Imperial College London

Imperial College Healthcare NHS Trust

PARTICIPANT INFORMATION SHEET
CIVICs 20-0004

CIVICs Influenza
Screening Protocol for Future Challenge and Vaccination Studies

CONCISE SUMMARY

You are being invited to take part in this registry if you are between the ages of 18 and 64 years and if you are willing to be contacted in the future for participation in influenza virus challenge and vaccine studies. Investigators at Imperial College will use this registry to recruit people who may fit the requirements for enrolling in new research studies at Imperial College.

To participate in this registry, you must be willing to be contacted for potential recruitment into future influenza infection or vaccine studies. The main purpose of the registry is to establish a list of healthy volunteers who may be recruited into future challenge and vaccine studies.
Should you agree to participate in this registry, you are not agreeing to be in any other specific research studies. If you are approached for participation in a human infection challenge or vaccine study at some point in the future, you will be free to decline and still remain in this registry. *Please note that there may be no challenge studies actively recruiting at the time you are reading this, but trials may be in the pipeline and the study team may contact you when recruitment for such a study opens.*

During the first visit, you will be asked questions about your medical history, medications and vaccinations you have received, as well as provide a sample of your blood (approximately 6.5 tablespoons). You may also have nasal swabs and saliva collected. You will be asked to return for follow up visits four times a year, for up to 6 years. Additional follow up visits may be requested if you receive a flu vaccine or get sick with the flu. The data you provide and any data collected from analysing your blood or swab samples will be deposited in this registry and will be reviewed by investigators at Imperial College London, as well as our collaborators at Duke University in the United States who are also recruiting participants for new research studies. These blood tests will provide information about your levels of immunity against different strains of influenza virus. Whether you are invited to participate in a future challenge or vaccine study will depend on your suitability, partly as a result of these tests.

The potential risk of participating in this registry involves bruising or temporary pain and discomfort experienced when having your blood drawn. Obtaining nasal swabs can cause discomfort in the nose, a gag reflex and watery eyes. There is also a potential risk of loss of confidentiality.

In this registry we will use information from you and your medical records. We will only use information that we need for the registry. Only registry staff who need to know your name or contact details (for example, to keep in touch with you) will have access to this information. Everyone involved in this registry will keep your data safe and secure. We will also follow all privacy rules. We may save some of the data and samples we take for future research. We will make sure no one can identify you from the reports we write.

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You are being invited to take part in this research registry. Research is voluntary and includes only people who choose to take part. Please read this information sheet carefully and take your time making your decision. As the registry doctor or registry staff discusses this information sheet and consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research registry. The nature of the registry, risks, inconveniences, discomforts, and other important information about the registry are listed below.

Please tell the registry doctor or registry staff if you are taking part in another research study already.

The research is being run by the Department of Infectious Disease at Imperial College London. This study has been reviewed and given a favourable opinion by the London Fulham Research Ethics Committee (REC). Professor Christopher Chiu will oversee the registry at Imperial College, and it is supported by Duke University in the US through the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID). The supporter of this registry, Duke University, will pay Imperial College to perform the activities described in this information sheet, and this support may reimburse part of his salary.

WHO WILL BE THE DOCTOR ON THIS REGISTRY?
If you decide to participate, Professor Christopher Chiu will be the lead doctor overseeing this registry throughout the time that you are in it.

WHY IS THIS REGISTRY BEING CREATED?
The purpose of this registry is to establish a list of healthy adult volunteers 18 to 64 years of age who may potentially be eligible for participation in influenza studies. The registry will contain information about people and results from blood, nasal and oral tests done on their samples. The information will be used by investigators at Imperial College to screen and contact people who appear eligible for certain research studies. Depending on the results of your antibody measurements, you may be contacted in the future to discuss participation in a human infection challenge or vaccine study. Also, a small amount of extra blood, nasal and oral samples will be placed in a freezer to be used for new screening tests that have not yet been approved for use.

WHAT DOES PARTICIPATION IN THIS REGISTRY MEAN?
If you sign the consent form for this registry, it does <u>not</u> obligate you to participate in any other research studies. It simply means that you agree to having your information,

including medical history and data generated from your blood, nasal and oral samples, entered into the registry and reviewed by Imperial College investigators. It also means that you agree to be contacted about participation in future research studies. If you agree to participate in a future research study, you will sign a separate consent form for it. You are free to refuse to participate in any study that you are contacted about.

HOW MANY PEOPLE WILL TAKE PART IN THIS REGISTRY?
Approximately 1,200 people will take part in this registry at a minimum of four different hospitals and medical facilities, and approximately 300 people will take part at Imperial College.

