Participant Information Leaflet

Combining Influenza and COVID-19 Vaccination (ComFluCOV) Study

We are recruiting adults who have received their first dose of an approved COVID-19 vaccine to a study which is looking at the safety and immune response of giving the COVID-19 vaccines at the same time as the recommended seasonal influenza (flu) vaccines.

If you want to get involved, please read this information leaflet and let us know you are interested by completing a short questionnaire here: https://trials.ovg.ox.ac.uk/trials/comflucov-pre-screening-knowle-house-surgery-plymouth

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Participation in this study could really make a difference during a public health emergency.

Thank you for reading this information leaflet. Your help, whatever your final decision, is very much valued. We would like to invite you to take part in our 'Combining Influenza and COVID-19 Vaccination (ComFluCOV) Study'. Before you make any decision, it is important you take the time to understand why we are doing this research and what it would involve. Please read the following information carefully and discuss it with friends, relatives or others as you wish.

What is the purpose of this study?

There are now vaccines that have been approved to protect against COVID-19 in the UK. The duration of protection of these COVID-19 vaccines is unknown but further booster doses may be required to give continued protection.

With the challenges of immunising large numbers of people against COVID-19 and the need to continue the seasonal influenza (flu) vaccination schedule, it would be preferable if we could give people both their COVID-19 booster and flu vaccine at the same appointment.

This would mean receiving two vaccines on the same day, one in each arm. It would also mean fewer appointments for those who need both vaccines and would reduce the burden on the NHS.

Therefore, the purpose of the ComFluCOV study is to see what side effects, such as fever and tiredness, people get when they are given their second dose of the COVID-19 vaccine at the same time as the currently recommended flu vaccine. We will also look at people's immune responses to both vaccines when given together.

We will be enrolling people aged 18 years and over. We particularly welcome participants from all communities and those with underlying health conditions who would usually be offered the influenza vaccine. **To take part, you must have already received your first dose of either the Pfizer/BioNTech COVID-19 vaccine or the Oxford/AstraZeneca COVID-19 vaccine and be awaiting your second dose.**

Summary of the study

We are looking at the side effects and immune responses of giving the currently approved COVID-19 vaccines at the same time as the flu vaccine compared to giving them separately. We hope to enrol 756 participants.

- Interested volunteers should complete the online screening questionnaire https://trials.ovg.ox.ac.uk/trials/comflucov-pre-screening-knowle-house-surgery-plymouth. If you are eligible to take part you will be called by the research team and invited to join the study.
- Participants will attend 3 study appointments at their nearest participating hospital. There will be a gap of about 3 weeks between each study visit.
- Participants will be allocated into one of two groups:
    - One group will receive their second dose of COVID-19 vaccine and the flu vaccine at visit 1 and then a saline injection (placebo) at visit 2.
      Note: The saline injection (placebo) is a salt and water solution which looks like the flu vaccine but does not contain any active ingredients.
    - The other group will receive their second dose of COVID-19 vaccine and a saline injection (placebo) at visit 1 and then the flu vaccine at visit 2.
- The group you are allocated to will be chosen at random by a computer. This is so that we can be sure that participants in the two groups are as similar as possible and can be compared fairly.
- The second dose of COVID-19 vaccine given in the study will be the same as the one you received in the UK mass vaccination programme.
- You will not know in which order you received the flu vaccine and the placebo until after the study is completed.
- No vaccines will be given at visit 3.
- A blood sample and a saliva sample will be taken at each study visit to look at the immune responses to the vaccines.
- Participants who could become pregnant will also be required to take a urine pregnancy test at visit 1 and inform the study team if they become pregnant during the study.
- You will need to complete an online diary for seven days after visit 1 and seven days after visit 2. This will be reviewed at the following visit.
- The study will take roughly 6 weeks to complete (from the time of the first visit to the third and final visit).
- We will not be offering diagnostic COVID-19 testing as part of this study, but it is important that you access COVID-19 testing outside of the study as required, and follow government guidance on self-isolation.
- We cannot guarantee that the flu vaccine received through this study will protect you against flu through the 2021/22 flu season. We advise that you accept your next NHS flu vaccine as usual, where relevant.

