Pregnant Partner Release of Information Form

TITLE:	A PHASE 1 / 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE ESCALATING DOSES OF PF-07868489 IN HEALTHY ADULT PARTICIPANTS AND, ADDITIONALLY, CLINICAL ACTIVITY OF REPEAT DOSES IN PARTICIPANTS WITH PULMONARY ARTERIAL HYPERTENSION
PROTOCOL NO.:	C5001001
SPONSOR:	Pfizer
INVESTIGATOR:	Name Address United Kingdom
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

PFIZER STUDY INFORMATION: (to be completed by investigator/study doctor)

Study/Protocol ID: C5001001

Subject ID: _____

USE AND DISCLOSURE OF PREGNANCY INFORMATION

In compliance with the requirements of the study noted above, your partner has informed the study doctor that you are pregnant. Pfizer, the study sponsor, continuously improves knowledge of its products and meets the recommendations of regulatory agencies by collecting information about pregnancy in women who are pregnant or become pregnant while they or their partner are participating in a Pfizer study. Pfizer therefore requests that you participate in an important safety monitoring activity. This will help Pfizer and others to understand the effects, if any, that PF-07868489 may have on your pregnancy or your unborn child.

The study drug may have unknown risks that could harm a foetus or a breast-feeding baby. At this time, it is not known whether PF-07868489 can cause foetal harm when administered to pregnant women or their partners.

Pfizer requests this information whether the pregnancy goes to term or not. Although the study doctor will collect information about your pregnancy and outcome, neither Pfizer nor the study doctor will be responsible for any expenses related to this pregnancy.

If you sign this document, you are giving permission for the use and disclosure of your and your child's health information for the purposes of the safety monitoring activity described below. You do not have to give this permission. If you do not sign this document it will not affect your or your partner's right to receive healthcare or other benefits you would normally receive within your country.

TYPE OF INFORMATION REQUESTED

Information related to the progress of your pregnancy and its outcome will be collected by the study

doctor. This may include information related to your health, the date of conception, the course of your pregnancy, medical treatments that you receive and the health of your child after birth.

CONFIDENTIALITY

Pfizer respects the confidentiality of personal and medical information, and recognises the importance of protecting the privacy of information collected. The information will be collected by the study doctor and his or her research staff and provided to Pfizer or its representatives. The information sent to Pfizer will not include your name or address, only a code, and may be transferred, used and processed (both by computer and manually) by Pfizer and its representatives during and after your participation in this safety monitoring activity. The information collected may be sent to government health agencies, the institutional review board or ethics committee that approved the study and others working on Pfizer's behalf. Some of the entities that will have access to your information may be based in other countries where data protection and privacy laws may be less strict. However, the study sponsor and people working with the sponsor will take appropriate steps to maintain confidentiality. Sensitive personal data (e.g., date of birth) will be collected and processed but Pfizer will use and disclose your information only for safety monitoring activities or for regulatory purposes. Information will be collected until the birth of your child, although additional information may be requested by the study doctor, if needed. You and your child will not be referred to by name or identified on any report or publication.

You have a general right to access your health information and, where it is shown to be incorrect, request its correction. Any request seeking access or changes to any information should be directed to the study doctor.

RIGHT TO WITHDRAW AUTHORISATION TO RELEASE INFORMATION

Your participation is voluntary, and you are free to withdraw your authorisation at any time by informing the study doctor in writing at the contact address provided. If you withdraw your authorisation the study doctor will not collect any new health information about you or your child. However, Pfizer and its representatives may continue to use and disclose any information already collected. Refusal to participate in this safety monitoring activity will not affect your partner's continued participation in this PF-07868489 study or future Pfizer studies.

QUESTIONS

If you have any questions about this form or how your information will be used, please contact the study doctor or their representative at the address and/or telephone number provided. The study doctor is collecting only information related to the progress of your pregnancy and its outcome; you should contact your regular health care provider for any health concerns you may have.

Investigator/Study Doctor (or representative) Name: _____

Address: _____

_____

Telephone: _____

Please complete this release of information form and return it to the study doctor. PLEASE PRINT.

AUTHORISATION FOR RELEASE OF MEDICAL INFORMATION

- I voluntarily agree to allow the use and disclosure of my health information related to the progress of my pregnancy and its outcome in connection with this safety monitoring activity as described in this Authorisation form.
- I understand that I will receive a signed and dated copy of this Authorisation form.
- I understand that I may revoke my Authorisation at any time.
- I have had a chance to ask questions and I understand the answers I received.

_____	_____	_____
Full Name *(Printed)*	Signature	Date

If individual is a minor or non-legally consenting adult:

Legally Acceptable Representative Full Name (Printed): _____

Legally Acceptable Representative Signature: _____

Date: _____

Relationship to Minor: _____

(e.g., father, maternal grandfather):

Pregnancy Healthcare Provider's Name: _____

(e.g., physician, midwife)

Address: _____

_____

Telephone: _____

A copy of this signed authorisation form may be provided to your pregnancy healthcare provider by the study doctor.

Your information is very important to us. Thank you for taking the time to complete this form.

UK PRIVACY SUPPLEMENT (version 9 Apr 2024)

This Privacy Supplement describes how the study site and the Sponsor will collect, use, transfer, store, analyse and share your personal information (called "processing") to conduct the study based upon its legitimate interests in (1) ensuring high standards of quality and safety in medicinal products and (2) conducting and publishing research. It also describes your privacy rights.