WHAT IS INVOLVED IN THE REGISTRY?
If you agree to be in this registry, you will be asked to sign and date the consent form. You will have the following tests and procedures to make sure that you are eligible:

- Medical and vaccination history
- Vital signs
- Blood tests
- Medical record review
- Nose and throat swabs

Prior to your first visit you will be registered at the NIHR Imperial Clinical Research Facility (ICRF), where the study visits will be held. The facility is part of the Imperial College Healthcare NHS Trust. On registration, you will have an electronic hospital record created on the Imperial College Healthcare NHS Trust system (if you do not already have one). You will have been sent this participant information sheet (PIS) to read at least 24 hours before attending the first visit. We would like you to take this time to consider the study, think of any questions, and discuss it with your family, friends or Doctor should you wish, before consenting to the study.

Visit 1. (Approximately 45 minutes)
During Visit 1, we will provide a hardcopy of this PIS and you can discuss the registry and ask questions to the study team. After you have had time to think about whether to participate in the registry and ask the study team any questions, you will be asked to sign and date the consent form agreeing to take part in the registry. If you agree to take part, we will undertake the following procedures:

- Obtain your demographic information including your age, sex, race.

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- Obtain information to confirm whether you are eligible to participate in this registry, including alcohol use, that if you are female you are not pregnant or breastfeeding, that you have no significant medical issues, and any allergies you may have
- Review your medical history including vaccination history against influenza (the flu), SARS-CoV-2, as well as any influenza and/or respiratory illness due to SARS-CoV-2 in the past 12 months
- Review all medications that you have taken within the past 30 days
- Collect your vital signs including heart rate, respiratory rate, blood pressure and temperature
- Measure your height and weight
- Draw blood from you for research lab tests for serum antibodies (a substance that is in your blood that fights germs) (about 6.5 tablespoons) by a needle stick in your arm.
- For a subset of participants: collect nasal and oral samples

Once generated, the influenza antibody test results can be shared with you upon request.

Visits 2 through 25 (about every 3 months, approximately 30 minutes each) and Unscheduled Illness/Post-Vaccination Visits

- Review your eligibility
- Review your medical history including influenza vaccination history, vaccination history against SARS-CoV-2, as well as any influenza and/or respiratory illness due to SARS-CoV-2 since your last visit.
- Review all medications you have taken within the past 30 days
- Collect your vital signs including heart rate, respiratory rate, blood pressure and oral temperature
- Measure your weight
- Draw blood from you for research serum antibodies (about 6.5 tablespoons) by a needle stick in your arm
- For a subset of participants: collect nasal and oral samples

Following each quarterly blood collection, some serum will be stored at Imperial College London, accessible only by designated personnel, to be used for analysis, mainly related to influenza. Samples will be used for screening purposes into other ethically approved protocols, such as influenza infection and influenza vaccine studies, that permit stored blood to be used for screening without additional consent.

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In addition to this registry protocol, eligible participants will be asked to sign a separate consent form for a biorepository protocol called CIVICs 19-0025 (Duke University Health System IRB Pro00104290) for the use of leftover samples and associated data in other ethically approved research. If you give consent, the pseudonymised participant identification codes (barcode label) will stay on the samples and the samples may be stored indefinitely or used for other types of research. Personnel at the storage facility and testing lab will not know your identity. However, the researchers who enrolled you will keep in a secured area a "key" that could connect the barcodes or tracking codes with your data to identify you, if needed. No genetic testing will be performed using these samples as part of this registry or in future studies.

HOW LONG WILL I BE IN THIS REGISTRY?
You may be in this registry for up to six years.

You can choose to stop participating at any time and it will not affect your medical care now or in the future.

WHAT ARE THE RISKS OF THE REGISTRY?
As a result of your participation in this registry, you are at risk for the following:

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks associated with collecting nasal and oral samples include discomfort in the nostrils, a gag reflex, watery eyes, nosebleeds or coughing.

There is a small amount of risk to participants who report that they are in good health but who have an unknown health problem at the time of screening.

There may be risks, discomforts, or side effects that are not yet known.

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ARE THERE BENEFITS TO TAKING PART IN THE REGISTRY?

If you agree to take part in this registry, you are unlikely to have a direct medical benefit.

There is however, a potential benefit to supporting future studies to better understand protection from influenza resulting from information gained from your participation in this registry.

WHO IS THE SPONSOR OF THIS STUDY?

Imperial College London will act as the Sponsor and Data Controller for this study site.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will need to use information from you and from your medical records for this research registry. This information will include your initials, name, date of birth, NHS number, hospital number and contact details. Study team members and authorised individuals will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data and samples will be labelled with a code number instead. We will keep all information about you safe and secure.

Some of your information will be sent to research partners and collaborators in the United States. They must follow our rules about keeping your information safe. Your data may also be shared with people who oversee the conduct of this registry. Monitors, sponsor, funder/supporter, auditors, the Institutional Review Board (IRB), and regulatory authorities, such as the FDA, will be allowed to look at your medical and research records. They check that the procedures are being done correctly. They will protect your confidentiality within the fullest extent of the law. Further details about these confidentiality and data protection rules can be found in Appendix 1 at the end of this document.

As a university, we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

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Once we have finished the research, 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 registry. If you agree to participate, the personal information you provide is added to our registry and will be kept for 10 years after the end of the study, according to Imperial College London policy.

