Participant Information Leaflet
Combining Recombinant Herpes Zoster and Influenza or COVID-19 Vaccination (ZosterFluCOV) Study

We are recruiting adults aged 50 and over to a study which is looking at the safety and immune response of a vaccine against shingles (Herpes Zoster) given at the same time as influenza (flu) vaccine or COVID-19 vaccine.

This is a summary of the study. More information can be found in the Patient Information Leaflet on page 3.

Why are we doing this study?
We want to know whether receiving a shingles vaccine at the same time as either a flu or COVID-19 vaccine is safe and works as well compared to when the shingles vaccine is given alone. In the UK, a shingles vaccine is offered to people when they reach 70. Flu and COVID-19 vaccines are also offered to people in this age group. If we could give the shingles vaccine at the same time as either the flu or COVID-19 vaccine it may make it easier for people, and for GPs, as fewer appointments would be needed. *See page 3.*

Who can take part in the study?
We are looking for volunteers aged 50 years and over. In order to take part in the study you must not have received a shingles vaccine within 5 years of your enrolment in the study. It is also important that you have received your initial COVID-19 vaccinations (usually two doses) *page 3.*

Taking part is voluntary
It is up to you to decide whether 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.

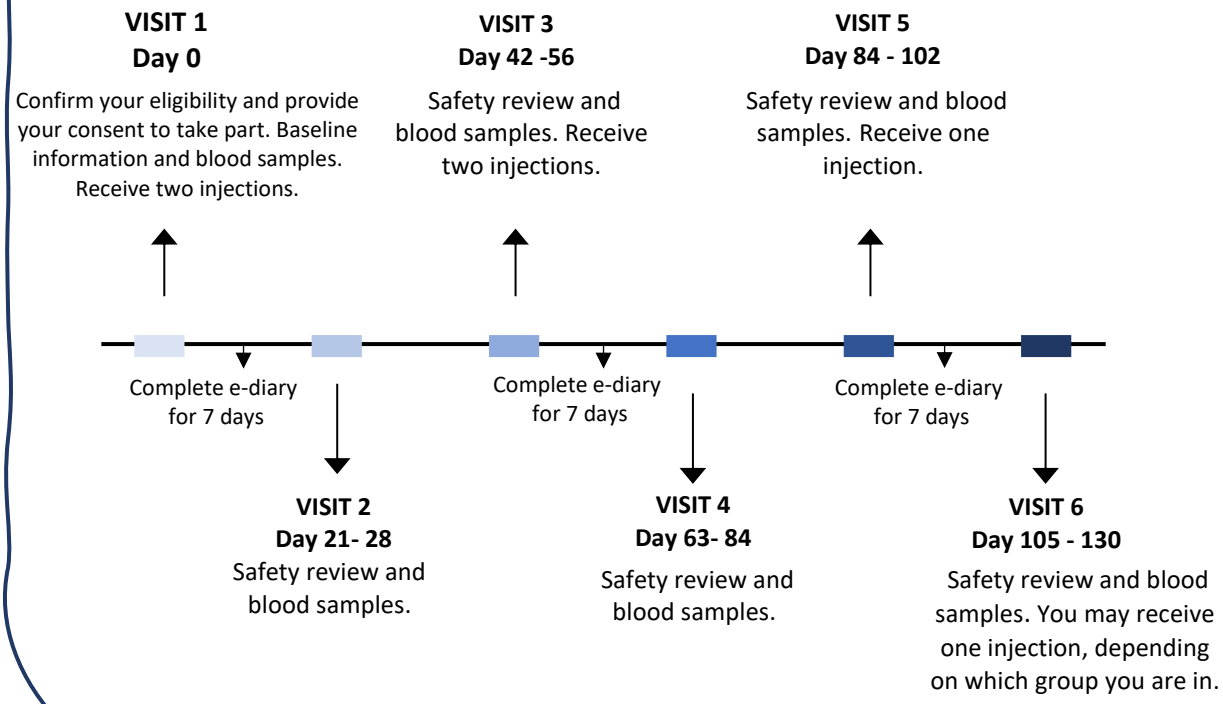
What are the benefits?
The information gained from the study will help us to determine whether it is safe and effective to give the shingles vaccine at the same time as the flu vaccine or the COVID-19 vaccine. If you attend all study visits you will receive both the flu and COVID-19 vaccination as part of the study.

