

CONSENT DOCUMENT COVER LETTER

TITLE:

HERO Together: A post-Emergency Use Authorization observational cohort study to evaluate the safety of the Pfizer-BioNTech COVID-19 vaccine in US healthcare workers

PROTOCOL NO.:

C4591008
IRB Protocol #20204110

SPONSOR:

Pfizer, Inc

INVESTIGATOR:

Emily O'Brien, PhD
200 Morris Street
Durham, North Carolina 27701
United States

STUDY-RELATED PHONE NUMBER(S):

[1-844-846-6747](tel:1-844-846-6747)

Dear Sir or Madam,

Thank you for taking the time to consider joining this study. This consent can help you make your decision by explaining **what you can expect to happen during this study**, also known as a research study.

Your participation in this study is **completely voluntary (your choice)**. Take as long as you need to make your decision. You also can choose to take part in the study now, and then change your mind later at any time.

We encourage you to speak **with your family, caregivers, doctors, and the study team** about taking part in this study and whether it is right for you. The study team at the Duke Clinical Research Institute (DCRI) will work with you to answer any questions that you may have about the study. If you choose to participate, **you will be asked to sign this consent form before starting the study**. You will also be asked to allow the study sponsor **to review your relevant (or important) health records** if you experience certain health events.

If you agree to participate, a copy of this signed consent will be available to you through the online portal.

We appreciate that you are thinking of taking part in this study.

Sincerely,

The HERO-Together Study Team

Key Study Information and Contact Information

Members of the HERO-Together study team will answer any questions, concerns or complaints you may have before, during and after you complete the study. The study team includes the principal investigator, call center staff and others who work with the principal investigator.

If you have concerns about your participation, you may contact Dr. Emily O'Brien and the DCRI HERO-Together research team at [1-844-846-6747](tel:1-844-846-6747) or HERO-Together@duke.edu.

If you have concerns about your privacy, or your rights when you are in the study, you may contact WCG IRB. The IRB is a group of people who review the research to protect your rights as a participant. You can reach WCG IRB at [1-855-818-2289](tel:1-855-818-2289) or researchquestions@wcgirb.com.

Name of Study: **Healthcare Worker Exposure Response and Outcomes (HERO)-Together**

Sponsor Consent Version Number (Study/Country/Site): **1.0**

Sponsor Study Number: **C4591008**

Name of Company Sponsoring the Study: **Pfizer, Inc**

Name of Principal Investigator: **Dr. Emily O'Brien**

Study Team Contact Information

Contact Person: **Emily O'Brien, PhD**

Address: **Duke Clinical Research Institute, Department of Population Health Sciences, 215 Morris Street, Suite 210, Durham, NC 27701**

Phone Number: [1-844-846-6747](tel:1-844-846-6747) (Mon.-Sat.: 9am-11pm ET, Sun. 12pm-11pm ET)

Email address: HERO-Together@duke.edu

Institutional Review Board Contact Information:

Address: **1019 39th Avenue SE Suite 120 Puyallup, Washington 98374-2115**

Email: researchquestions@wcgirb.com

Phone Number: [1-855-818-2289](tel:1-855-818-2289)

Brief Summary of this Study

This study will collect information about how you feel after receiving a vaccine to prevent COVID-19 infection in order to monitor (or check) the effects of the vaccine.

You are being asked to take part in a study that is sponsored by Pfizer (the "**Sponsor**"). The Sponsor is paying to support this study, including the online platform operated by a company called Verily and all study activities overseen by the Duke Clinical Research Institute (DCRI) Coordinating Center.

You are being asked to take part in this study because you previously enrolled in the HERO Registry or in the Project Baseline Community Study, are 18 years or older and living in the United States, and have received the first dose of a vaccine to prevent COVID-19 infection within the last 60 days. Both the HERO Registry and the Project Baseline Community Study use the Baseline Platform by Verily. The HERO Registry is managed by DCRI; the Project Baseline Community Study is managed by Verily.

You will be asked to take part in the study for about 2 years. If you agree to participate, this study will involve regular responses to surveys about your health. If you report experiencing certain health events, the study team may collect medical records or bills related to the event from you or your healthcare provider.

This study does not involve any change in your usual healthcare and is for research purposes only. There is no direct benefit to you from taking part, but information learned from the study may help other people in the future.

