PARTICIPANT INFORMATION SHEET

SARS-CoV-2 VACCINATION for COVID-19 DISEASE SAFETY STUDY (VAC4COVID STUDY)

Chief Investigator

Professor Thomas MacDonald

Principal Investigator

Professor Isla Mackenzie

Invitation to participate

We would like to invite you to take part in a research study.

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you. Please take the time to read this information sheet carefully and use the VAC4COVID website (www.vac4covid.com) or email us at vac4covid@dundee.ac.uk to ask any questions you have. You can also discuss this study with other people such as your family or your family doctor (GP). If you decide to participate in this study, you will be asked to complete an electronic consent form.

The VAC4COVID Study is sponsored by the University of Dundee. The study has been organised by Professors Thomas MacDonald and Isla Mackenzie, and will be run by MEMO Research (www.memoresearch.com), at the University of Dundee.

Part 1 tells you the purpose of the study and what will happen to you if you take part.

Part 2 gives more detailed information about the conduct of the study.

Please note that the VAC4COVID Study will not be giving COVID-19 vaccines to participants.

PART 1

About the study and your participation

Background to the study

Vaccines are crucial for reducing COVID-19 and the harm it causes to health, with mass COVID-19 vaccination programmes now rolling out in response to the worldwide pandemic. All licensed or authorised vaccines have already been tested extensively for effectiveness and safety in large clinical trials. As with every new medicine, governments and researchers will keep watching how vaccines are working once they are being used in the wider population. This is an important part of how medicines and vaccines are regulated.

VAC4COVID is an online study to assess how well COVID-19 vaccines work in widespread use. It will also detect if there are any unexpected, rare side effects of vaccination. VAC4COVID should add useful information to the already extensive knowledge about the use of COVID-19 vaccines.

By taking part in the VAC4COVID Study, you can help us understand more about how people do after vaccination and support public confidence in COVID-19 vaccines.

What is the purpose of the study?

The aim of the study is to monitor COVID-19 vaccines by gathering information from a large number of participants about their health in real-time before and after they are vaccinated. We will not be giving participants COVID-19 vaccines but will be monitoring their health before and after being vaccinated by, for example, national vaccination programmes. We intend to recruit at least 1 million participants into this study worldwide.

A minimum condition of participation in this study is that any health information provided by participants can be verified with health professionals and medical records; this is to ensure that the information we collect is valid. During the study we will report our findings only to the Medicines and Healthcare Regulatory Authority (MHRA); this will help them make informed decisions about vaccine programmes.

Am I eligible to register for the VAC4COVID Study?

Anyone 18 years of age or over is eligible to register for the study. You can sign up any time before or after you are vaccinated against COVID-19. Even if you don't end up being vaccinated, for whatever reason, you can provide useful information to the study.

Can children register for the VAC4COVID Study?

People under 18 years of age cannot register to take part themselves. However, participating parents or carers will be able to submit information on behalf of children or young people under their care (under 18's). They can do this through their study homepage. They should do this only with the child's agreement and after reviewing the appropriate Participant Information Sheet for under 18 years together. There is one Participant Information Sheet for younger children and one for older children/young adults which parents/carers can choose from. Both are available on the VAC4COVID website (www.vac4covid.com).

Do I have to take part?

It is up to you to decide whether or not to take part. Participation in this study is entirely voluntary. If you do start the process, you are then free to withdraw at any time, without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you. This can be done on the study website.

What will happen to me if I take part?

If you are interested in taking part in this study, please visit our secure study website www.vac4covid.com for more information and to register with your email address (this cannot be used to register more than one adult participant, although your children can be registered within your account). You will receive an email link that will take you to a study consent form which you can download once completed. You will then be asked to enter details on the secure study website such as your medical history, list any medicines you take and answer some lifestyle questions. If and when you receive a vaccination, we will ask you to provide details about the vaccine (name of vaccine and batch number – you can ask the person who administers your vaccine to give these to you). The batch number is a series of numbers and/or letters, along with the name of the vaccine (or the name of the manufacturer of the vaccine). Obtaining the batch number is optional. We will display examples of COVID-19 vaccine batch numbers on our website (www.vac4covid.com) once available, which will help you identify them if/when you are vaccinated.

You will be sent monthly emails throughout the study asking you to complete questionnaires about your health (emails will be sent **weekly** for the 4 weeks after the date of your vaccination(s) or boosters). These emails will contain a link that will automatically take you to a secure online questionnaire which will ask you various questions about your health and wellbeing (e.g. if you have experienced health changes, and whether you have been hospitalised for any reason). By collecting this information

from many people before and after vaccination, we should be able to tell if any reported changes in health and wellbeing are likely to have been due to the vaccine.
If you have no health changes to report, the questionnaires will be very quick to fill in. If you indicate that you have experienced any health changes since we last contacted you, we will ask you to answer some more questions about this, which may take a few minutes to complete depending on how much information you have to give.

We may need to contact you for more information or contact your GP or hospital to look at your electronic or paper medical records to find out more information about the problem you had.