What are the vaccines used for?

The vaccines being used in this study are vaccines against flu and the coronavirus SARS-CoV2 that causes the disease COVID-19.

Common symptoms of COVID-19 include fever, tiredness, dry cough, and changes to taste and smell. Whilst most infected people have no or mild symptoms and recover without needing special treatment, some people develop severe symptoms and become critically ill. Older people and those with underlying medical conditions are more likely to develop serious illness and people in some ethnic groups (Black and Asian) might be at a greater risk of severe illness.

Symptoms of flu include fever, body aches, fatigue and a dry cough. Most people will have mild symptoms and recover, but certain groups are at higher risk of severe disease and complications such as older people and those with underlying medical conditions. In the UK, people in higher risk groups are invited to receive a flu vaccine every winter. This is why an effective vaccine programme against both of these diseases is so important.

Which vaccines are being used in this study?

The COVID-19 vaccines being used in this study are:

- ChadOx1 nCoV-19 (Oxford/AstraZeneca)
- BNT162b2 (Pfizer/BioNTech)

You would receive the same COVID-19 vaccine as you did for your first dose as part of the UK mass vaccination programme. Neither COVID-19 vaccine contains the SARS-CoV-2 coronavirus and therefore cannot give you COVID-19.

The flu vaccines in this study are:

- Flucelvax QIV (recommended for people aged under 65 years old)
- Flublok QIVr (recommended for people aged under 65 years old)
- FluAd (MF59) (recommended for people aged over 65 years old)

You would receive one of the flu vaccines recommended for your age group from the 2020/21 season. For those aged under 65 years old, some hospitals will use Flucelvax, and others will use Flublok.

Flucelvax QIV (recommended for people aged under 65 years old)

This vaccine contains four of the main strains of the flu virus that has caused infection over the winter. The vaccine contains parts of the influenza viruses that our immune system can ‘see’ and make protective responses against, which can provide protection in the future. The viruses that are used to make the vaccine are inactivated which means that they cannot cause infection. This type of vaccine is usually offered to healthcare workers and those with underlying medical problems who are at increased risk of flu.

Flublok QIVr (recommended for people aged under 65 years old)

This vaccine contains four of the main strains of the flu virus that has caused infection over the winter. The vaccine contains parts of the influenza viruses that our immune system can ‘see’ and make protective responses against, which can provide protection in the future. The parts of the virus used are manufactured using the genetic material of the virus and cannot cause infection. This type of vaccine is usually offered to healthcare workers and those with underlying medical problems who are at increased risk of flu.

FluAd (MF59) (recommended for people aged over 65 years old)

This vaccine contains three of the main strains of the flu virus that has caused infection over the winter. In addition to the inactivated parts of the flu virus this vaccine also contains MF59, an adjuvant. Adjuvants are added to vaccine to enhance the immune response to the vaccine. This is particularly important as we get older as our immune responses to both natural infection and vaccines weaken.

Influenza vaccines are usually given once a year to provide protection against infection during the flu season which is typically over the winter months but there is no reason why the vaccine cannot be given more than once a year. The protection provided by the flu vaccine is typically less than 6 months so even if you have had the flu vaccine already this year you can safely have another dose as part of this study.

Saline injection (placebo)

You would receive a placebo vaccine (saline) either at your first or second study visit. The placebo vaccine will look just like the influenza vaccine but just contains sodium chloride, which is sterile, salty water.

We are aiming for similar numbers of participants in each of the COVID-19 and flu vaccine groups so that we can compare all possible combinations of the COVID-19 and flu vaccines.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will need to read this information leaflet in full and will be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason.

Am I suitable to take part?

