PARTICIPANT INFORMATION LEAFLET

Study Title: Irish Coronavirus Sequencing Consortium

Chief Investigator: Prof Paul Cotter, Teagasc

Sites of Investigation:

Teagasc Food Research Centre, Moorepark, Fermoy, Co. Cork

Teagasc Animal and Grassland Research Centre, Grange, Co. Meath

APC Microbiome Ireland, University College Cork

Teagasc Crop Research Centre, Oakpark, Carlow, Co. Carlow

Cork University Hospital

University Hospital Limerick

Beaumont Hospital

NUI Galway

NUI Maynooth

Trinity College Dublin

NVRL, UCD

Genomics Medicine Ireland/Genuity Science

Helix Works Technologies Ltd

Why is this study being run?

The virus that causes COVID-19 is called SARS-CoV-2. It contains genetic information that can change over time. The Irish Coronavirus Sequencing Consortium is a group of scientists based throughout Ireland who need to look at this genetic information. If

we can ‘read’ possible genetic changes, we will have a better map of how the virus spreads across regions. Being able to determine the genetic makeup of the viruses circulating in Ireland will also support efforts to respond to clusters of infections as they arise, and minimise the spread of the virus. Collecting the sequences (genetic information) of the viruses in Ireland will also mean we can record important new changes that could affect the ability of the virus to cause disease or the efficacy of treatments or vaccines.

You have been approached by a medical professional involved in this study in the hospital you are being treated in, to partake in this study, as you have tested positive for COVID-19. If you agree to participate in this study, we will use the viral genetic material that is obtained during your diagnostic test (that is, the material that is gathered on the swab/cotton bud used, or your sputum collected, as part of your COVID-19 test) to create a map of the virus information. We will only use the material if you test positive for COVID-19.

Study Procedure

You will be advised of the purpose of this study and the sample process which will be undertaken. After reading this participant information leaflet, if you decide to take part in the study you will be asked to read and sign the consent form and will be given the signed copy for your records. If you agree to participate in the study, your eligibility to participate in the study will be determined. COVID- 19-positive males and females aged 18 years and over will be enrolled.

What is my involvement in the study?

You do not have to do anything beyond what happens when you present for diagnosis. The swabs or sputum that you will provide for the diagnostic test will be used for an additional laboratory test for this study. Inclusion of your sample will not result in any changes to your treatment. No additional involvement from you is required.

What happens if I start the study and change my mind later?

You do not have to take part in this study, participation is entirely voluntary. Refusal to participate, or discontinuing participation at any time, will involve no penalty.

Will I experience any unpleasant side effects?

There are no additional side effects beyond the discomfort you will experience during the diagnostic test and this will pass quickly.

Funding of trial

There are no cost implications for the Health Services Executive (HSE) or to you.
Science Foundation Ireland is contributing funding for this national study.

Confidentiality

All information will be stored securely and will be treated with the strictest confidence as per General Data Protection Regulations (GDPR) and the Irish Health Research Regulation. All the information gathered from this study will be stored on secure computers and paper files and will be treated confidentially. You will be identified with the study only by a subject code. In the event of any publication regarding this study, your identity will not be disclosed. Please see attached Data Protection Notice for more information on your rights and how your data will be treated.

What happens if there is anything I do not understand?

If there is anything you are not sure about, the Investigators will be happy to explain in more detail to you. The study will be fully explained to you before you sign the consent form.

Contact Information

Prof Paul Cotter
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Head of Department, Food Biosciences
Senior Principal Research Officer,
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Ireland

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Email: Paul.cotter@teagasc.ie

DATA PROTECTION NOTICE

At Teagasc, we treat your privacy seriously. Any personal data which you provide to us will be treated with the highest standards of security and confidentiality, in accordance with the Data Protection Acts 1988-2018 and the European General Data Protection Regulation 2016/679 (hereafter referred to as "Data Protection legislation"). This notice sets out details of the personal data that we collect, how we process it and who we share it with. It also explains your rights under Data Protection legislation in relation to processing of your data.

WHO WE ARE

Teagasc is the Agriculture and Food Development Authority, with its Head Office at Oak Park, Carlow, Co. Carlow (hereafter "Teagasc"). For this study, Teagasc provides protocol insurance and Teagasc will be responsible for study data and samples. Throughout this Notice, "we", "us" and "our" refers to Teagasc, as this will be the legal entity controlling and processing data for this study and Teagasc is therefore the data controller for the data generated in this study. Each clinical site is the data controller for the personal patient files and personal patient information.

HOW WE WILL USE YOUR PERSONAL DATA

By participating in the study and performing the study exams, your personal data (will be collected for the study purposes mentioned in the Subject/Patient information leaflet above. This personal data includes:

- Your age range;
- Your gender;
- Location sample was taken;
- Date sample arrives in diagnostic laboratory/ Collection date
- Your electoral constituency (in place of actual address)

Personal data collected at any time during the study will be kept strictly confidential. To ensure confidentiality, the data generated during the study is pseudonymised or **coded** with a number that will identify you in the study. Any information that leaves the site/sites of investigation will be labelled with your code instead of your name. Every person that has access to your uncoded data (that is kept at the clinical sites of investigation) is subject to professional secrecy and confidentiality.

A list or 'key' linking your study number to your name will also be kept by the clinical sites.

WHO WILL ACCESS MY PERSONAL DATA?