Taking part in this study is voluntary (your choice). There is no penalty or change to your regular medical care if you decide not to participate. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care. We encourage you to speak with your family, caregivers, health care providers, and the study team about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study.

If you agree to participate, a copy of this signed consent will be available to you through the online portal.

If you are interested in learning more about this study, please continue reading below.

What is the purpose of this study?

The HERO-Together study will collect information about people who have received a vaccine to prevent COVID-19. You will be asked to provide some information about yourself and your health after vaccination.

The Food and Drug Administration (FDA) has provided Emergency Use Authorization (EUA) for or approval of the vaccine that has been administered to you. The Sponsor is conducting this study to collect additional information about the health effects of a COVID-19 vaccine when given to healthcare workers. The study leverages the existing HERO Registry and Project Baseline Community Study online platforms to streamline data collection and reporting.

How long will I participate in this study?

After enrollment, you will be asked to complete follow-up surveys for up to 2 years after first vaccination.

How many people will take part in this study?

We expect about 20,000 people in the United States enrolled in the HERO Registry or in the Project Baseline Community Study will also participate in the HERO-Together study. The study is being conducted remotely using an online platform.

What will happen during this study?

Before any study activities begin, you will electronically sign this consent document in the online portal. If you experience certain health events during the study, you'll also be asked to sign a medical record release form in the online portal. The medical record release form will be used to collect your medical records from any hospital, office or other health care facility where you receive care for certain health events while you are enrolled in the study.

You will also provide information for one or more alternate contacts. These contacts may be asked to provide information about your health and well-being if you cannot be reached during the follow-up period.

We will ask you to provide the following personal information:

- Your date of birth so we can confirm your age;
- Your phone number, email address, and cell phone number so we can contact you to see how you are doing;
- Your primary health care providers and any primary/ secondary hospitals you may visit if you need care;
- Access to medical records so we can review any hospitalizations or non-routine medical visits that occur while you are participating in the study; and
- Contact information for a family member or friend so we can contact them if we can't reach you. These people may be asked to provide us some information about your health.

You will be asked to provide additional information about your medical history, medications (prescription and non-prescription), and pregnancy status at enrollment. This information will be combined with information you provided when you enrolled in the HERO Registry or in the Project Baseline Community Study, so that you don't have to provide the information multiple times. Only the information from the HERO Registry or the Project Baseline Community Study that is also necessary for the study will be used.

After enrollment, you will be asked to complete follow-up surveys using the online portal at 1 week, 2 weeks, 4 weeks, 8 weeks, and 12 weeks after the first dose of your vaccination. Thereafter, you'll be asked to complete follow-up every three months through 1 year after vaccination, and every 6 months for up to 2 years after vaccination. The total amount of time you'll participate in this registry is up to 2 years following vaccination. A map of the participant journey can be found here.

The follow-up surveys will ask information about your health and well-being, and about healthcare events that required medical care. You'll receive email reminders to complete the surveys at the necessary time points. If you don't complete the surveys within a specific timeframe, or if key information is missing or inconsistent, the Call Center at the Coordinating

Center will contact you via telephone to collect the information. The phone surveys will take about 15 minutes. The Call Center may also contact you via text message or email to collect the information. If you cannot be reached, the Call Center staff may contact your alternate contacts to collect the information.

If you report a medically significant event during the study, you'll be asked to sign a medical record release form so that the Call Center may contact your healthcare provider, or the hospitals where you received care, to obtain related medical records or bills. They may also collect records for care that occurred up to one year prior to your vaccination, to understand how the health event is related to your regular health status before receiving the vaccine. The Coordinating Center will review these records to understand more details about the event and whether it meets the definition of the events of interest in this study. The Call Center may contact you if assistance is needed in obtaining these records.

Once your participation in the HERO-Together study is completed, you will still be a member of the larger HERO Registry or Project Baseline Community Study programs, and you can continue to participate in those online communities as long as you wish. You may also be contacted about additional studies regarding the vaccine and how long it protects against COVID-19. If you are contacted about these studies, they will be explained to you at that time, and you will be asked to provide a separate consent. You do not have to participate in any of these studies.

What are the possible risks and discomforts of this study?