Adults that are aged 18 and over are able to take part in this study. In order to take part in the study you must have received your first dose of either the Pfizer/BioNTech COVID-19 vaccine or the Oxford/AstraZeneca COVID-19 vaccine and be awaiting your second dose. There may be some people who are not eligible to take part. This will be determined from your answers to the questions in an online screening questionnaire and a discussion with the local research team.

What will happen if I decide to take part?

Online screening questionnaire – 5-20 minutes

If you would like to take part in this study you first need to complete a two-part online questionnaire to check whether you are eligible. This can be found here: https://trials.ovg.ox.ac.uk/trials/comflucov-pre-screening-knowle-house-surgery-plymouth

Part 1 – This will check whether you are able to take part in the study (e.g., that you have received your first COVID-19 vaccine). The information you provide will not be saved, unless you progress to part 2.

Part 2 - If you are found to be potentially eligible on completing part 1 of the questionnaire, you will be asked to give your consent to:

- Provide details of your medical history and allow us to store this information. Some participants will be advised they are unable to take part on the basis of this additional information.
- Have a member of the research team at your nearest participating hospital contact you by phone to clarify the medical information given (if needed).
- Provide details of your registered GP, and consent for the local research team to contact them to confirm that you have had the first dose of the COVID-19 vaccine.
- Provide details/information about yourself such as your date of birth and address.

If you do not consent to these things, then you would not be able to join the study. If you consent and part 2 of the questionnaire does not identify any obvious reason why you should not participate, the local research team will review the information you provide. A member of the team will contact you to confirm your answers and then make an appointment for your first visit (Visit 1). At this visit, if you are eligible you will be invited to an in-person screening and vaccination visit where you will be asked to provide written consent.

Please note that it may not be possible to enrol everybody that wishes to take part in the study and passing through the screening process does not guarantee participation in the study. In the case that you are not enrolled in the study, your screening questionnaire data would not be stored beyond the end of the study.

What should I do about the appointment for my second dose of COVID-19 vaccine that I already have?

We are aiming to offer all participants a study appointment that is before their NHS vaccination appointment. This means that you can cancel your NHS appointment as soon as you have had your study vaccine. Some people are found not to be eligible to take part in the study at the first visit and so would not be able to have their second dose as part of the study. This means that they would still need to attend their NHS appointment.

Visit 1 - Enrolment and vaccination (up to 90 minutes)

Consent & eligibility

If you are eligible to take part in the study, a member of the local research team will ask you to attend Visit 1. They will explain the study and answer any questions you have about the study. If you decide to take part, they will ask you to complete a consent form at that appointment. You will be given a copy of the signed consent form to keep for your information.

They will check details of your medical history, and if needed, may perform a physical examination. If you are able to become pregnant, you will also be required to take a urinary pregnancy test.

They will also ask you to give your email address so that the online e-diary you will need to complete between study visits can be emailed to you. The e-diary collects important information about any symptoms you may have after you receive the vaccinations.

Samples

Blood and saliva samples will be taken just before vaccination. These samples will be compared with samples taken at later visits to check for immune responses to the second COVID-19 vaccine and the flu vaccine.

Randomisation

Following consent and collection of blood and saliva samples, you will be randomly allocated to one of two groups. The vaccines you receive at each visit will depend on which group you are allocated to. You will not be told which group you are in. The only exception to this would be if you were to become ill and it was felt to be medically necessary for you to know which order you had received the vaccines in.

Vaccination

After randomisation, you will be given two injections, one into each arm. One will contain the COVID-19 vaccine and one will contain either the flu vaccine or the placebo. The local study team will need to keep an eye on you for around 15 minutes after the vaccine has been administered.

Vaccines received at each visit

	Group 1	Group 2
Visit 1	Second dose of COVID-19 vaccine Flu vaccine	Second dose of COVID-19 vaccine Saline injection (placebo)
Visit 2	Saline injection (placebo)	Flu vaccine
Visit 3	No vaccination	No vaccination

Between Visits 1 & 2

Electronic Symptom Diary "e-diary"

You will receive a link by email to complete an online e-diary to record any symptoms, including symptoms at the vaccination sites, and your temperature every day for 7 days after Visit 1.