What are the risks?
The vaccines used in this study are already in use in the NHS and so have been well tested, however, people often experience side effects after receiving a vaccination and a part of the study is to investigate the side effects experienced as a result of receiving these vaccines at the same time. *See pages 4-5.*
As part of this study you may be asked to provide a blood sample at each study visit, this can cause discomfort. *See page 8.*

What would taking part involve?

- You will be required to attend 6 study visits over a period of 20 weeks.
- You will be randomly allocated to receive a COVID-19 or flu vaccine or saline placebo together with your first or second dose of the shingles vaccine.
- You will not be told which vaccines you are getting together in case knowing this would affect the results of the study.
- The vaccines used in the study are all licensed and are given routinely by GPs.
- You may be required to provide blood samples at your study visits. In some groups, some people won't need blood samples at some time points. Your bloods will be used to test immune responses to the vaccines.
- You may be asked if you are willing to talk to a researcher about your vaccinations and experiences, 3-4 months after you join the study. This interview is optional and you don't have to take part, it won't affect your participation in the rest of the study.

The timeline below shows what will happen as you progress through the study:



If you are interested in learning more about the study, please continue to read the patient information leaflet which will provide you with more detail. Additionally, you can scan the QR code to visit the study website.

Participant Information Leaflet
ZosterFluCOV Study

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://redcap.link/ZFC-pre-screen

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 Recombinant Herpes Zoster and Influenza or COVID-19 Vaccination (ZosterFluCOV) 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.

Why are we doing this study?

We want to know whether receiving a shingles vaccine at the same time as either a flu or COVID-19 vaccine is safe and works as well compared to when the shingles vaccine is given alone. In the UK, a shingles vaccine is offered to people when they reach 70. Flu and COVID-19 vaccines are also offered to people in this age group. If we could give the shingles vaccine at the same time as either the flu or COVID-19 vaccine it may make it easier for people, and for GPs, as fewer appointments would be needed.

The shingles virus infects nerves and the skin around it. Symptoms of shingles include a tingling or painful feeling in an area of skin, a headache or feeling unwell, and a rash which may develop into itchy blisters. Many people have pain at the site of the infection that can go on for many years and is difficult to treat, this is called postherpetic neuralgia and is thought to develop in 1 in 5 people with shingles.

The vaccine protects against shingles infection caused by the herpes zoster virus. The vaccine stops most people getting shingles, but those that do get shingles, have a milder and shorter illness. It is okay to have the shingles vaccine if you have had shingles before, it will boost your immunity.

Who can take part in the study?

We are looking for volunteers aged 50 years and over. We welcome volunteers from all communities and those with health conditions who would usually be offered the flu vaccine. **In order to take part in the study you must not have received a shingles vaccine within 5 years of your enrolment in the study.** It is also important that you have received your initial COVID-19 vaccinations (usually two doses).

If you have recently had a COVID-19 or flu vaccine you can still take part in the study but there will need to have been a gap of at least 90 days between you receiving these vaccines and volunteering to take part.

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.

Do I have to take part?

No. It is up to you to decide whether 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.

What are the vaccines being used?

There are 3 vaccines that are being used in this study: shingles vaccine, flu vaccine and the COVID-19 vaccine.

Shingles vaccine

The shingles vaccine being used in this study is the recombinant subunit herpes zoster vaccine (Shingrix, GSK). It is one of two vaccine options for shingles used in the UK. It is recommended if the live shingles vaccine (Zostavax) is not suitable for you, for example, if you have a condition that effects your immune system.

It is a non-live vaccine that provides immunity against shingles. The vaccine contains an adjuvant that is used to enhance the body's immune response to the vaccine. This is particularly important as we get older, as our immune responses to both natural infection and vaccines weaken.

Flu vaccine

The study will be using the flu vaccine for 2023/24, Fluad quadrivalent inactivated influenza A & B vaccine containing the adjuvant MF59 (aQIV).

This vaccine contains four inactivated (non-live) strains of the flu virus that cause infection over the winter. In addition to the inactivated parts of the flu virus, this vaccine also contains, an adjuvant (MF59) which will help to boost the immune system response to the vaccine.

