**Participant Information Sheet for HEAL-COVID**

* You have been invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve.
* You can ask a member of your clinical team if there is anything that is not clear, or if you would like more information.
* Taking part is voluntary. If you don’t want to take part then you don’t need to give a reason why.
	+ HEAL-COVID is a large national study to compare treatments for the long-term consequences of COVID-19, also known as “Long COVID”.
* We are inviting people to take part who are due to be discharged from hospitals across the UK after having COVID-19. People who take part will remain in the trial for a total of 12 months.

If you want to discuss this study further with your local research team please speak to:

**Name:** <PI/RN Name>

**Contact Number:** <PI/RN Number>

Why are we doing the HEAL- COVID study?

COVID-19 is a disease caused by a virus called SARS-CoV-2, which affects not just the lungs but other organs like the heart, kidneys and blood vessels too. Recently, we have become aware of people who have been unwell with COVID-19 developing new or worsened symptoms after being discharged from hospital – this is often called “Long COVID”. Long COVID is thought to represent a mix of conditions and around 1 in 5 patients with COVID-19 develop symptoms currently associated with the term Long COVID.

 This is a serious group of conditions that can result in death and disability for some people.

Long COVID is not well understood. We do not yet know which treatments are best to prevent and treat it. There are several commonly used medicines that might help people with Long COVID, but we do not know yet how well they work for patients who have had COVID-19, or which treatments are the best. The HEAL COVID study was set up to look at different treatments that work on the complications and symptoms seen in patients with Long COVID. The results from this study will be used to help us improve treatments and care for patients with long-term effects of COVID-19.

Why have I been asked to take part?

You have been approached to take part in this study because you have been diagnosed with COVID-19 and are due to be discharged from hospital in the next few days***.***

Do I have to take part?

No, taking part is voluntary. It is up to you to decide whether or not you want to take part.

If you decide not to take part then you will still receive the usual treatment your hospital offers. Your doctor or nurse can provide you with more information on this.

If you decide to take part you can also choose to stop at any time without giving a reason.

The decision you make on whether to take part or not will not affect the standard of care you receive now or in the future.

What will happen to me if I take part?

If you agree to take part, you will be asked to sign a consent form. You will be given a copy of the consent form and this information sheet to keep.

Once you have signed the consent form, we will check and confirm that this study is suitable for you.

If you take part in this study, we will collect some health data about you whilst you are in hospital. We will collect further information about your healthcare for 12 months after you agree to take part in the study. This information may include GP visits, referrals, hospital attendances or other healthcare you receive over your lifespan and beyond. Further information about the data we collect and how we collect it is available on the website (www.heal-covid.net).

We will provide you with the study treatments we would like you to take before you leave hospital. We will ask you to take the treatment yourself at home, and your doctor or nurse will explain to you how to take it, how often and for how long. If you are asked to take Atorvastatin, you will be given repeat prescriptions for this by your GP or your hospital, because the treatment lasts for longer than Apixaban. If you usually pay for your prescriptions, let your doctor or nurse know and shortly after you leave hospital, you will be sent a form or certificate that ensures you will not pay for these for HEAL-COVID.

Once you have been discharged, we would also like to ask you some questions about how you are feeling, any long-term effects of COVID-19 that you might be experiencing, and your experience of taking part in research.

Taking part in these questionnaires is optional, so you can still take part in HEAL-COVID even if you do not want to answer these questionnaires. The information you provide will help us to understand the impact of COVID-19 on long-term symptoms and quality of life, and to see if treatments used in the trial are working.

We would like you to complete the questionnaires about how you are feeling, but if you feel too unwell to do this then a family member, friend or caregiver can help to complete them on your behalf. Ideally, please ask the same person to help each time.

The questionnaires will be available through a HEAL-COVID app (called ‘ATOM5™’, by a company called Aparito) on your mobile phone or tablet. The research team will help you to download the app before you leave hospital, or give you details about downloading the app at home. We will ask you to complete these questionnaires once a week at the start, and then once a month thereafter.