In countries where it is possible, we plan to track any hospital admissions and other serious medical events that happen to our study participants using routinely collected health data throughout the study. This information is normally held by health services or government agencies. To do this we will need to give these organisations just enough details about you so that they can identify you on their computer systems.

We will ask you to record your registered GP (family doctor) practice so that we can approach them about any medical events that you have, and so that we can check your health status if we cannot get in touch with you. We will also ask you to provide contact details for a person (two if possible) whom we can approach if you do not respond to our emails unexpectedly. This person can be a relative or friend and may be taking part in the study themselves. You should check that they are happy for you to give us their email address and telephone number. You can update these contact details on the study website.

If you expect to be uncontactable by email for a time (e.g. due to travel) you will be able to record this on the study website so that we do not need to contact your doctor or nominated contact person unnecessarily.

We expect that you will be in this study for approximately 3 years, but some participants may be involved for longer or shorter, depending on when vaccination becomes available to them. If we need to change the duration of the study, for example due to changes in the vaccination programme, we will inform you directly. You do not need to make any extra visits to your GP or the research team during this time.

Taking part in this research study will have no effect on whether or not you receive the COVID-19 vaccination – that is a decision for you and your doctor.

What are the possible benefits of taking part?

Your participation in this study will not have any direct benefit for you but it will help us learn about the effectiveness and safety of COVID-19 vaccination in large numbers of people. The information that we learn in this study will be valuable to authorities and healthcare providers in planning effective future vaccination programmes worldwide.

What are the possible disadvantages and risks of taking part?

We do not think there are any risks in taking part in this study. It will take up some of your time to complete the questions online. There is a remote possibility that you could find some of the questions we ask you distressing, for example if we ask you about hospital admissions which may have been difficult for you.

Will my taking part in the study be kept confidential?

Your participation in this study will not be disclosed to anyone other than the organisations or individuals described in the patient information sheet for the specific and limited purposes explained herein. The details are included in Part 2. People who do not need to know who you are will not be able to see your identifiable information.

Who is funding the study?

This study will initially be paid for by internal MEMO Research funds. No future funder(s) will have any direct input into the running of the study, which is under the control of the University of Dundee and as such is entirely independent.

Are there other systems monitoring COVID-19 vaccines in the general population and what does VAC4COVID add to this?

The Medicines and Healthcare products Regulatory Agency (MHRA) operates a "Yellow Card" system to allow healthcare staff and members of the public to report suspected side-effects to medicines and vaccines. You may also find details on how to report any side-effects to public health and other organisations in the leaflets you receive when you are vaccinated. It is important that you follow any advice that you receive from your vaccine provider about reporting of side effects.

VAC4COVID collects similar information from participants as well as more detailed additional information about general health before and after vaccination. We also ask participants to confirm if they have had *no* health problems after vaccination. This additional information will be very useful in determining if any reported events are likely to have been caused by vaccination.

The ongoing Kings College COVID Symptom Study (widely known as the ZOE app) is still collecting information from its participants about COVID-19 symptoms and now also asks about COVID-19 vaccination. We will be collecting similar information, and this will be useful for regulatory authorities to monitor ongoing vaccine effectiveness.

Vaccine manufacturers are also expected, as a condition of vaccine authorisation, to conduct their own monitoring studies.

The VAC4COVID Study is unique in collecting detailed health information in near real-time from people who have been vaccinated. Combining this with information from people who have not yet been vaccinated, makes VAC4COVID a powerful source of vaccine information.

Contact details?

If you have any problems, concerns or other questions about this study, you can find more information on the website at www.vac4covid.com, or email us at vac4covid@dundee.ac.uk.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

Detailed information about the conduct of the study

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason. This can be done by visiting the website to register your withdrawal. Your medical care and legal rights will not be affected by this.

Can I change how I participate in the study?

If you wish to change how you participate in the study the following options are available:

1. Pause scheduled emails
2. Stop all non-essential study communication

These options can be reversed at any time and do not constitute withdrawal from the study.

What will happen to the results of the research study?

The results will be published in a leading medical journal and also in national and local media. You will not be individually identified in any report/publication. Any personal details will be kept strictly confidential and no information will be given in any publications through which you can be identified. We will inform vaccine regulatory authorities of our findings. It is the role of these agencies to inform the public of significant new research findings.

Who is organising the research?

MEMO Research at the University of Dundee is organising this study. No member of the research team is being directly paid for including you in this study.

How will we use information about you?

We will need to use information from you, your medical records, and your electronic health records for this research project.

This information will include your initials, name, address, postcode, and NHS number (in Scotland your community health index number or CHI). Research staff will use this

information if we need to check your records to make sure that we do not miss side effects of vaccination.

In the UK we will also request information from centralised electronic databases in Scotland, England, Wales and Northern Ireland on any events, including deaths, that may have occurred in participants who are taking part in the study. This will require us to send your identifying details to NHS bodies so they can check your records. In Scotland, this information comes from Public Health Scotland (PHS), in England it comes from the Health and Social Care Information Centre (HSCIC), also known as NHS Digital, in Wales from the NHS Wales Informatics Service (NWIS) through the Secure Anonymised Information Linkage (SAIL) Databank and in Northern Ireland, the Northern Ireland Electronic Care Record (NIECR). We may also request information about deaths from the Office of National Statistics (ONS) and death certificates from local authorities.

