**Professional Legal Representative Information Sheet for HEAL-COVID**

* You have been asked to consider a research study on behalf of a patient who cannot consent for themselves. 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 the patient’s 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 think the patient would 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 the 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 approached about this study?

You have been approached about this study because you are not involved with this study and are being asked to give consent as the professional legal representative on behalf of a patient diagnosed with COVID-19 who is unable to consent for themselves

A “Professional Legal Representative” is someone who gives consent on behalf of another person to participate in research when they are unable to make their own decisions and so cannot give consent themselves.

The patient is unable to tell us if they are willing to participate in this research study and cannot give consent themselves. We have not been able to identify someone who has a close personal relationship with the patient to act as a personal legal representative. As an independent medical professional who is not involved in this study, we are asking you to consider this study on behalf of the patient and respond as you think they would respond.

If you decide to give consent for the patient to take part in this study and they later become able to make decisions for themselves again (“regain capacity”), you should let their ongoing (post-discharge) caregiver know about the patient’s involvement in the study. If they no longer want to take part, they can contact their hospital research team via the contact details on page 1 of this information sheet. They are free to withdraw without providing a reason.

Do I have to agree for the patient to take part?

No, taking part is voluntary. It is up to you to decide whether or not you want to give consent for the patient take part.

If you decide not to agree for the patient take part then they will still receive the usual treatment their hospital offers. Their doctor or nurse can provide you with more information on this.

If you decide that the patient can take part you can also choose to stop at any time without giving a reason. The patient can also choose to stop if they become able to make decisions for themselves again in future.

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

What will happen to the patient if they take part?

If you agree for the patient 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 the patient.

If the patient takes part in this study, we will collect some health data about them whilst they are in hospital. We will collect further information about their healthcare for 12 months after you agree for them to take part in the study. This information may include GP visits, referrals, hospital attendances or other healthcare they receive over their 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 the person responsible for the patient’s care with the study treatments we would like them to take before they leave hospital. We will ask that the patient takes the treatment at home, and their doctor or nurse will explain to their caregiver how to take it, how often and for how long. If they are asked to take Atorvastatin, they will be given repeat prescriptions for this by their GP or hospital, because the treatment lasts for longer than Apixaban. If the patient usually pays for their prescriptions, shortly after they leave hospital they will be sent a form or certificate that ensures they will not need to pay prescription charges for the medications needed to participate in HEAL-COVID.

Once participants in the trial are discharged, we would also like to ask some questions about how they are feeling, any long-term effects of COVID-19 that they might be experiencing, and their experience of taking part in research. The information provided 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 to improve these things.

If patients are unable to complete the questionnaires themselves, a family member, friend or caregiver can help to complete them on their behalf. Ideally, the same person would complete these each time.

Taking part in these questionnaires is optional, so you can still give permission for the patient to take part in HEAL-COVID if you feel that that the patient is unable to complete the questionnaires.

After 12 months from the day the patient enters the study, their participation will be complete and we will only contact you or them after this time if you have asked us to. In the future we might also link the data about the patient from this study with other databases or clinical trials to answer questions about COVID-19.

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 the patient is given Atorvastatin they will take this once a day for 12 months.

Apixaban is a medication commonly referred to as a “blood thinner” or anticoagulant. If the patient is given Apixaban they 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 the patient is 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 they would receive if they were not taking part in the study). This means any treatment usually offered by their hospital, as appropriate for their symptoms and/or other conditions they might have. The other groups will receive standard care plus Atorvastatin, or plus Apixaban. We use a computer programme that puts patients into groups ‘at random’. Neither you nor the patient’s doctor choose which group they 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 consent for the patient to take part in HEAL-COVID, they will receive the standard care that their hospital provides, depending on their symptoms and what their doctors or nurses think is appropriate for them.

What are the benefits and risks of taking part?

There is potential that the treatment the patient is given as part of the study may improve their symptoms and help them to recover from their 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 the patient is given Atorvastatin, some common side-effects they 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 about the patient or they are at increased risk of diabetes, please consult their doctor. Women of childbearing potential will also need to use appropriate contraception while taking Atorvastatin.

If the patient is given Apixaban, some common side-effects they might experience are:

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

If the patient is due to have surgery or dental treatment while they are taking Apixaban, their doctor or dentist should be informed.

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

What happens if I change my mind?

