post COVID-19 restart clinical activities are being conducted after having been reviewed by one Ethics Committee.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. However, even after having signed that document, you can stop participating in the Generic Post COVID-19 restart clinical activities at any time, by informing the PCRU medical team of your decision.
- The data collected in the scope of the Generic Post COVID-19 restart clinical activities are confidential and shall be processed in conformity with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data. Your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in these Generic Post COVID-19 restart clinical activities.
- You may contact any member of the PCRU medical team at any time, should you need any additional information.
- If you have expressed a specific consent for this, your general practitioner will be informed of your participation in these Generic Post COVID-19 restart clinical activities. Nevertheless, you will have to inform your General practitioner of the result of your COVID-19 test if positive.

Further information about the "Participant Rights" can be found on page 5.

Benefits

You will not personally derive any benefit from your participation in these Generic Post COVID-19 restart clinical activities.

Withdrawal from the Generic Post COVID-19 restart clinical activities

Your participation is voluntary, and you are entitled to withdraw from the Generic Post COVID-19 restart clinical activities for any reason, without having to justify your decision. Nevertheless, it may be useful for the PCRU medical team to know if you are withdrawing from the Generic Post COVID-19 restart clinical activities because the constraints or discomfort are too great (too many uncomfortable side effects, for example).



It is also possible that the PCRU medical team withdraws you from the Generic Post COVID-19 restart clinical activities because they think it is better for your health or because they find out that you are not following the instructions given to participants.

Finally, the competent national, European or international authorities, the Ethics Committee that initially approved the Generic Post COVID-19 restart clinical activities or the Sponsor may decide to interrupt or discontinue the Generic Post COVID-19 restart clinical activities for any reason.

If you take part in these Generic Post COVID-19 restart clinical activities, we ask you:

- > To cooperate fully in the smooth running of these Generic Post COVID-19 restart clinical activities.
- Not to conceal any information relating to your state of health, the medication you are taking or the symptoms you are experiencing.

Contact

If you need further information, but also if you have any problems or concerns, you can contact the Pfizer Clinical Research Unit on the following telephone number +32(0) 2/556 70 02.



II. Supplementary information

Additional information on protecting participants and their rights in each clinical study

Assistance or advice

This Generic Post COVID-19 restart clinical activities document has been submitted to an independent Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', which has issued a favourable ethical opinion as regards to its implementation. The Ethics Committees are responsible for the protection of the subjects who take part in clinical research in accordance with the Law of 7 May 2004 concerning experiments on humans.

However, the decision to participate in these Generic Post COVID-19 restart clinical activities must be your own personal decision. Under no circumstances, should you take the Ethics Committee's favourable opinion as an incentive to take part in these Generic Post COVID-19 restart clinical activities.

If you have any questions, concerns or complaints concerning the role of the Ethics Committee or your rights as a participant in clinical research, you may contact the Ethics Committee 'Comité d'Ethique Hospitalo-Facultaire Erasme-ULB', during office hours, dialling the following number: 02/555 37 07.

Participant rights

Before signing, do not hesitate to ask any questions that you consider useful. Take the time to discuss it with a person you trust if you so wish.

Your participation in these Generic Post COVID-19 restart clinical activities is voluntary and you must remain free from any constraint. This means that you have the right not to take part to the Generic Post COVID-19 restart clinical activities or withdraw from it, at any time, without giving any justification and without losing your legal rights, even if you previously agreed to take part to it.

If you decide to withdraw from the Generic Post COVID-19 restart clinical activities, we ask you to inform the PCRU medical team. The PCRU medical team in charge of the Generic Post COVID-19 restart clinical activities can decide to remove you from the Generic Post COVID-19 restart clinical activities, if they deem that it would be harmful for you to continue to take part to it.

The Generic Post COVID-19 restart clinical activities may also be discontinued if the Ethics Committee takes a new decision on the Generic Post COVID-19 restart clinical activities.

You will be informed of any new data that may influence your decision to take part or not in the Generic Post COVID-19 restart clinical activities.

If you agree to take part in the Generic Post COVID-19 restart clinical activities, you must sign the informed consent form. The PCRU medical team, or designee, will also sign this form and will thereby confirm that she/he has provided you with all the necessary information on the Generic Post COVID-19 restart clinical activities. You shall receive a paper copy of that document.

Compensation and insurance

Your compensation for the inconveniences caused by your participation to the Generic Post COVID-19 restart clinical activities will be available three weeks after the last contact (see point 8 of the "Participant Agreement and Consent Form").

