# CCP-UK Patient Notification Form

The purpose of this document is to **inform** our participants about how their **data is used** in our study.

## What is CCP-UK?

The CCP-UK (Clinical Characterisation Protocol – United Kingdom) is a study that collects information about infectious diseases of public health importance quickly and efficiently in response to potential public health crises. The study was activated in January 2020 in response to the emergence of what was then called Wuhan Flu, which led to the **COVID-19 pandemic**. Since being activated, we have recruited over **300,000** patients to the **data collection** aspect of our study. CCP-UK is the **largest** study of its kind answering questions about COVID-19 **in the world**. We have also been activated for cases of Ebola, Monkeypox, Lassa Fever and Middle East Respiratory Syndrome (MERS).

## What data do we collect?

Research nurses and medical students at hospitals across the UK recruited people who tested positive for **COVID-19**. The research nurses and medical students recorded information on patients' hospital stay, such as whether they had any underlying conditions, what medicine they were given and what the result of their hospital stay was (discharged well, discharged disabled or death).

The research team then input this information into our study database. All data inputted on the database is **anonymised** – each patient is given a unique participant ID, so no names are stored on the database and individuals cannot be directly identified.

Participants' **date of birth**, **NHS number** and **postcode** are also recorded on the database. This information is hugely important for the study, which is why we cannot leave it out for confidentiality purposes. **Date of birth** is important to allow us to analyse the impact of **age** on COVID-19 outcomes. **NHS numbers** are important as these let us **link** to other NHS databases to obtain further information, such as which of our participants received a particular drug to treat COVID-19, or who has received a COVID-19 vaccine. **Postcodes** are important to allow us to analyse the impact of **deprivation factors**, such as living in a poorer area, on COVID-19 outcomes. Without

these key pieces of information, we wouldn't be able to complete most of the analysis that we have done and would not have been able to have the same positive impact on the UK's COVID response.

## Why are we allowed to collect this data without consent?

In March 2020, in order to boost the UK's response to COVID-19, the Department of Health and Social Care served the NHS with a COPI (Control of Patient Information Regulations 2002) Notice, **requiring** them to share confidential patient information **without consent** for specific purposes. These specific purposes included **research** on COVID-19. Because of the COPI Notice, our study has been collecting data from patients admitted to hospital in the UK with COVID-19 **without getting their permission first**.

Being able to collect this data without obtaining permission has been very important in enabling our study to achieve what we have done. Many of the people admitted with COVID-19 were too sick to give consent themselves and because of COVID-19 precautions, they were not accompanied by relatives who could speak for them. Because we were not required to obtain consent from each of our participants, we have been able to recruit **many more participants** than usual and we were able to include the sickest patients who are often missed from studies like ours. We have also been able to work **very quickly**. Because of this, our data has been able to capture what is happening with COVID around the UK in near real-time. This allowed us to provide the health policy teams and doctors in the NHS with the most up-to-date information to guide the health response throughout the pandemic.

## What has the study achieved?

Because we have been able to collect and analyse this data quickly and efficiently, we have been able to achieve a lot through our study.

- We provide reports to SAGE and NERVTAG weekly. These are the committees that provide advice to health and social care policy makers for the UK COVID-19 response.
- We have been able to identify several risk factors in the UK population that are strongly associated with poor outcomes in COVID-19, including the impact of obesity, respiratory conditions and different outcomes between ethnic groups.
- We have been able to provide data supporting identification of high-risk groups for COVID-19 vaccination which meant they were given priority and this saved lives.
- We have been able to conduct research into the usefulness of COVID-19 drugs treatments and shown what works well and what does not.

You can review these outcomes at our website: https://isaric4c.net/outputs/.

## How is the data collected kept safe?

We make sure that the data on our database is as **secure** as possible. The database is only accessible by approved colleagues with passwords, and is run by IT systems with **very high standards of security**. The physical notes that research nurses complete before transferring the information to the database are kept in locked rooms accessed only by hospital staff, or on hospitals' secure electronic healthcare record system.

We make sure the data is as **confidential** as possible by anonymising it (using unique participant IDs rather than names). The data collected (including date of birth, NHS number, postcode) is only accessible by members of the study team, and is **not** disclosed beyond this. Once the NHS number is used for linkage we remove it from the research database.

## How can I opt out of having my data collected?

If you have opted out of your data being used for research via the National Data Opt-Out (https://www.nhs.uk/your-nhs-data-matters/), we will remove your data from our database if you have been recruited.

If you have not opted out of your data being used for research via the National Data Opt-Out but you would like to opt out from your data being used for our study, you can contact the study team to request this at ccp@liverpool.ac.uk. **If you want to opt out please send us an email including your name, date of birth, NHS number and postcode.** You do not need to give a reason for why you want to opt out. We will look for your details in our data and if we find it we will delete it. In any case we will email back to you within 14 days to tell you if we found your data and if we did, to confirm that your data has been removed.

**If you would like to learn more about our study and how patient data is collected, used and protected, please visit https://isaric4c.net/privacy/.**