This is a non-interventional study, so there are no physical risks associated with taking part in this study. This study is non-interventional because it collects information only. Your usual health care provider will manage your care no differently than if you were not taking part in this study. There may be non-physical risks such as the risk of accidental disclosure of your personal data (including your medical information), but we will do our best to keep your data secure.

The COVID-19 vaccine that you received prior to enrollment in the study may cause some side effects, including certain risks or discomforts. These side effects were described in the information sheet provided at the time of vaccination. If you experience any side effects that are severe or do not go away (for example, any illness for which you are hospitalized) or become pregnant during the study, you should inform your healthcare provider that you received a COVID-19 vaccine.

Pregnancy Follow-up

If you become pregnant during the study, please tell the doctor who will be taking care of you during the pregnancy that you received a COVID-19 vaccine. The study team may ask if you are willing to participate in a study related to the health effects of a COVID-19 vaccine during pregnancy.

What are possible benefits of this study?

This study is for research purposes only. While there are no direct benefits for participating in this study because you will continue to receive your regular medical care, you may feel benefit from knowing that your participation will help researchers understand the effects of a vaccine against COVID-19 and help other people in the future.

What other choices do I have if I do not join this study?

This study is for research purposes only. Your alternative is to not take part in this study. If you choose not to take part in the study you will continue to receive your regular medical care.

What happens if I am injured during this study?

This study collects information only, so it is unlikely that you will have a study-related injury. You were vaccinated with a COVID-19 vaccine as part of your medical care outside of this study. Any negative reaction you may experience while taking part in this study will not be considered a study-related injury.

What if I join this study and then change my mind?

If you agree to participate and then change your mind for any reason, you are free to stop participating at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study team if you are thinking about stopping or decide to stop taking part.

The principal investigator or the Sponsor may decide to take you out of the study if:

- The study is stopped by the Sponsor, the institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency;
- You do not agree with consent updates;
- The study ends; or
- The principal investigator or the team who oversees research recommends you no longer participate.

There may be other reasons not listed here. If your participation ends without your permission, the reason will be explained to you at that time.

The study team will give you a Privacy Supplement, which is considered part of this consent document. It describes what happens to your personal information and how it may be used if you withdraw from the study.

What will I have to pay for if I take part in this study?

There are no costs to you to join the study.

This study is collecting information only and there is no change to your regular medical care. So, the Sponsor will not pay for any treatments or procedures that you may receive during your participation in this study including the COVID-19 vaccine.

If you access the study using a mobile device, or if you receive text messages related to the study, you will be responsible for any data usage or other charges from your wireless service.

Will I be paid for taking part in this study?

You may receive up to \$200 over the two years you participate in this study. You will be asked to complete a form to agree (“opt-in”) to receive this reimbursement. Duke University employees and students will also be asked to provide their unique ID number.

The Sponsor may use information resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. The Sponsor will own all products or processes that are developed using information from the study.

What will happen to my personal information?

The Privacy Supplement, accessed below, is considered part of this consent document. The Privacy Supplement tells you about:

- What personal information may be collected from you during the study;
- How your personal information will be used and by whom (including by the study team and the Sponsor);
- How your personal information might be used for other research;
- How your personal information will be protected during transfer;
- Your data protection rights, and whom you may contact about these rights or any related concerns or complaints; and
- What happens to your personal information if you decide to stop taking part in the study.

Where can I find additional information about this study or the study results?

You will not receive personal health information from this research. Research is not the same as medical care. We may contact you by phone, email, or other methods with updates related to the study. We will share the results with you and others, including through publications. Any results shared or published will be anonymous, meaning they will not identify you in any way.

A description of this study will be available on the European Union (EU) post-authorization study (PAS) register www.encepp.eu/encepp/studiesDatabase.jsp. This Web Site will not include information that can identify you. At most, this Web Site will include a summary of the results. You can search this Web Site at any time. It may be many years, however, before research results are posted.

If you need assistance understanding this Web Site, please ask the study Principal Investigator.

Signatures

Now it's time to sign the HERO-Together study consent!