Any research carries a risk, however small it is. If you suffer damage as a result of your participation in these Generic Post COVID-19 restart clinical activities, you (or in the event of death, your dependants) will be compensated for this damage by the sponsor in accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004). You do not have to prove a fault for this. In this regard, the sponsor has taken out an insurance policy.

In the event of disagreement either with the PCRU medical team or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependents may bring proceedings against the insurer directly in Belgium (Insurer: Chubb European Group SE, policy number: BECANA07085, Tel: +32 (2) 516 97 11).



The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer's registered offices.

Provision has been made for insurance to cover research injury liability of the sponsor established in relation to the generic post-COVID-19 restart clinical activities.

Protection of your personal data

Your participation in the Generic Post COVID-19 restart clinical activities means that you accept that the PCRU medical team will collect data related to you (the "Personal Data") such as your name, postal address, email address, phone number, your date and place of birth, sex, age, your general practitioner's name (with your consent), bank details, as well as ethnic origin and data relating to your health status, and that the Sponsor (Pfizer) will use this Personal Data for research purposes as specified in this document, and for scientific and medical publications on that research (fully anonymously).

Your Personal Data will be collected, stored, accessed and otherwise processed in compliance with the applicable EU and Belgian laws on clinical trial, and with the applicable EU and Belgian privacy legislations as they may be amended or repealed and replaced from time to time (collectively referred to as "Data Privacy Laws") and as specified in the Appendix 1 "Supplement related to personal data protection" (p. 9).

You have the right to consult, correct or request deletion of your Personal data by writing to the following address: Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels.

If you want to ask for removal of Your Personal Data, please send a signed and dated letter to Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels. Your data will be deleted by Pfizer and will no longer be stored or processed by us (except for your letter requesting the removal – see point F of the "Supplement related to personal data protection"). You will therefore not be able to participate to any of our future studies.

However, if you have taken part to a study or a screening, we will not be able to delete your data, but your file will be inactivated, and you will not be contacted again.





PARTICIPANT AGREEMENT AND CONSENT FORM

- 1. I freely agree to take part in these Generic Post COVID-19 restart clinical activities.
- 2. I have received full explanations from the people in charge of the Generic Post COVID-19 restart clinical activities about the nature, purpose and likely duration of the Generic Post COVID-19 restart clinical activities, and about what is expected of me. I have also been informed of all the possible side effects. The information document, which was sent to me, is attached hereto and is an integral part thereof. In this regard, I was given the Generic Post COVID-19 restart clinical activities Information Leaflet pertaining to the abovementioned Generic Post COVID-19 restart clinical activities.
- 3. I have been given the opportunity to question the PCRU medical team on all aspects of the Generic Post COVID-19 restart clinical activities and have understood the advice and information given as a result.
- 4. I have been informed that NP or OP swabs and blood samples will be taken for COVID-19 screening. These results will be communicated to me and I will need to contact my general practitioner in case of positive result, in application of article 9, paragraph 2 (i) GDPR and the recommendations of the Belgian Authorities. I understand that my general practitioner will do the necessary declaration of my case with the competent national authorities and inform me about the isolation measures to adopt.
- 5. I agree to comply with any instruction given during the Generic Post COVID-19 restart clinical activities and to co-operate faithfully with the PCRU medical team and to tell them immediately if I suffer any change of any kind in my health or well-being or any symptoms of whatever kind.
- 6. I understand that data about me will be collected throughout my participation in these Generic Post COVID-19 restart clinical activities and that the PCRU medical team and the Sponsor of the Generic Post COVID-19 restart clinical activities will guarantee the confidentiality of these data.

I agree to my personal data being processed as described under "Protection of your personal data" in the section "Additional information on protecting participants [...]" (page 6). I also consent to these data being transferred to and processed in countries other than Belgium (United States).

- 7. It is understood that I am free to leave the Generic Post COVID-19 restart clinical activities at any time without having to justify my decision and without losing my legal rights. However, I shall, in that case, continue to benefit from all treatments and check-ups my condition may require.
- 8. The Sponsor (Pfizer) confirms that:
- i) I shall receive the sum of € 55.00 (fifty-five euros) for my participation in these Generic Post COVID-19 restart clinical activities.

Due to the ongoing COVID-19 pandemic and to the associated extra safety measures which are or could be put in place during your stay at the PCRU, your study compensation will be increased with an extra amount of €30,00 (thirty euros) per residence night in the PCRU. We understand that these extra safety measures may inconvenience your stay at the PCRU. This increase of study compensation is temporary and only applicable during the COVID-19 pandemic.