They will take approximately 10 minutes to complete each time. You will receive an alert and reminders on your smartphone or tablet each time a questionnaire is ready to be completed. If you do not have a mobile phone or tablet, a nurse can call you to ask you these questions over the phone, with a translator if you need one. The doctors and nurses looking after you will not be able to see your answers to the study questionnaires, and the information you provide will not inform the care you receive.

After 12 months from the day you enter the study, your participation will be complete and we will only contact you after this time if you have asked us to, or if you have said you might like to take part in future research. In the future we might also link the data about you from this study with other databases or clinical trials to answer questions about COVID-19.

If while you are taking part in HEAL-COVID you lose the ability to make decisions for yourself (e.g. because of a severe illness), you will remain as a participant in the study unless someone acting as your legal representative asks us to withdraw you.

What are the drugs being tested?

The treatments we want to compare in HEAL-COVID are called Atorvastatin and Apixaban. 877 people will be given each of these treatments. These treatments are very commonly used to treat patients with a variety of conditions.

Atorvastatin is a statin and is commonly used to lower cholesterol, but also has activities that reduce inflammation in the body. If you are given Atorvastatin you will take this once a day for 12 months.

Apixaban is a medication commonly referred to as a “blood thinner” or anticoagulant. If you are given Apixaban you will take this twice a day for 2 weeks.

Patients with Long COVID can have symptoms caused by inflammation and excess clotting, so these medications might help with preventing or treating some of the long-term effects of being unwell with COVID-19.

How will I know which treatment I’m going to have?

In this study, patients will be split into three treatment groups and each group will have a similar mix of patients. One group will receive “standard care” (the same as you would receive if you were not taking part in the study). This means any treatment usually offered by your hospital, as appropriate for your symptoms and/or other conditions you might have. The other groups will receive Atorvastatin, or Apixaban in addition to standard care. We use a computer programme that puts patients into groups ‘at random’. Neither you nor your doctor choose which group you are in.

What are the alternatives for treatment?

Because COVID-19 is a new disease, we are still learning how best to treat patients who have long-term symptoms. If you decide not to take part in HEAL-COVID you will receive the standard care that your hospital provides, depending on your symptoms and what your doctors or nurses think is appropriate for you.

What are the benefits and risks of taking part?

There is potential that the treatment you are given as part of the study may improve your symptoms and help you recover from your COVID-19 illness more quickly. Though these medications are well-established treatments with a known profile of safety, like most medication, they also have potential side effects.

If you are given Atorvastatin, some common side-effects you might experience are:

* Headaches
* Cold-like symptoms, including sore throat
* Feeling sick (nausea)
* Flatulence, diarrhoea or constipation
* Indigestion
* High blood sugar
* Nosebleeds
* Sore muscles or muscle spasms, sore or swollen joints, or back pain
* Abnormal liver function test results

Statins can increase glucose levels, and if you have concerns or are at increased risk of diabetes, please consult your doctor. Women of childbearing potential will also need to use appropriate contraception while taking Atorvastatin.

If you are given Apixaban, some common side-effects you might experience are:

* Haematoma and bruising
* Feeling sick (nausea)
* Anaemia
* Increased risk of bleeding

If you are due to have surgery or dental treatment while you are taking Apixaban, you should make sure to tell your doctor or dentist.

We will stop your medication if the study shows that there is no evidence of its benefit over standard care. If this happens, you will be offered standard care.

What happens if I change my mind?

You can contact us at any time if you wish to stop taking part in the study. You will still receive the standard care and the follow up usually offered by your hospital. With your permission, we would like to continue collecting information about your health from routine healthcare records.

In some cases, we may need to continue to collect limited information about any side-effects of the study treatment you may experience. We will only do this where we are required to do so by law.

What if new information becomes available?