To do so, you will be asked to log in to the portal. Logging in acts as a legally binding signature, just as your handwritten signature, and confirms that you:

- Are at least 18 years old, and live in the United States
- Received the first dose of a vaccine against COVID-19 within the last 60 days

You can review this consent information as many times as you'd like. You can reach out to us with questions at [1-844-846-6747](tel:1-844-846-6747) or HERO-Together@duke.edu. After signature, you'll receive an email confirming your enrollment, and providing access to your copy of the signed consent in the online portal.

- I confirm I have read and understand this consent for the study described above and have had the opportunity to ask questions. I have had enough time to review this consent. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate.
- I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.
- I understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent to the processing of my personal information at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study.
- I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the course of the study, and if necessary, contacting my doctor or any other health care providers treating me for access to such information.
- I understand that the Sponsor and/or others working with or on behalf of the Sponsor, institutional review boards (IRBs) or independent ethics committees (IECs), and regulatory agencies may need access to personal information about me collected by the study team for the study and any other research. I agree that they may have access to my personal information.
- I agree that the study team (or others working on behalf of the Sponsor) may send me text messages as described above.
- I do not give up any of my legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.
- I agree to take part in the study described in this document.

PRIVACY SUPPLEMENT

This Privacy Supplement describes how we will collect, use, and share your personal information. It also describes your privacy rights.

You are not required to authorize the use and disclosure of your personal information as described below. If you do not agree, you cannot participate in this study, but there will be no penalty or change to your regular medical care or payment for that care.

A. What personal information may we collect about you during this study?

The study team will collect or provide information about you, some of which is sensitive. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, email address, and date of birth.
- **Sensitive personal information** such as your medical history, data from this study, demographics (for example, age and gender) and other sensitive information that is needed for this study such as HIV/AIDS, tuberculosis, substance use disorders, mental health disorders, diagnoses and treatment, race, ethnicity.
- **Data captured from electronic devices** if you complete the consent process using an online tablet or if you use a mobile application or other digital tool during the study. This information may include data about your use of the eConsent 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, and your electronic signature. Mobile applications and other digital tools used in the study 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 information, how will they use it, and where will it be stored?

Any personal information collected about you during this study will be stored by the study teams at Verily and DCRI. The study teams must keep your personal information private. A U.S. privacy law called HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects the privacy of your personal health information. DCRI and Verily must get your permission to use and share with others any personal health information that could identify you.

Your personal information will likely be accessed by:

- The study Principal Investigator and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People, or organizations providing services for, or collaborating with, the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities (including the U.S. Food and Drug Administration and authorities in other countries); and

- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.

The individuals and groups listed above will use your personal information to conduct this study, and to comply with legal or regulatory requirements, including to:

- determine if you are eligible for this study;
- verify that the study is conducted correctly and that study data are accurate;
- answer questions from IRB(s), IEC(s), or government or regulatory agencies;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests or the interests of your pregnant partner (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 data protection requests (if any).

The study team will retain your personal information for the period necessary to fulfill the purposes outlined in the consent document(s), which could be up to 25 years after the end of the study.

If you provide someone else's personal information (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 information in accordance with this informed consent and applicable law.

Please note the following information regarding the delivery of text messages:

- The study team, or a company working on behalf of the Sponsor may send text messages to remind you of available surveys or check-ins, or other study-related information. Texts messages will be sent only to the contact telephone number that you have provided. The number of messages per month may vary depending on the specific requirements of the study.
- Message and data rates may apply. Please contact your wireless phone provider to inquire about the details of your plan.
- The messages received through this program may appear on your mobile phone screen as soon as they are received, even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received.
- Text messages are not encrypted. Encryption is a way of coding a message so that only authorized people can access it. There is a risk that information contained in unencrypted text messages may not be secure and could be read, used or disclosed by people other than the study team or the Sponsor, such as your wireless service provider or other unauthorized people.
- For questions regarding text messages, please contact the DCRI study team at [1-844-846-6747](tel:1-844-846-6747).

C. What happens to my personal information that is sent outside DCRI or Verily?

DCRI and Verily are required by HIPAA to protect your personal information. After your information is shared with others, such as the Sponsor, it may no longer be protected by HIPAA.

Before the study team transfers your personal information outside, DCRI or Verily will replace your name with a unique code and remove information that directly identifies you. We call this "**Coded Information.**" The study team will keep the link between the code and your personal information confidential, and the Sponsor will not have access to that link. The Sponsor's employees and representatives are required to protect your Coded Information and will not attempt to re-identify you.