The flu vaccine (aQIV) being used in this study is currently authorised for use in adults aged 65 years and older. For volunteers aged 50- 64 years it is being used outside of its current authorisation.

COVID-19 vaccine

You will receive the Comirnaty® Original/Omicron BA.4-5 COVID-19 mRNA bivalent vaccine as part of this study, this is one of the COVID-19 vaccines that is currently being used in normal care.

Saline injection (placebo)

It is possible that at vaccination study visits 1 and 3 that one or more of the vaccines you receive will be a placebo (saline) injection. More detail is provided on this in the table on

page 8. The placebo injection will look just like the other vaccines but just contains sodium chloride, which is sterile, salty water, typically used to dilute other vaccines.

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.

After vaccination it is common to experience the following side effects for all vaccines. These side effects are reported to be severe enough to interfere with activities of daily living in up to 10% who have received the shingles vaccine in previous trials. The most common sides effects are fatigue (tiredness) and muscle ache. They usually last for less than a week (more commonly 24-48 hours after vaccination).

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

Other less common side effects are:

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

If you do experience any side effects, then taking paracetamol may help.

Rare side effects

Vaccines may cause serious but rare side effects these include the following:

Severe 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.

Heart inflammation (myocarditis or pericarditis) has been reported following administration of the COVID-19 vaccine in up to 1 in 10, 000 people. Symptoms include chest pain and shortness of breath which occur a few days after vaccination. Most people have had mild symptoms with no evidence of long-term problems so far.

Guillain-Barré Syndrome (GBS) affects the nervous system. GBS is an illness in which people can develop severe weakness and be fatal. Following immunisation with the flu vaccine GBS has been reported very rarely, resulting in 1 additional GBS case per million people. A slightly increased risk of GBS (estimated 3 additional cases per million doses administered) has been reported in people aged 65 years and above after receiving Shingrix.

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.

What will happen if I decide to take part?

After reading this leaflet if you decide you would like to take part in this study you will need to complete a two-part online questionnaire to check your eligibility.

The link to complete this questionnaire is: https://redcap.link/ZFC-pre-screen

If you do not wish to complete the online questionnaire you can contact your local research site directly using the contact information provided on the final page of this information leaflet.

Part 1 – This will check whether you are able to take part in the study. 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. You may be advised that you are unable to take part on the basis of this additional information.
- Have a member of the research team at a participating site near to you 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 your vaccine history is in line with study requirements (if needed).
- Provide details/information about yourself including your name, email address, date of birth, telephone number and address, and allow the University of Bristol to store this information on behalf of Bristol Trials Centre and the Sponsor

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).

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.

The table below provides an overview of study visits 1-6 and what will happen at each, you will be enrolled in the study for a total of 5 months and receive vaccine(s) at the first visit and then 2 and 4 months later at study visits 3 and 5. More detail on these is provided in the text below.

Visit	What will happen at the visit?
1 **Day 0**	Informed consent Assessment of eligibility Medical history and physical examination Clinical information Blood samples may be taken at this time point Pregnancy test* Randomisation **Vaccination**
You will complete an e-diary for 7 days and report any hospitalisations or concerns.	
2 **Day 21-28**	Safety review Blood samples may be taken at this time point You may end the study at this point depending on what group you have been randomised to. *See page 8, 'Group 3' for more details.*
3 **Day 42 - 56**	Safety review Temperature Blood samples may be taken at this time point Pregnancy test* **Vaccination**
You will complete an e-diary for 7 days and report any hospitalisations or concerns.	
4 **Day 63 - 84**	Safety review Blood samples
5 **Day 84 - 112**	Safety review Temperature Pregnancy test* **Vaccination**
You will complete an e-diary for 7 days and report any hospitalisations or concerns.	
6 **Day 105 - 140**	Safety review Blood samples may be taken at this time point Vaccination, depending on which group you have been randomised to.
Day 112 – 140	**This part is optional –** We will be asking a few participants if they'd like to talk to a researcher about their experiences of having two vaccines given at the same time.

*You will only need to do a urine pregnancy test only if you are of childbearing potential.