Sometimes during the course of a research project, important new information becomes available about the treatments that are being studied. If this happens, your doctor or nurse will tell you about it and discuss with you whether you want to or should continue in the study. If the study is stopped for any other reason you will be told why and your continuing care will be arranged.

 What happens when the study stops?

At the end of the study your treatment will return to standard care. If you are still experiencing symptoms your healthcare team will arrange appropriate ongoing care for you.

It is intended that the results of the study will be presented at conferences and published in medical journals, so that we can explain to the medical community and public what our research results have shown. Confidentiality will be ensured at all times and you will not be identified in any publication. We will keep all information from the study for 10 years.

 Will my taking part in the study be kept confidential?

Yes. The only people that have access to your data are those that need it for the conduct of the study. This includes the study doctors and nurses, the central trial team, Aparito (who provide the ATOM5 study app), inspectors or auditors on behalf of the Sponsor organisations and the regulatory authorities. With your permission, we will let your GP know that you are taking part in this research study.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

In order to access your routine healthcare data, Liverpool Clinical Trials Centre (LCTC) will securely send your date of birth and NHS/CHI/Health & Social Care number to NHS Digital, or the equivalent organisations in Scotland, Wales and Northern Ireland who look after NHS data records. We plan to ask for your data for 12 months from the day you enter the study, but this may be extended in future to follow-up your long term health status. The NHS Digital (or equivalent) data returned to LCTC will be shared securely with Bangor University, who are doing some of the study analysis. Researchers at Bangor University will not receive your personal details and will not be able to identify you.

Further information about how we use your data and keep it safe can be found on the HEAL-COVID website, [www.heal-covid.net](http://www.heal-covid.net).

Who is running the study?

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge jointly Sponsor this study and are responsible for managing it. They are based in United Kingdom. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool). The central trial team are researchers from the University of Cambridge, LCTC and Bangor University.

The study has been reviewed by the Medicines and Healthcare Products Regulatory Agency, the Health Research Authority and the National Research Ethics Service Committee to make sure that the study is scientifically and ethically acceptable. This study is funded by the National Institute for Health Research (NIHR).

Your doctor will not receive any payment for including you in this study.

Information sharing for other research

If you agree to take part in this study, you will have the option to allow future research at other organisations using your data collected as part of this study. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health. and Social Care Research, or equivalent standards.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

* on the HEAL-COVID trial website [www.heal-covid.net](http://www.heal-covid.net)
* at [www.hra.nhs.uk/information-about-patients](http://www.hra.nhs.uk/information-about-patients)
* in the Health Research Authority leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by contacting the Cambridge University Hospitals NHS Foundation Trust Data Protection Officer on infogov@addenbrookes.nhs.uk
* by contacting the University of Cambridge Data Protection Officer on dpo@admin.cam.ac.uk
* by contacting the University of Liverpool Data Protection Officer on legal@liverpool.ac.uk
* by asking one of the research team at your hospital

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.If you have a concern about any aspect of this study, you should ask to speak with one of your research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient Advice and Liaison Service (PALS) or equivalent. Members of your local hospital team should be able to provide this information to you. Every care will be taken in the course of this clinical study. However, in the unlikely event that you are harmed by taking part in this research project, and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against the NHS Trust where you are being treated but you may have to pay for your legal costs. The normal National Health Service complaints procedures should be available to you.

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the clinical trial caused through the negligence of its employees and honorary contract holders.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the clinical trial. If you believe you have been harmed by taking part in this study, you should contact the research team at your hospital in the first instance, via the contact details on page 1 of this information sheet.

**Thank you for taking the time to read and consider this information sheet. Should you decide to take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.**

This study is funded by the National Institute for Health Research (NIHR; reference NIHR133788) and the NIHR Cambridge Biomedical Research Centre. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Your hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the study and the study Sponsor accepts no liability for negligence on the part of your hospital’s employees.