Your Coded Information will be used by the following:

- The Sponsor and its representatives (including its affiliated companies);
- People and/or organizations providing services to or collaborating with the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or the rights to the product under study;
- Other researchers;
- The IRB or IEC that approved this study;
- Government or regulatory authorities;

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

- **Conducting the study**, including:
 - Examining your response to the COVID-19 vaccine;
 - Understanding the study and the study results and learning more about the COVID-19 vaccine; and
 - Assessing the safety and efficacy of the COVID-19 vaccine.
- **Complying with legal and regulatory duties** such as:
 - Ensuring the study is conducted according to good clinical practice;
 - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities;
 - Seeking approval from government or regulatory authorities to market the COVID-19 vaccine (it is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research); and
 - Sharing study data with other researchers not affiliated with the Sponsor or study team (including through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers).
- **Publishing summaries of the study results** in medical journals, on the internet or at educational meetings of other researchers. You will not be directly identified in any publication or report of the study. But, some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information

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from the study that does not directly identify you be made available to other researchers for further research projects.

- **Improving the quality, design and safety** of this study and other research studies.

The Sponsor will retain your Coded Information for the period necessary to fulfill the purposes outlined in the consent document(s), which could be up to 25 years after the end of the study.

D. Can my personal information be used for other research?

Your Coded Information may be used to advance scientific research and public health in other projects that will occur in the future. At this time, we do not know the specific details of these future research projects. This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources:** Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your Coded Information, which may include:
 - Limiting access to Coded Information to specific individuals who will be obligated to keep this information confidential and will be prohibited from attempting to re-identify your Coded Information.
 - Using security measures to avoid data alteration, loss and unauthorized access.
 - Anonymizing the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
 - Assessing data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
 - When required by applicable law, ensuring that the scientific research has the approval of IECs, IRBs, or other similar review groups.

E. How will my personal information be protected when transferred from DCRI to the Sponsor?

Your personal information will be treated in compliance with applicable data protection laws, including requiring people and/or organizations providing services to or collaborating with the Sponsor to use appropriate measures to protect the confidentiality and security of your personal information. Some of the people using your personal information, including your Coded Information, may be based in countries other than your country. Data privacy laws may be different in these countries. If your personal information is transferred by the Sponsor to other

countries, the Sponsor, and people working with the Sponsor, will take steps to maintain the confidentiality of your personal information.

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

You have the right to access your personal information that is held about you by the study team. *To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.*

If you wish to exercise this right, or have concerns about how your personal information is being handled, it is best to contact the DCRI study team and not the Sponsor. Generally, the Sponsor will not know who you are (by name) because the Sponsor usually holds only your Coded Information, which does not include your name or other information that can easily identify you. To contact a study team representative, please see the **contact information at the beginning** of the consent document.

G. What happens if I 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 by telling the study team. Your authorization for the study team to disclose your personal information does not expire unless you withdraw your authorization.

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 and check whether you wish to continue in the study. If the study team is unable to reach you, the Sponsor may use publicly available records about your health to monitor the long-term safety of the vaccine. This will only be done if allowed by the law.

If you stop taking part in the study but do not withdraw your consent, your personal information will continue to be used in accordance with this Privacy Supplement and applicable law. No new information will be collected about you or from you by the study team, unless you have agreed to provide them.

If you decide to withdraw your consent:

- You will no longer be able to participate in the study;
- No new information will be collected about you or from you by the study team;
- The study team may still need to report any safety event that you may have experienced due to your participation in the study to the Sponsor;
- Your personal information, including Coded Information, that has already been collected up to the time of your withdrawal will be kept and used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of the COVID-19 vaccine, to satisfy legal or regulatory requirements, and/or for any other purposes permitted under applicable data protection and privacy laws;

- Your personal information (including Coded Information) will not be used for further scientific research. However, if your personal information has been anonymized so that the information does not identify you personally, that information may continue to be used for further scientific research (as described in [Section E of this Privacy Supplement](#)), as permitted by applicable law.

I acknowledge that the name below is my legal name and I adopt the signature below as the electronic representation of my name and initials. I agree and acknowledge that the signature below is my legal, binding signature just as my handwritten name and initials.