After 7 days and until Visit 2, we will ask you to record if you feel unwell or if you are taking any new medications. You will also be asked to record any unplanned visits to the doctor/dentist and any serious medical illnesses or hospital visits you make. You will receive a daily email reminder with a link to record any relevant information.

Your local research team will check your e-diary entries and may telephone you to discuss an entry further, if required.

Visit 2 – Second study vaccination visit (up to 90 minutes)

Around three weeks after Visit 1, you will attend Visit 2 to complete some follow-up study activities and receive your second study vaccine (flu or placebo).

At this visit a member of the local research team will review your medical history since your first visit and your e-diary entries with you and ask for any additional information that may be required. They may perform a physical examination. You will be asked to provide blood and saliva samples before receiving your final study vaccination. You will receive either the flu vaccine or the placebo, depending on which group you are in. You will not receive a COVID-19 vaccination at this visit.

Between Visits 2 & 3

You will be asked to complete the e-diary as you did between Visits 1 and 2. Again the local research team will continue to check your e-diary entries and may telephone you to discuss an entry further, if required.

Visit 3 - Final follow-up visit (30 minutes)

Around three weeks after Visit 2, you will attend a final study appointment. The local research team will check your diary as before and you will be asked to provide final blood and saliva samples.

IMPORTANT: If you develop a fever or cough, or loss of sense of smell or taste, or become unwell then you must contact the study team on 01752 705090 for advice before attending any study visit.

Should you be unable to attend a scheduled study visit (for example because you are self-isolating or quarantining), you should let your local study team know as soon as possible. They will try to rearrange your visit for another suitable time. If this is not possible, they may telephone you instead. If you were to test positive for COVID-19 during the study, you should inform your local research team of this.

Will this impact my private medical insurance?

If you have private medical insurance, you are advised to contact the insurance company before agreeing to take part in the ComFluCOV study to ensure that your participation will not impact your cover.

Are there things I will be asked to avoid doing during the study?

You should not donate blood in the 7 days following vaccination at Visits 1 and 2 or take part in other studies that involve blood sampling or the administration of drugs or vaccines, including studies testing other interventions for COVID-19.

If during the study you require any other vaccinations, you should inform your local study team using the contact details at the end of this information leaflet. We will discuss with you the most appropriate time to receive them.

What are the risks of taking part in this study?

The potential risks and side effects of vaccinations and study procedures are detailed below.

Blood samples

Drawing blood may cause discomfort and occasionally bruising at the site where the needle enters. Light headedness and fainting can also occur when having blood taken, though this is less frequent. We will need to take approximately 10mL of blood at each study visit (approximately 2 teaspoons). The total amount we will take over the period of the study will be approximately 30mL. This is well below the recommended limit of 470mL every 3 – 4 months for blood donations to the National Blood Transfusion Service.

Vaccination Side Effects

People very often have tenderness, pain, warmth, redness, itching, swelling or bruising or less commonly have a small lump in their arm where they have been vaccinated.

Some people can develop the following symptoms after vaccination. They usually last for less than a week (more commonly 24-48 hours after vaccination).

- Fatigue
- Headaches
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Muscle aches
- Joint aches
- Feeling unwell (malaise)
- Feeling sick or nauseated, vomiting or diarrhoea

Other less common side effects are:

- Abdominal pain
- Decreased appetite
- Feeling dizzy
- Swollen lymph nodes (glands)
- Excessive sweating, itching skin or rash

These symptoms can be reduced by use of paracetamol around the time of immunisation and over the next 24 hours. We would not routinely recommend the use of ibuprofen or other anti-inflammatory medication at this time.

After immunisation with the BNT162b2 (Pfizer/BioNTech) vaccine, difficulty sleeping has been observed in fewer than 1 in 100 people, and weakness of the muscles on one side of the face has been observed in fewer than 1 in 1000 people.