For us to follow you up through record linkage we need to tell PHS (if you live in Scotland) or NHS Digital (if you live in England) or SAIL (if you live in Wales) or NIECR (if you live in Northern Ireland) who you are, so that they can supply your records to us. We may need to supply different identifying information depending on where you live. For example, in Scotland we send your Community Health Index (CHI) number, date of birth, postcode and gender, and they will return any hospital admission and mortality records to us. Other systems may require other data such as your name and address. All transfer of data is handled securely, in line with strict NHS standards.

People who do not need to know who you are will not be able to see your identifiable information. Your data will have a code number allocated instead. We will keep all information about you safe and secure.

For the purposes of checking that we are conducting the study properly in compliance with the regulations for research, monitors from the University of Dundee or regulatory authorities may need to examine your study records.

Once we have finished the study, we will keep some of the data so we can check the results in the future if required. We will write our study reports in a way that ensures no one can be identified.

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 up to that date.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't always be able to let you change the data we hold about you.

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 reading the privacy policy and FAQs available at www.vac4covid.com
- by sending an email to dataprotection@dundee.ac.uk

What if something goes wrong with my study participation?

If you are concerned about your participation in the study, you have the right to discuss your concern with a researcher involved in carrying out the study or a doctor involved in your care.

If you have a complaint about your participation in the study, first of all you should talk to a researcher involved in the study. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for the University of Dundee. You can find further details on how to do this here: https://www.dundee.ac.uk/governance/dca/complaints/

Additional contact information:

Directorate of Academic and Corporate Governance
University of Dundee
Nethergate
Dundee
DD1 4HN
Phone: +44 (0)1382 383000
Email: complaintsresolution@dundee.ac.uk

We do not think that participation in this study is likely to cause any harm. However, if you think you have come to harm due to taking part in the study, there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice, but you might have to pay for your legal costs.

Insurance

The University of Dundee is sponsoring the study in the UK and it has a policy of public liability insurance, which provides legal liability to cover damages, costs and expenses of claims.

If you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you have or have had in the past. You might also be asked if you have had any genetic tests or about taking part in this study. We do not expect that taking part in the present study will adversely affect your ability to buy insurance as we are simply collecting data on you before and after vaccination. Your insurer may take into account any medical conditions you have, including any which are diagnosed as part of a research study/trial, when deciding whether to offer insurance to you, but we will not disclose any data without your express consent.

Who has reviewed this trial/study?

This study has been reviewed and given a favourable opinion by the South Central: Berkshire B NHS Research Ethics Committee who are responsible for reviewing research which is conducted in humans.

Contact details for further information.

If you have any queries about this study, please see the FAQs available at www.vac4covid.com, or email us at vac4covid@dundee.ac.uk.

Thank you for taking the time to read this information sheet and for considering taking part in this study.

Data Protection Privacy Notice

How will personal information be used?

We will only use your personal information to carry out this study, or to contact you again if you have agreed to this.

The University of Dundee is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will be the data controller for this study. This means that the University of Dundee has overall control over how your data is used and processed in this study. University of Dundee will keep non-identifiable information about you for 25 years after the study has finished. After 25 years this information will be destroyed. Identifiable (personal) information about you will only be kept for 12 months after the end of the study. If you would like to be informed about future studies that you might be interested to participate in, we will ask you to provide consent to allow us to hold your contact details for a longer period of time.

Your rights to access, change or move your information are limited, as we need to manage your information in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained up to the point of your withdrawal.

University of Dundee will use your name and contact details to contact you about the study. They will use this information to make sure that relevant information about the study is recorded for your care and to check the quality of the study. Staff from University of Dundee and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in University of Dundee who will have access to information that identifies you will be people who need to contact you to carry out the study or check how the information is collected. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number/hospital number or contact details.

Your study information, with any information which identifies you removed from it, may be shared with other researchers in the UK/EU/other regions.

Lawful reason for using your information

It is lawful for the University to use your personal data for the purposes of this study. The legal reason for using your information is that using it is necessary for the research which is carried out in the public interest (GDPR article 6(1)(e)).

It is lawful for the University to use your sensitive personal data (if applicable) for the purposes of the research this study. The reason we use sensitive personal information such as data concerning health is that using it is necessary for scientific research purposes

(GDPR article 9(2)(j)). Legally we must ensure we have technical and organisational processes in place to respect your rights when we use your information.

If you wish to find out more about your individual rights under GDPR you can find further details here: https://www.dundee.ac.uk/corporate-information/individual-rights-under-gdpr. If you wish to complain about the use of your information, you can find further details on how to do so here: https://www.dundee.ac.uk/governance/dca/complaints/, or you may wish to contact the Information Commissioner's Office.

Thank you for taking the time to read this information sheet.