You can contact us at any time if you wish for the patient to stop taking part in the study, or if the patient regains capacity and wishes to stop taking part in the study themselves. They will still receive the standard care and the follow up usually offered by their hospital. With your permission, we would like to continue collecting information about the patient’s 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 that the patient 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, the patient’s doctor or nurse will tell you (or their main caregiver if this is not you) about it and discuss with you whether you want the patient to, or whether they should, continue in the study. If the study is stopped for any other reason you will be told why and continuing care will be arranged for the patient.

 What happens when the study stops?

At the end of the study the patient’s treatment will return to standard care. If they are still experiencing symptoms their healthcare team will arrange appropriate ongoing care for them.

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 and the patient will not be identified in any publication. We will keep all information from the study for 10 years.

Will the patient taking part in the study be kept confidential?

Yes. The only people that have access to the patient’s 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 the patient’s GP know that they are taking part in this research study.

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

In order to access the patient’s routine healthcare data, Liverpool Clinical Trials Centre (LCTC) will securely send their 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 their data for 12 months from the day they enter the study, but this may be extended in future to follow-up their 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 the patient’s personal details and will not be able to identify them.

Further information about how we use the patient’s 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).

The patient’s doctor will not receive any payment for including them in this study.

Information sharing for other research

If you agree for the patient to take part in this study, you will have the option to allow future research at other organisations using the 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. The patient’s 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 the patient’s information is used?

You can find out more about how we use the patient’s 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 the patient’s hospital

What if there is a problem?

Any complaint about the way you or the patient have been dealt with during the study or any possible harm the patient might suffer will be addressed.If you have a concern about any aspect of this study, you should ask to speak with one of the research team at the hospital caring for the patient, 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 the patient’s 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 the patient is harmed by taking part in this research project, and this is due to someone’s negligence, then they may have grounds for a legal action for compensation against the NHS Trust where they are being treated but they may have to pay for their legal costs. The normal National Health Service complaints procedures should be available to you and the patient.

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.

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

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 the patient has been harmed by taking part in this study, you should contact the research team at their hospital in the first instance, via the contact details on page 1 of this information sheet.

The hospital where the patient receives their treatment has a duty of care to them whether or not you agree for them to participate in the study, and the study Sponsor accepts no liability for negligence on the part of their hospital’s employees. If you have concerns about the patient’s well-being you should speak to a member of their clinical team before they leave hospital. Once home, contact their GP or call 111. Resources for support and advice following a COVID-19 illness can be found on our website ([www.heal-covid.net](http://www.heal-covid.net)).

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|  ***To be completed by the professional legal representative:***  |
| 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 my consent at any time, without giving a reason, and without the patient’s care or legal rights being affected. I understand that the patient can also withdraw at any time if they regain capacity to do so. However, the study team may need to collect some limited information for safety reasons.
 |  |
| 1. I understand that relevant sections of the patient’s 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 the patient’s records and data.
 |  |
| 1. I agree for the patient’s 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 the patient’s long term health status.
 |  |
| 1. I agree for the patient’s 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 the patient’s data, including their identifiers and my name as entered below, will be kept by LCTC, the University of Liverpool and at their 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 the patient’s GP to be informed of their participation in this study.
2. I understand that my contact details may be used to get in touch with me about the participant’s involvement, if necessary.
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| 1. **I agree to the above statements and give consent for the patient to take part in the study.**
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| ***To be completed by the independent professional legal representative:*** |  |

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| --- | --- |
| The statements below are optional (the patient can still take part in the study even if you do not wish to agree to these): |  |
| 1. I agree to the patient being contacted about completing follow-up questionnaires regarding their health and wellbeing after their hospital admission.

Please provide the contact details for the patient: |  |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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
 |  |
| 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 the patient’s and my confidentiality is maintained. I understand that future research may involve private companies as well as universities or NHS organisations.
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| --- | --- |
| **Patient** name:(please print) |  |
| **Your** role *(e.g. independent doctor):* |  |
| **Your** full name: |  |
| **Your** signature: |  | Date: |  |
| **Your** contact details *(professional legal representative):* |
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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Telephone number:  |   |  |  |  |  |  |  |  |  |  |  |  | Same as above:  |
| Email address: |  | Same as above:  |
| Postal address: |  |

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

Please file the original wet-ink copy in the HEAL-COVID Investigator Site File, and make three copies: one for the legal representative, one for the participant or their caregiver (if not the legal representative) and one for the medical notes.