Serious/Allergic Reactions

With any vaccination there is a small risk of rare serious adverse events, such as an allergic reaction. Mild to severe allergic reactions can occur in response to any part of a vaccine or medicine. Severe allergic reactions (anaphylaxis) can be fatal but are extremely rare (about 1 in a million vaccine doses). In case of this unlikely event, medication for treating allergic reactions is available and the researchers are appropriately trained in the management of anaphylaxis. Serious blood clots, sometimes with bleeding, have occurred very rarely after

the first dose of Oxford/AstraZeneca vaccine. These have not yet been seen after the second dose and it is not known if the vaccine is definitely causing the blood clots. Unless you experienced these problems after your first doses you should continue to receive the second dose. If you would like to know more about this Public Health England have produced a fact sheet (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/977653/PHE_COVID-19_AZ_vaccination_guide.pdf).

As the COVID-19 vaccines are new there may be side effects that we are not yet aware of. Further information about vaccine safety is being collected as the vaccines are rolled out in the UK and internationally. You will be informed of any significant change in the vaccine safety profile.

If you experience unexpected events or become in any way concerned you will be provided with a 24hr contact number to call one of the study doctors at any time.

Unwanted media attention

Taking part in this study could potentially lead to unwanted attention from the media. If you participate in this study, the local research team will provide you with a guidance document on how to manage this.

Independent oversight

This study is being overseen by a data monitoring and safety committee and a steering committee, who will evaluate the safety and immune response to the vaccine combinations. If there were any safety concerns, we would take the committees' advice and inform participants where appropriate to do so.

What are the advantages of taking part?

The information gained from the study will make a valuable contribution to the pandemic response and help us to determine whether it is safe and effective to give the flu vaccine at the same time as the COVID-19 vaccine.

The protection by the influenza vaccine is unlikely to last until the next winter flu season so you would still need to have your flu vaccine if invited later this year.

What should you do if you believe you may have developed COVID-19 during the study?

A common and expected side effect of vaccines is fever. If you develop fever in the first 48 hours post-vaccination only, you would not need to self-isolate unless you had other symptoms of COVID-19. If your fever continues (or you had another episode of fever) after 48 hours, then you would need to follow the current government advice. We would also ask you to record any fever that you have in your e-diary. If the fever didn't continue, then it is likely that it was a vaccine effect, and you can carry on as normal.

If during the study you develop symptoms that meet current UK government COVID-19 testing criteria, you would need to arrange an NHS test as soon as possible. If this test is positive, you would need to follow government guidance regarding self-isolation as usual. If you receive any positive COVID-19 test result (including via work or commercial tests), we

would also ask you to contact your local research team using the contact details at the end of this information leaflet. Please do not attend the clinical study site until you have been asked by the local research team to do so.

If you are unwell and unable to contact the study team directly then contact the NHS 111 service or phone 999 if you are severely unwell.

Do I get access to extra medical treatment from being in the study?

If you become unwell and need to be admitted to hospital, the standard referral routes within the NHS will be used. We are unable to offer extra medical support outside what is available within the NHS for the general public.

If you are admitted to hospital during the study, then you should inform the medical or nursing staff that you are taking part in this study. We will provide a contact card for you to show to the staff in this situation.

Will I be compensated for taking part in this study?

Once enrolled you will be compensated for your time, the inconvenience of giving blood and saliva samples and undergoing study procedures, and your travel expenses. The total amount compensated will be up to **£45** per visit (up to a total of **£135**)**.** A member of the local research team will inform you of how to claim this compensation when you attend your visits.

What if the area I live in, or where the study is taking place, goes back into lockdown or high-level restrictions?

Travel for visits for study purposes are exempt from government restrictions, as it is considered an essential journey.

What if new information becomes available?

Sometimes during the course of a study, we get new information about the treatments/ vaccines being studied. If this happens, your study doctor will discuss the new information with you and any necessary further actions.