- ii) It has subscribed a no-fault insurance to cover injuries or significant deterioration in health or wellbeing in connection to my participation in the Generic Post COVID-19 restart clinical activities.
- 9. I have been made aware of the reasons for which personal data will be processed and/or transferred as part of the Generic Post COVID-19 restart clinical activities and of my legal rights concerning these personal data as described in the Participant Information Sheet.



In agreement, the participant:

Printed name of participant

Signature of participant

§Participant or impartial witness must personally date their signature.

Person Obtaining Consent:

I hereby confirm having provided the participant with all the necessary information about the Generic Post COVID-19 restart clinical activities, without exercising any pressure to cause the subject to participate. I further confirm that I have handed over a copy of the Information and Consent Leaflet signed by the participant and by me, and that I am willing to answer any additional questions if necessary. I state that I work in compliance with the ethical principles set out in the "Helsinki Declaration" and the Belgian Law of 7 May 2004 concerning experiments on humans.

Printed Name of the Person Conducting the Consent Discussion

Signature of the Person Conducting the Consent Discussion [†]

[†] PCRU medical team member, or an appropriately qualified and trained person designated by the PCRU medical team to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

Consent for Participant Who Cannot Read:

The Generic Post COVID-19 restart clinical activities participant has indicated that he/she is unable to read. One or more members of the Generic Post COVID-19 restart clinical activities team read the consent document to the Generic Post COVID-19 restart clinical activities participant, discussed it with the participant, and gave the Generic Post COVID-19 restart clinical activities participant an opportunity to ask questions.

Printed name of impartial witness [‡]

Signature of impartial witness

□ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the participant cannot read.*)

[§]Participant/impartial witness must personally date their signature.

[‡] Impartial Witness: A person, who is independent of the Generic Post COVID-19 restart clinical activities, who cannot be unfairly influenced by people involved with the Generic Post COVID-19 restart clinical activities, who attends the informed consent process if the participant cannot read, and who reads the informed consent and any other written information supplied to the participant. See Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

Clinical Research Unit Brussels

Date of signature§

Date of Signature

Date of signature§



APPENDIX 1

SUPPLEMENT RELATED TO PERSONAL DATA PROTECTION

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This **Supplement related to personal data protection** describes how we will collect, use, and share your personal data. It also describes your rights as data subject of whom personal data are being collected and processed. Your personal data shall be processed in compliance with the General Data Protection Regulation and the Belgian law of 30 July 2018 relating to the protection of natural persons with regards to the processing of their personal data.

A. What personal data may we collect about you during these Generic Post COVID-19 restart clinical activities?

The PCRU team and others assisting you with care will collect information related to you (personal data), in the framework of the Generic Post COVID-19 restart clinical activities. Amongst these personal data; some are sensitive data. These data may include:

- Information that directly identifies you such as your name, address, telephone number, e-mail address, date and place of birth, national ID number.
- Your bank details.
- With your consent, the identification of your general practitioner.
- Sensitive personal data such as your medical history, data from this Generic Post COVID-19 restart clinical activities (including results from tests and procedures), demographics (for example, age and gender) and other sensitive personal data that is needed for this generic post COVID-19 restart clinical activities such as ethnic origin, genetic information, sexual orientations, dietary preferences.
- Data from testing and analysis of biological samples (such as blood or swab).
- Data captured from electronic devices, if you complete the consent process using the eConsent tablet or if you use a mobile application or other digital tool during the generic post COVID-19 restart clinical activities. This information may include data about your use of the eConsent tablet, application or tool, such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, your electronic signature. Mobile applications and other digital tools used in the Generic Post COVID-19 restart clinical activities may have their own privacy policies. Those policies provide additional information about the data processing activities performed by the digital tools.

B. Who will use my personal data, how will they use it, and where will it be stored?

Any personal data collected about you during these Generic Post COVID-19 restart clinical activities will be stored by the PCRU team at the site. The PCRU team must ensure the confidentiality of your personal data.

Your personal data shall be accessed by:

- The PCRU medical team and other members of the PCRU-team;
- Your General Practitioner, only with regards to the result of your COVID-19 testing, in case of positive result;
- Government or regulatory authorities (including those in other countries); and
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this Generic Post COVID-19 restart clinical activities.



The individuals and groups listed above will use your personal data to conduct these Generic Post COVID-19 restart clinical activities, and to comply with legal or regulatory requirements, including to:

- determine if you are eligible for participation to the Generic Post COVID-19 restart clinical activities;
- provide you with reimbursement for your time, effort and certain expenses related to your participation;
- verify that the Generic Post COVID-19 restart clinical activities are conducted correctly, and that data are accurate;
- answer questions from IRB(s), IEC(s), or government or regulatory agencies, including performing any mandatory declaration of positive testing to the COVID-19 Coronavirus;
- assess your use of electronic devices in the Generic Post COVID-19 restart clinical activities, for example, to determine how long it takes you to complete any e-consent module used for the Generic Post COVID-19 restart clinical activities and your comprehension of the e-consent process;
- contact you during and after the Generic Post COVID-19 restart clinical activities (if necessary);
- protect your vital interests (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- answer your personal data protection requests (if any).