Your uncoded data will only be accessible to clinical site employees (where relevant), and the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, 6 Little Hanover Street, Cork so that they can check if the study is being conducted to the best standards.
Results of the study will be provided to the ethics committee approving the study in compliance with national and international regulations on clinical studies.

THE PURPOSE AND LEGAL BASIS FOR COLLECTING YOUR DATA

Any personal data you provide to us during the course of this study will be processed fairly and lawfully. As a legal basis for the processing of data in this study, Teagasc are relying on Article 6(1)(e) of GDPR, which states that a data controller may process personal data where it is necessary for the performance of a task carried out in the public interest, As there is sensitive personal data involved, Teagasc are also relying on Articles 9(2)(i) and 9(2)(j), where it is necessary for reasons of public interest in the area of public health and necessary for scientific research purposes.

Signing the Informed Consent Form means that your personal data and biological samples will be used for the purposes outlined in the Participant information leaflet (PIL).

Personal data collected during this study and the results of the study may be presented for scientific purposes or in reports to our funders (SFI/Teagasc). However, you will never be identified individually during these presentations. Your identity will not be revealed in any reports or publications.

Non-identifiable general information relating to participants (such as gender, age range and electoral constituency) together with the information relating to the make-up of the virus will be uploaded to publicly available databases. This is for the purpose of epidemiology testing and assisting in global efforts to contain and manage the virus. Your identity will not be revealed in this uploaded information.

The study chief investigator and the members of the study's team will use your personal data within the scope defined above. If the study team wish to use your data for a purpose other than the purpose specified, they must contact you again to give you more information and ask your permission to use your data for the new purpose.

The General Data Protection Regulation allows us to process your data because you have provided your consent. You are entitled to withdraw your consent, but please note that it may not be possible for us to comply with your request to withdraw your consent after non-identifiable general information relating to you is uploaded to publicly available databases as referred to above.

HOW LONG WE WILL KEEP YOUR DATA

The personal data collected in the study will be kept indefinitely a period of up to 15 years after the end of the study. Thereafter, they may be stored for a further period of time for legal reasons (e.g. revised retention obligations), or more if required by law.

CROSS-BORDER DATA TRANSFERS

Study data/results may be shared with the study funders but at no point will personal uncoded data be shared with the study funders.

YOUR RIGHTS

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- to have inaccurate/incomplete information corrected and updated;
- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data;
- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form);
- to withdraw your consent to the processing of your data without giving a reason by notifying your decision to the study Researcher. This will not affect the lawfulness of processing data about you based on your consent before the withdrawal. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study Researcher will present you the options you have concerning your personal data.
- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing.

If you wish to exercise any of these rights, please address your request to the study Chief Investigator or the Data Protection Officer, (details below).

QUESTIONS OR COMPLAINTS

If you have any queries in relation to this study please contact the PI, Paul Cotter, or the Teagasc Data Protection Officer, Della Hunter (contact details below).

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Ms. Della Hunter,

Data Protection Officer, Teagasc.

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Teagasc – The Agriculture and Food Development and Food Authority, Head Office, Oak Park, Carlow. R93X E12 is the Data Controller for this Research Project.

If you have any complaints in connection with our processing of your personal data, you can contact Teagasc's Data Protection Officer (DPO): **E: dpo@teagasc.ie Tel: +353 59 9183423.**

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

CONSENT BY SUBJECT FOR PARTICIPATION IN A HUMAN OBSERVATIONAL STUDY

Participant Name: _____

Study Title: Irish Coronavirus Sequencing Consortium

Chief Investigator: Prof Paul Cotter

Phone: 025 42694

Email: Paul.cotter@teagasc.ie

Participation in this study is voluntary and you may withdraw for any reason

This research study and procedure associated with it have been fully explained to me. All experimental procedures have been identified and no guarantees have been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the study and any procedures involved. I am aware that participation is voluntary, and I may withdraw consent, though I acknowledge that it may not be possible to withdraw my consent after coded non-identifiable information relating to me (such as age, gender and electoral constituency) is uploaded to dedicated websites to assist with epidemiology tracing, as referred to below. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this study will be maintained in an appropriate manner. I understand that the investigators have such insurance as is required by law in the event of injury resulting from this research.

I, the undersigned, hereby consent to participate in the above described study. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the Investigator listed.
If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, 6 Little Hanover Street, Cork.

Analyses of all samples and information collected will be conducted in one of the sequencing labs associated with this project (Teagasc Moorepark, APC Microbiome Ireland, Teagasc Oakpark, Teagasc Grange, NUIG, NUI Maynooth, Trinity College Dublin, GMI, HelixWorks Ltd and the National Viral Reference Laboratory (NVRL)). In all cases, samples and data will be coded with study subject codes.
Samples will be destroyed once sequencing has been completed and recorded. Coded data will be uploaded to dedicated websites to assist with epidemiology tracing. Associated data that will be uploaded will be date and location the sample was collected/tested, gender and approximate age and electoral constituency.

After reading the entire consent form, if you have no further questions about giving consent and if you have read and understood the Data Protection Notice, please sign where indicated.

Participant's Signature: _____ Date: _____
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NAME (BLOCK LETTERS): _____ Time: _____

Investigator's Signature: _____ Date: _____
dd mon yy

NAME (BLOCK LETTERS): _____