What will happen if I do not want to carry on with the study?

You are free to stop taking part in the study at any time, without giving a reason. Withdrawing from the study will not affect your routine medical care or rights. Unless you state otherwise, any blood and saliva samples taken whilst you have been in the study will continue to be stored and used for research as detailed above. You are free to request that your samples are destroyed at any time during the study. Your data would be managed as laid out in the section 'What will happen to my data'. If you choose to withdraw from the study, your standard medical care will not be affected.

What if something goes wrong?

The investigators recognise the important contribution that volunteers make to medical research and make every effort to ensure your safety and well-being. If you have any concerns or questions about this study, please contact the local research team listed on the last page of this information leaflet. Alternatively, you can discuss these with a member of the team who will see you at each visit.

We have no reason to believe that you will be placed at any greater risk by taking part in this research study. However, if something goes wrong and you are harmed during the research study there are no special compensation arrangements. The study Sponsor, University Hospitals Bristol and Weston NHS Foundation Trust (UHBW), does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

If anything goes wrong as a consequence of taking part in the study because negligence has occurred, UHBW will compensate you. Negligence would include, for example, a situation in which injury is caused by a deviation from the study protocol by the researcher. Your legal right to claim compensation for injury where you can prove negligence is not affected. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action against the UHBW, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

If you have concerns about the way you have been approached or treated during the course of the study, you may wish to contact;

PALS Devon: 0300 123 1672, pals.devon@nhs.net

What will happen to my data?

Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2016. Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The UHBW is the sponsor for this study. UHBW and the Bristol Trials Centre Clinical Trials and Evaluation Unit (BTC CTEU) at the University of Bristol are joint data controllers for this study based in the United Kingdom, which means they are responsible for looking after your data and using it properly.

The coordinating centre (BTC CTEU) will receive the data collected about you from your local research team via a secure study database and from the online e-diaries you complete. Information about you will be stored electronically on a secure server at the University of Bristol, and any paper notes will be kept in a key-locked filing cabinet or restricted access office at Knowle House Surgery, Plymouth.

Information entered on the online screening questionnaire will be stored on a secure server at the University of Oxford until recruitment to the study closes. Following closure to recruitment your information will be deleted. Prior to deletion these data will be sent securely to the University of Bristol to allow the information to be included in study reports. Your contact details will not be sent to the University Bristol.

Your identifiable information such as your name and date of birth will only be seen by people who need this information to carry out the study. People who do not need to see your personal information but need to see the other information we collect from you, such as those analysing the data, will only be able to see your unique participant ID number. **All information about you will be kept strictly confidential, safe and secure.** Under no circumstances will you be identified in any way in any report arising from the study.

Your local research team will use your name, phone number, address and email address to contact you about the research study, to make sure that relevant information about the study is recorded for your care and to oversee the quality of the study. Individuals from the sponsor organisation (UHBW), the coordinating centre (BTC CTEU) and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local research team will pass these details to the sponsor and the coordinating centre. The only people from the sponsor and the coordinating centre who will have access to information that identifies you will be people who need to audit the data collection processes. The people who analyse the study information will not be able to identify you and will not be able to find out your name, address or phone number.

The e-diary is sent to you by email to complete online. Your email address will be stored on a secure server at the University of Bristol. Access to the e-diary system is password controlled and only the local research team and IT management staff at the coordinating centre can view your email address.

Your non-identifiable data collected in the study may be used in future research projects that may take place in hospitals, universities, non-profit institutions, or commercial laboratories worldwide. We would not share anything that could identify you.

Non-identifiable information may also be shared with third parties such as Public Health England (PHE) or laboratories undertaking analysis of your blood and saliva samples to help us conduct this research. Retention of data by these third parties will be as per PHE/local policies. Anonymised reports on safety information related to the ChAdOx nCoV-19 (Oxford/AstraZeneca) vaccine will be shared with AstraZeneca.