The site will retain your personal data for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the Generic Post COVID-19 restart clinical activities.

If you provide someone else's personal data (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us. We will only use such personal data in accordance with this informed consent and applicable law.

C. What happens to my personal data that is sent outside the site?

Before the PCRU team transfers your personal data outside the site, the site will replace your name with a unique code and remove all information that directly identifies you. We call this "**Coded Information**." The site will keep the link between the unique code and your personal data confidential.

Your Coded Information will be used by the following persons:

- Other researchers;
- The IRB or IEC that approved this Generic Post COVID-19 restart clinical activities;
- Government or regulatory authorities, if necessary;

The above parties may use your personal data for the following purposes:

- Complying with legal and regulatory duties, such as:
 - Ensuring the Generic Post COVID-19 restart clinical activities are conducted according to good clinical practice;
 - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in the consent document(s). This period could be up to 25 years after the end of the Generic Post COVID-19 restart clinical activities.



D. How are my biological samples handled?

If biological samples of you are taken during the Generic Post COVID-19 restart clinical activities, those samples will be handled in the same way as your Coded Data. All samples will be treated as required by law.

E. How will my personal data be protected?

Your personal data will be treated in compliance with applicable data protection laws. The Sponsor and Pfizer Clinical Research Unit (PCRU), part of Pfizer SA, are the data controllers of your personal data.

F. What are my data protection rights? Whom may I contact about these rights or any concerns or complaints?

If you wish to exercise any of the rights described below or have concerns about how your personal data is being handled, you may contact the PCRU. Please contact the PCRU, Data Privacy Steward, at the following address: Participants Recruitment Department, Pfizer Clinical Research Unit, route de Lennik 808, 1070 Brussels, Phone: 0800/99.256 or +32 2/556.70.02; Email: werespectyourprivacy@pfizer.com.

- You have the right to access your personal data that is held about you.
- You have the right to correct or update your personal data.
- You have the right to limit the collection and use of your personal data under certain circumstances (for example, if the information is inaccurate).
- You have the right to receive your personal data in a structured, commonly used and machinereadable format (for example, in a readable text electronic file or chart) for your own purposes or for giving it to others.
- You have the right to request the deletion of your personal data if you are no longer participating in the Generic Post COVID-19 restart clinical activities and you have withdrawn your consent to process your personal data as described in this document. *However, there are limits to the ability to honour a request to delete your personal data. Some or all of your personal data may be kept and used if your personal data is needed to comply with legal requirements.*
- You have the right to file a complaint with the data protection authority:

Data Protection Authority

Rue de la Presse 35, 1000 Brussels Tel.: +32 (0)2 274 48 00 Fax: +32 (0)2 274 48 35 Email: contact@apd-gba.be https://www.dataprotectionauthority.be/contact-us



G. What happens if I do not wish to continue with the Generic Post COVID-19 restart clinical activities?

As noted in the main consent document, you are free to stop taking part in these Generic Post COVID-19 restart clinical activities at any time by informing the PCRU team of it.

If you stop taking part in the Generic Post COVID-19 restart clinical activities and you do not inform the PCRU team about your withdrawal, your contact information may be used by the PCRU team to contact you and check whether you wish to continue in the Generic Post COVID-19 restart clinical activities.

If you stop taking part in the Generic Post COVID-19 restart clinical activities but do not withdraw your consent for the processing of your personal data, your personal data will continue to be used in accordance with this document and applicable law.

If you decide to withdraw your consent:

- You will no longer be able to participate in the Generic Post COVID-19 restart clinical activities;
- No new information or samples will be collected about you or from you by the PCRU team.
- Your personal data, including your Coded Information, that has already been collected up to the time of your withdrawal of consent, will be kept, to satisfy legal or regulatory requirements and/or for any other purposes permitted under applicable data protection laws.;
- Your personal data, including your Coded Information, will not be used for further scientific research.
- Biological samples that have been collected but not analysed will no longer be used, unless permitted or required by applicable law.

You have the additional right to request that any remaining samples that have been collected from you as part of the Generic Post COVID-19 restart clinical activities be destroyed. You may exercise this right by communicating to the PCRU team your wish to have the samples destroyed.

However, we cannot guarantee the destruction of all samples because they may have been entirely used up or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your biological samples and any related data.