Visit 1 – (up to 90 minutes)
Consent and 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 required your temperature will be taken, and a medically qualified doctor will 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, and the study results can be emailed to you. The e-diary collects important information about any symptoms you may have after you receive the vaccinations. You will also receive a quality of life questionnaire via email, to complete 7 days after your vaccination.

If you do not have access to an internet enabled device please make the research team aware of this before your first visit. They will be able to provide you with a paper version of the e-diary for you to complete and a paper version of the quality of life questionnaire. Between visits, please let the study team know if you are feeling unwell, or have any unplanned visits to the doctor, dentist or hospital. Please remember to bring your completed paper diary with you at each subsequent study visit to return to the research team.

Baseline Information and Samples

Blood 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 shingles, flu and COVID-19 vaccines.

Randomisation

Following consent and collection of your baseline blood samples at visit one, you will be randomly allocated to one of five groups. To try to make sure the groups are the same to start with, you will be put into a group randomly, so that neither you or the study team can select which group you will be in. 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.

Visits 1, 3 and 5: vaccinations

After randomisation at visit 1 you will be given two injections, one into each arm. You will also receive two injections, one into each arm at visit 3 and one injection at visit 5 and visit 6 (depending on which group you are randomised to). The contents of the injections will depend upon which group you are randomised to. The local study team will need to keep an eye on you for around 15 minutes after the injection(s) have been administered.

If you are able to become pregnant, you will be required to take a urinary pregnancy test prior to receiving any injections at visits 1, 3 and 5.

Vaccines received at each visit per group:

	Group 1	Group 2	Group 3	Group 4	Group 5
Visit 1	COVID-19 + Placebo	Shingles + Placebo	Flu + Placebo	Shingles + Flu	Shingles + Placebo
Visit 3	Shingles + Placebo	Shingles + COVID-19	Shingles + COVID-19	Shingles + Placebo	Shingles + Flu
Visit 5	Shingles	aQIV	Shingles	COVID-19	COVID-19
Visit 6	aQIV	-	-	-	-

Group 3

Half of the study volunteers randomised to the group will be asked to end the study after their second study visit and so if you are randomised to group 3 you may not receive the shingles and COVID-19 vaccine. Whether or not you continue in the study will be determined by the study team. We are unable to tell you at the start of the study whether you will be asked to do the whole study or just the first two visits, as this would mean you would know which vaccines you were receiving. If you end the study after visit 2 and it is recommended for your age group you will be encouraged to take up the shingles and future COVID-19 vaccine with your GP.

Between Visits 1 and 2, 3 and 4 and 5 and 6: online symptoms diary and quality of life questionnaire

You will receive a link by email to complete a daily online e-diary for the first 7 days after vaccination to record any symptoms, including symptoms experienced at the vaccination site and a questionnaire to assess your how you are feeling. We will provide you with a ruler and thermometer to help in reporting the details of any symptoms. You will also receive a link to complete an online quality of life questionnaire, 7 days after your vaccination. You will receive instructions on how to complete the e-diary and contact details for any queries that you may have regarding completion of the e-diary.

After the first 7 days post vaccination and until the next study visit, 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.

Visits 2, 3, 4, 5 and 6: safety review and blood samples

Safety review

You will need to attend appointments at your local site with a research staff member who will check any symptoms that you have reported and confirm that it is safe for you to continue in the study; this will include having your temperature taken and if clinically indicated a physical examination conducted by a doctor.

End of participation – Visit 6

The end of the study will be considered to be Visit 6, this will be the final safety review and blood sample collection. Depending on which group you are in, you may also receive a vaccination at visit 6.

Blood samples

You may be asked to provide blood samples at these visits, a subset of these samples will be used to assess the immune response to the shingles, COVID-19 and flu vaccinations. In some groups, some participants won't need blood samples at every visit.

Should you be unable to attend a scheduled study visit (for example because you are unwell), 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.

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 ZosterFluCOV study to ensure that your participation will not impact your cover.

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

You should not donate blood in the 48 hours following vaccination at Visits 1, 3 or 5 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 of the 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 50mL of blood at the first study visit and 40ml at subsequent study visits (approximately 8 teaspoons). The total amount we will take over the period of the study will be approximately 250ml. This is well below the recommended limit of 470ml every 3 – 4 months for blood donations to the National Blood Transfusion Service.