A. What information may be collected about you during this study?

In order to conduct the study, your study team will collect information about you. Information about you may include personal information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, genetic information, sex, race, and ethnicity). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history, you should inform that person or those persons you have done so and that their information will be used as described in this document.

B. How will your information be used?

Your information will be treated in compliance with applicable data protection laws. Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The Sponsor is the controller for any information collected about you by the site for purposes of conducting the study and is also the controller of your coded information once it leaves the site. The study site will retain your information for the period necessary to fulfil the purposes outlined in this Privacy Supplement, in the main consent document, and/or for the maximum period permitted by applicable law, which could be at least 25 years after the end of the study.

Your information may be accessed and used by:

- The study team;
- The Sponsor (including its affiliated companies) and its representatives, for example, study monitors and auditors;
- People and/or organisations providing services to or collaborating with the Sponsor;
- Any organisation that has or obtains rights to the product under study or that obtains all or part of the Sponsor's business;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- Regulatory authorities, including those located in other countries, such as the United States Food and Drug Administration; and

Typically, your name will be removed from your information before it is sent outside the study site. As described in the main consent document, your name will be replaced with a unique code before your information (and/or your biological samples, images and/or audio/video recordings, if collected as part of the study) leaves the study site. This information is referred to as your "Coded Information." Data generated using biological samples, images and/or audio/video recordings of you if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this Privacy Supplement or the main consent document. Sometimes the study site may be unable to remove information that can identify you from your images, meaning that the images shared with others may be identifiable as yours.

The study site will upload your information (which will not include any information that personally identifies you) to a designated secure electronic system maintained by a third party engaged by the Sponsor. The Sponsor and/or the Sponsor's representatives will use this secure system to review and verify study data as they would at the study site. The Sponsor is the controller of the information uploaded to this electronic system. These uploaded records will be kept for the period necessary to fulfill the purposes outlined above and in the main consent document, as required by applicable law and/or for the maximum period permitted by applicable law on the secure electronic system.

The individuals and groups listed above will use your information, including your Coded Information, to:

- conduct this study;
- comply with legal or regulatory requirements, including for all of the purposes listed in the main consent document that you were provided and to seek approval from government or regulatory agencies to market study drug;
- publish the study results;
- improve the quality, safety, and design of this study and other research studies

The Sponsor may be required to provide information gathered from this study, including your Coded Information, to regulatory authorities for public disclosure. In such cases, the Sponsor will take steps to minimize the risk that you could be re-identified.

Some of the people and/or organisations using your information may be based in countries other than your country of residence, including the United States. When transferred to countries with legal standards that have not been found by the European Commission to offer an adequate level of protection of personal information, the Sponsor uses officially approved agreements (called Standard Contractual Clauses) to ensure a similar degree of protection is afforded. A copy of the agreement may be obtained by contacting your study team.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in this Privacy Supplement and in the main consent document, indefinitely or the maximum period permitted by applicable law after the end of the study.

C. Can your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

Yes. The Sponsor may use and has a legitimate interest in using your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, in the future to support and advance other scientific research projects, including improving the quality, design and safety of

other research studies, research supporting public health aims and developing medicines, vaccines, diagnostic products and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information and biological samples, images, and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information, biological samples, images and/or audio/video recordings used in any other research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimize the risk that you could be re-identified; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, are anonymised such that they can no longer be identified with you, they may be used for other research purposes.

D. What are your rights to your personal information?

You may request access to your personal information, to correct, delete or restrict its processing; however, these rights are limited, as your information needs to be managed in specific ways in order for the research to be reliable and accurate or to comply with legal duties. The right to object to further research may also be limited by applicable law. To exercise any of these rights, contact the [Institution] (please see the **contact information at Page 1** of the main consent document) and not the Sponsor. However, you may find contact details for the Sponsor's data protection officer at DPO.Pfizer.com. You also have the right to file a complaint with a Data Protection Authority in the place you live, work or where any breach of data protection law may have occurred. Contact details of UK and EU Data Protection Authorities can be found by consulting the list here: http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index_en.htm.

E. What happens to your information, and biological samples, images, and/or audio/video recordings that may be collected as part of the study if you do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time. If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor, or to search publicly available records to find out how you are doing. These uses of your information may continue until the Sponsor determines the study is complete, which may take many years. Your information will continue to be used in accordance with the main consent document, this Privacy Supplement and applicable law, as the Sponsor needs to manage your information in specific ways in order for the research to be reliable and accurate. The Sponsor, may continue to use your Coded Information even if you stop taking part in some or all of the study activities as necessary for the Sponsor (a) to comply with its legal and regulatory obligations; (b) for the Sponsor's legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of its products and advancing public health and scientific research and publishing the results of its studies; and (c) any other purposes permitted under applicable data protection and privacy laws.

No new information, biological samples, images and/or audio/video recordings will be collected about you or from you by the study team, unless you have told the study team that you agree to provide new information or samples. Even if you do not agree to the collection of new information or samples, the study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to the Sponsor.

In the event the Sponsor has already removed all information that could reasonably be used to identify you, it may use all resulting anonymised data for any purpose.

Any biological samples that have been collected about you or from you will be handled as described in the “Process for Participants who Wish to End Study Participation” section in the main consent document.