**Participant Information Sheet**

**Improving the management of COVID-19 through data-driven research**

**You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.**

|  |
| --- |
| **What is the purpose of the study?** |
| We would like to invite you to take part in a study about COVID-19 (the illness caused by the new coronavirus). Most people with COVID-19 have an unpleasant but not serious illness, but some people do become more unwell and need admission to hospital. We need to understand more about who is most likely to become more unwell. This is so that doctors and nurses can make better decisions about how to treat people. For example, deciding who needs admitting to hospital, or who needs extra monitoring at home. We are also creating a database of people who are willing to be contacted about other COVID-19 research projects, although this is optional and you can take part in this study without joining the database. |
| **Why have I been invited to take part?** |
| You have been asked to take part in this study as you have engaged with an NHS service providing advice for people with potential symptoms of COVID-19. |
| **Do I have to take part?** |
| No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information about the study and asked to provide verbal and/or written consent. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. |
| **What will happen if I take part?** |
| The study involves completing a short questionnaire about the symptoms that you have as well as answering some questions on other information about your health. We will then link your answers to other data that the NHS holds about you (for example, the conditions you have and the medicines you take; whether you are admitted to hospital with COVID-19). The data collection is done using DataLoch – a secure electronic platform where confidential information can be transmitted and stored securely. We will collect this data for 36 months. In order for us to link your data we will collect your Community Health Index Number (CHI- number). Your CHI number is a unique identifier which is allocated to everyone who is registered with a Scottish GP.  You can take part in two ways.  1. Go to <https://edin.ac/COVID-study> where is more information about the study. You can complete the survey online if you decide to take part.  2. Contact the research team on 07341030159. Someone will phone you and can tell you more about the study. You can complete the survey on the phone if you decide to take part. |
| If you decide to take part and complete the consent form online, we will collect your IP address. An IP address is a label which is used to identify one or more devices on a [computer network](https://simple.wikipedia.org/wiki/Computer_network), such as the [internet](https://simple.wikipedia.org/wiki/Internet). It is comparable to a postal address.  If you agree, we will ask you to complete a brief daily online symptom diary until you have recovered. We will also ask if you are happy to be contacted about other COVID-19 research studies that are happening in the area. These include studies to understand why some people with COVID-19 become very unwell, and trials of drug treatments for early COVID-19. You will only be agreeing to be *contacted* about studies that might be relevant to you, and offered the opportunity to hear more about them if you are interested. You do not have to take part in any studies that you are contacted about. |
| **What are the possible benefits of taking part?** |
| There are no direct benefits to you taking part in this study, but the results from this study might help to improve care for people with COVID-19 in the future. |
| **What are the possible disadvantages of taking part?** |
| We do not foresee that there will be any disadvantages of taking part in the study. |
| **What if there are any problems?** |
| If you have a concern about any aspect of this study please contact Bruce Guthrie on 0131 650 3216 or email [COVID.Community@ed.ac.uk](mailto:COVID.Community@ed.ac.uk) who will do their best to answer your questions.  In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). |
| **What will happen if I don’t want to carry on with the study** |
| To withdraw from the study you will need to contact the study team on [COVID.Community@ed.ac.uk](mailto:COVID.Community@ed.ac.uk) or 07341030159. We’ll keep and use the data we’ve already collected from you, and we’ll carry on collecting data from the NHS unless you withdraw consent for this. |
| **What happens when the study is finished?** |
| At the end of the research we will analyse the data and publish the results. We will also publish a summary of the results online. This will give you the information about what we found through undertaking this trial. The data generated from the study will be stored on a secure server for up to 5 years. Anonymised data will be made available to accredited researchers for additional analyses. |
| **Will my taking part be kept confidential?** |
| All information about you will be kept strictly confidential. We need to ask you your name and contact details in order to link your answers to your health data. All personal information about you will be kept strictly confidential. For details on what data will be held about you and who will hold and store this information please refer to the Data Protection Information Sheet. |
| **What will happen to the results of the study?** |
| The study findings will be communicated to policymakers and will be written up and published in a journal. We will also upload a link to this article or provide a summary of the results on the study website. |
| **Who is organising and funding the research?** |
| This study has been organised by Edinburgh Clinical Trials Unit (ECTU) and is sponsored by University of Edinburgh and NHS Lothian. |
| **Who has reviewed the study?** |
| The study proposal has been reviewed by the senior management team at ECTU.  All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from North of Scotland (2). NHS Management Approval has also been given. |
| **Researcher Contact Details** |
| If you have any further questions about the study please contact Bruce Guthrie on 0131 650 3216 or email [COVID.Community@ed.ac.uk](mailto:COVID.Community@ed.ac.uk) |
| **Independent Contact Details** |
| If you would like to discuss this study with someone independent of the study please contact Professor Stewart Mercer on [stewart.mercer@ed.ac.uk](mailto:stewart.mercer@ed.ac.uk) |
| **Complaints** |
| If you wish to make a complaint about the study please contact:  Patient Experience Team  2 – 4 Waterloo Place, Edinburgh, EH1 3EG  [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk)  0131 536 3370 |

**CONSENT FORM**

**Improving the management of COVID-19 through data-driven research**

|  | | | | | **Please initial box** |
| --- | --- | --- | --- | --- | --- |
| 1. I confirm that I have read and understand the participant information sheet version 4.0 dated 05 Jun 2020 and the data protection information sheet v 2.0 dated 05 Jun 2020 for the above study and have understood its contents. | | | | | ⬜ |
| 1. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. | | | | | ⬜ |
| 1. I give permission for my IP address to be collected if I complete the consent form online. | | | | | ⬜ |
| 1. I give permission for the research team to access my medical records for the purposes of this research study. | | | | | ⬜ |
| 1. I understand that relevant sections of my medical notes and data collected during the trial may be looked at by the trial researchers and individuals from the Sponsor or from NHS organisations, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | | | | | ⬜ |
| 1. I give permission for my personal information (including name, address, date of birth, telephone number and consent form) to be passed to the University of Edinburgh and ECTU for administration of the study. | | | | | ⬜ |
| 1. I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and ECTU in order to perform data linkage in DataLoch. | | | | | ⬜ |
| 7. I agree to be contacted for future COVID-19 research studies. | | | | | Yes ⬜ No ⬜ |
| 1. I agree to take part in the above study. | | | | | ⬜ |
|  |  |  |  |  | | |
| Name of Person Giving Consent |  | Date |  | Signature | | |
|  |  |  |  |  | | |
| Name of Person Receiving Consent |  | Date |  | Signature | | |

1x original – into Site File; 1x copy – to Participant;