Interviews

Between days 112 – 140 (roughly 3-4 months) from the start of your participation in the study, we will be asking a few study participants if they would be willing to talk to a researcher about their experiences of being given two vaccines at the same time. This interview is optional and you do not have to take part; it won't affect your participation in the rest of the study. If you are happy to be contacted about an interview, you may be contacted by a researcher who will provide more information and answer any questions.

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 you where appropriate to do so.

The protection by the flu 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 are the advantages of taking part?

The information gained from the study will help us to determine whether it is safe and effective to give the shingles vaccine at the same time as the flu vaccine or the COVID-19 vaccine.

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. You can claim up to £15 towards your travel expenses, £10 for the inconvenience of giving blood and £20 for the time taken to attend the visit. The total amount compensated will be up to £45 per visit.
If an accompanying carer's travel expenses are not covered by the £15 expenses payment, you may be able to claim additional funds.

A member of the local research team will inform you of how to claim this compensation when you attend your visits.

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 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?

If you have any concerns or questions about this study, please contact the research team listed at the end of this leaflet. Alternatively, you can discuss these with a member of the research team at your first study visit.

If you have concerns about the way you have been approached or treated during the course of the study you may wish to contact the Patient Advice and Liaison Service (PALS) on:

North Bristol Patient Advice & Liaison Service
Tel: 0117 414 4569
pals@nbt.nhs.uk

To make a formal complaint please write to:

Tel: 0117 414 9330
Email: zosterflucov@nbt.nhs.uk

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 legal action, but you have to pay your legal costs, The normal NHS complaints mechanisms will still be available to you.

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.' University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) is the sponsor for this study. UHBW and the Bristol Trials Centre (BTC) 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.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, email address, date of birth, phone number, address, details of your GP practice and your medical history. We will also be collecting ethnicity data. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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.

The coordinating centre (BTC) 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 North Bristol NHS Trust.

Information entered on the online screening questionnaire will be stored on a secure server at the University of Bristol, these data will be stored securely at the University of Bristol to allow the information to be included in study reports.

Individuals from the sponsor organisation (UHBW), the coordinating centre (BTC) 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.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

As part of the study you will need to complete an informed consent form. This will be securely stored by your local research team and a copy given to you for your own records. If

you consent to any leftover samples being stored at a licensed Research Tissue Bank (RTB) then a copy of your consent form will be shared with the BTC so that it can be provided to the RTB for their records.

BTC will use your email address to send you a link to the e-diary and quality of life questionnaire 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 and questionnaire system is password controlled and only the local research team and IT management staff at the coordinating centre can view your email address. BTC may also use your email address to send you a summary of the results of the study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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 external laboratories undertaking analysis of your blood samples to help us conduct this research. Retention of data by these third parties will be as per local policies.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- our leaflet available from https://www.uhbristol.nhs.uk/media/3672235/gdpr_guidance_document.pdf
- by sending an email to InformationGovernance@uhbw.nhs.uk
- or

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. Identifiable data collected as part of the pre-screening website will be kept on a secure University of Bristol server until the end of the study. No identifiable information will be stored on the study database. Your local study site 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 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 to your contact details being stored on a database by your local research team, they may contact you about future studies relevant to you. If you do not agree to this your local research team will not be able to contact you about any relevant future research. If you have agreed that leftover samples can be retained for future research, samples will be shared with minimal information but it will not be possible to identify you.

What will happen to any blood samples I give?

Your study samples will be analysed by UKHSA (UK Health Security Agency) and other specialist laboratories, including University of Bristol and GSK laboratories. Some of the tests may be performed in collaboration with laboratories which are outside of the UK.

If you consent, your leftover blood samples will be stored in a licensed Research Tissue Bank (RTB) and used for future, ethically approved, infectious disease or vaccine-related research. If you do consent, a copy of your informed consent form will be provided to the RTB by BTC for their own records. 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 may be asked to confirm your vaccination history 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 a grant from GSK, a pharmaceutical company. 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, 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 – Hampshire B. The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has also reviewed the study.

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

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 Edward Moran

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Coordinating centre

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