If you are not enrolled on the study, either because you were not eligible during screening or there was not capacity to enrol you, then any data collected will be kept until the end of the study and then destroyed.

How long will you keep my data?

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally identifiable information possible. No identifiable information will be stored on the study database. We will keep identifiable paper records about your study participation, such as your consent form, for 15 years. These will be retained in a secure location. After 15 years the identifiable paper records will be destroyed. The anonymised data will be stored indefinitely by the BTC CTEU on a secure University of Bristol server. This means that no one will be able to identify you from these data.

If you have agreed that leftover samples can be retained for future research, samples will be shared with no identifying information about you. If you do not agree for your samples to be shared for future research, any leftover samples will be destroyed at the end of the study.

You can find out more about how we use your information at:
www.hra.nhs.uk/patientdataandresearch

The data protection officer for this study, based at UHBW, can be contacted by emailing:
InformationGovernance@UHBW.nhs.uk

What will happen to any blood/saliva samples I give?

Your study samples will be analysed by Public Health England and other specialist laboratories, including University of Bristol laboratories. Some of the tests may be performed in collaboration with laboratories which are outside of the UK.

If you consent, some of your leftover blood and saliva samples will be stored in the University of Bristol (Infection and Immunity) Biobank and used for future infectious disease or vaccine-related research. This is optional and your participation in this study will not be affected if you decide not to allow storage and future use of your leftover samples. If you do not consent for your leftover samples to be stored, they will be destroyed at the end of the study.

Involvement of the General Practitioner (GP)

Your GP will be informed that you are taking part in the study to keep your medical records up to date. Your GP will be asked to confirm you have received your first COVID-19 vaccination and may be asked for other information from your records which is required for the study.

What will happen to the results of the research study?

The results of this study may be reported in medical journals or presented at meetings, but your identity will never be disclosed in any report or publication. This may not happen for some time after the study is completed.

Who is sponsoring, organising and funding the research?

The research is funded by the National Institute for Health Research (NIHR). UHBW, as the sponsor, has overall responsibility for conduct of the study. The research is being organised and run on their behalf by the BTC CTEU, University of Bristol.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by South Central - Berkshire Research Ethics Committee. The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to use the COVID-19 and influenza vaccines, as described in this information leaflet.

Further information and contact details

We hope this information leaflet has answered all your questions. **You can obtain general information on clinical research** from the UK Clinical Research Collaboration (UKCRC) who produce a booklet called "Understanding Clinical Trials". This provides in-depth information on the design and conduct of clinical trials and aims to answer the questions of those considering taking part. Electronic copies can be downloaded from the UKCRC website https://www.ukcrc.org/public-awareness-of-clinical-research/information-resources-on-clinical-research/ or printed copies can be requested by emailing: info@ukcrn.org.uk

Or contact:

UK Clinical Research Collaboration,
C/O Medical Research Council
One Kemble Street
London WC2B 4TS
Tel: 020 7395 2271

email: crncc.info@nihr.ac.uk

For independent advice about participating in this study you may wish to contact your GP. If you would like to speak to one of our team members to discuss any aspect of this study or **if you are interested in taking part in the study, please contact us** using the below details.

Contact Details

Local Research Team

Principal Investigator: Dr Jonathan Garstang

Address:
Knowle House Surgery
4 Meavy Way
Crownhill
Plymouth
Devon
PL5 3JB

Email: sallyfeltham@nhs.net

Working Hours: Monday-Thursday 8am-6pm

Contact Number: 01752 705090

Emergency/Out of Hours Numbers: 07799 833580 and 07971 555185

Coordinating centre

Address:
ComFluCOV study team
Bristol Trials Centre Clinical Trials and Evaluation Unit (BTC CTEU)
Level 7, Bristol Royal Infirmary
Upper Maudlin Street
Bristol BS2 8HW

Email: comflucov-trial@bristol.ac.uk

Thank you for taking the time to read the ComFLuCOV participant information leaflet

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