If you have concerns about your well-being you should speak to a member of your clinical team before you leave hospital. Once home, contact your GP or call 111. Resources for support and advice following your COVID-19 illness can be found on our website (www.heal-covid.net).

|  |
| --- |
| ***To be completed by the participant:***  |
| Once you have read and understood each statement please enter your initials in each box. | Initial |
| 1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.
 |  |
| 1. I understand that participation is voluntary and that I am free to withdraw from the study at any time, without giving a reason, and without my care or legal rights being affected. However, the study team may need to collect some limited information for safety reasons.
 |  |
| 1. I understand that relevant sections of my medical notes and any data collected during the study may be looked at by authorised individuals from the central study team and representatives of the Sponsor, regulatory authorities and the local NHS Trust. I give permission for these individuals to have access to my records and data.
 |  |
| 1. I agree for my data held by NHS Digital, their equivalent bodies in Scotland, Wales and Northern Ireland, or their successor, to be obtained by Liverpool Clinical Trials Centre (LCTC) and shared with Bangor University for use in this study. I understand that records maintained by NHS Digital and their equivalent bodies may be used to follow-up my long term health status.
 |  |
| 1. I agree for my details and data from this study to be linked to other data sources, including data from other clinical trials, for research purposes.
 |  |
| 1. I understand that my data, including my identifiers, will be kept by LCTC, the University of Liverpool and at my hospital in a confidential manner for 10 years from the end of the study. I understand that the data held by Bangor University does not include directly identifiable data and will be kept in a confidential manner for 10 years from the end of the study.
 |  |
| 1. I agree for my GP to be informed of my participation in this study.
 |  |
| 1. **I agree to the above statements and would like to take part in the study.**
 |  |
| The statements below are optional (you can still take part in the study even if you do not wish to agree to these): |  |
| 1. I agree to complete follow-up questionnaires about my health and wellbeing after my hospital admission. I understand that the questionnaires I complete will not be used to inform my care directly.

I would like to complete these questionnaires *(please initial your preferred option):* By downloading the study app (Atom5™) onto my phone or tablet If you would like to take part via the app please provide your email address below:

|  |  |
| --- | --- |
| Email address: |  |

 |  |
| By being called by a nurse or researcher to answer over the phone If you would like to take part over the phone please provide your telephone number below:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Telephone number:  |   |  |  |  |  |  |  |  |  |  |  |  |

 |  |
| 1. I would like to receive newsletters or updates about the progress of HEAL-COVID, including the results at the end of the study

 (if you agree to this statement provide your details below). |  |
| 1. I agree to allow information or results arising from this study to be used in future healthcare and/or medical research, in the UK and abroad, providing my confidentiality is maintained. I understand that future research may involve private companies as well as universities or NHS organisations.
 |  |
| 1. I agree that I may be contacted in the future in relation to this or other related studies.

 (if you agree to this statement provide your details below):

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Telephone number:  |   |  |  |  |  |  |  |  |  |  |  |  |  | Same as above:  |
| Email address: |  |  | Same as above:  |
| Postal address: |  |  |

 |  |
| ***To be completed by the participant:*** |  |
| Your full name (please print): |  |
| Your signature: |  | Date: |  |
| ***To be completed by the Researcher (after participant has completed the form):*** |
| Researcher full name (please print): |  |
| Researcher signature: |  | Date: |  |

|  |
| --- |
| ***To be completed by an independent witness if the participant is not able to read and/or sign for themselves but has capacity to give consent.*** |
| I witnessed the reading of the patient information sheet and consent form to the potential participant. They had the opportunity to ask any questions, all questions were answered and they gave their consent freely. |  |
| Witness fullname (please print): |  |
| Witness signature: |  | Date: |  |
| Participant’s full name (please print): |  |
|  |

Please file the original wet-ink copy in the HEAL-COVID Investigator Site File, and make two copies: one for the participant and one for the medical notes.