There is a potential risk of loss of privacy. Every effort will be made to maintain your privacy. While this cannot be absolutely guaranteed, the study team will strictly follow the Data Protection Act 2018 and General Data Protection Regulation (GDPR) throughout the study.

Full details regarding how your information will be used, stored and transferred can be found in Appendix 1 at the end of this document.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

- We need to manage you records in a specific way for the research to be reliable. This means that you will not be able to see or change the data we hold about you.
- If you agree to take part in this registry, you will have the option to take part in future research using your data saved from this study.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE REGISTRY?

You are free to choose not to be in the registry. If you agree to be in the registry, you can stop being part of the registry at any time, without giving a reason, but we will keep information about you that we already have.

If you withdraw from the registry, no new data about you will be collected for research purposes unless the data concern an adverse event (a bad effect) related to the registry. If such an adverse event occurs, the study team may need to review your entire medical record. All pseudonymised data that have already been collected for research purposes may be sent to the registry sponsor in this case. If, for any reason, you lose capacity during the study, you would be withdrawn from the study.
Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out on or in relation to you.

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You may also decide to withdraw permission for us to use your previously collected specimens. In this situation, we will ask you to confirm in writing that you want your unused specimens to be destroyed. Otherwise, your specimens (with all identifying information removed that would link the sample to you) will continue to be used in research.

To withdraw from the registry, please write to either Professor Christopher Chiu or the Study Team to let them know. Contact details are as follows: flu-rsv-study@imperial.ac.uk.

Your decision not to participate or to withdraw from the registry will not affect your medical care now or in the future. Your study doctor may decide to take you off this study if they determine that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without asking your permission.

WHAT ABOUT COMPENSATION?
You will be paid £30 or £40 for each visit for your expenses related to your participation (time and travel), depending on whether or not you will have any additional blood or nasal/saliva samples collected. You will only be compensated for the visits you complete. Should you attend Visit 1, but found to not be eligible for the registry, you will still be paid £30 for your expenses.

WHAT ABOUT RESEARCH RELATED INJURIES?
Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator, Professor Chris Chiu, email: flu-rsv-study@imperial.ac.uk, tel: 07872 850212. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

Immediate necessary medical care is available at Imperial College NHS Trust in the unlikely event that you are injured as a result of your participation in this research study.

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No long-term medical care or financial compensation for research-related injuries will be provided by the NIH, U.S. Federal government, or Duke University in the US.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the registry or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Professor Christopher Chiu (PI) at 07872 850212.

COMPLAINT
If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk or via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO), www.ico.org.uk or 0303 123 1113. The ICO does recommend that you seek to resolve matters with the data controller first before involving the regulator.

FURTHER INFORMATION
If you require further information about the study, please contact:

Professor Christopher Chiu
Professor of Infectious Diseases
Department of Infectious Disease
Imperial College London, Hammersmith Campus
Commonwealth Building, Du Cane Road
London W12 0NN

E-mail: flu-rsv-study@imperial.ac.uk

All research in the NHS is looked at by independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and deemed acceptable by such a Committee.

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APPENDIX 1

CONFIDENTIALITY
We will need to use information from you and from your medical records for this research registry. This information will include your initials, name, date of birth, NHS number, hospital number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data and samples will be labelled with a code number instead. We will keep all information about you safe and secure.

Some of your information will be sent to research partners in the United States. They must follow our rules about keeping your information safe.

Once we have finished the research, 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 registry.

The Department of Health and Human Services (HHS) in the U.S. has issued a Certificate of Confidentiality to further protect your privacy. The certificate provides protection of data originating in the U.S. or transferring to the U.S. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is supporting this project or for information that is required by the U.S. Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer,

medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- the following Research Collaborators in the registry who are part of the same protocol, performing comparable research;

    - Duke University in the U.S.
    - The Statistical, Data Management, and Coordination Center (SDMCC) through the National Institutes of Health (NIH) in the U.S.
    - University of Maryland School of Medicine, in the U.S.
    - SUNY Upstate Medical University, in the U.S.
    - Vanderbilt University, in the U.S.
    - University of Iowa, in the U.S.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

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- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to flu-rsv-study@imperial.ac.uk, or
- by ringing us on 07872850212.

All of the blood studies are being done only because you are in this registry. No test results will be provided. If you agree to participate, the personal information you provide that is added to our registry will be kept for 10 years after the end of the study, according to Imperial College London policy. If you change your mind and decide that you do not want to participate in the registry, we will change your status in our database to ensure you will no longer be contacted. No new information about you will be collected for the registry other than data needed to keep track of your withdrawal, and you will not be contacted for future studies.

While the information and data resulting from this registry may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

There is a potential risk of loss of privacy. Every effort will be made to maintain your privacy. While this cannot be absolutely guaranteed, the study team will strictly follow the Data Protection Act 2018 and General Data Protection Regulation (GDPR) throughout the study.