

**Participant Information Sheet – HRA (PIS-HRA)**

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| **Study Title**: mySmartCOPD - A randomised controlled trial to explore the safety and clinical efficacy of a treatment re-alignment algorithm using data from a digital self-management application for patients with COPD |
| **Researcher**: Prof Tom Wilkinson |
| **ERGO number: 81603****IRAS number: 355764** |
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You are being invited to take part in the above research study.

To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve.

Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research.

You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

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| **What is the research about?** |

We would like to invite you to take part in the mySmartCOPD research trial run by researchers at the University of Southampton and my mhealth.

Please read the information below to understand why the research is being done and what it will involve. If anything is not clear or you would like more information before you decide to take part in this research, you can contact the trial team on: 02380599130

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| **Why are we doing the mySmartCOPD trial?** |
| We are studying a new digital technology called an algorithm to see whether it can help COPD patients get onto the right medication for their symptoms. Receiving the right medication can help patients control their symptoms, lower the risk of COPD flare-ups (exacerbations) and avoid side effects from over-medication.The University of Southampton is sponsoring this study and it has been reviewed an approved by a NHS research ethics committee and the University of Southampton research ethics committee.  |
| **Why have I been asked to participate?** |

You have been approached to participate because this trial is for COPD patients like you who are using the myCOPD app. If you agree to take part, the information collected on the myCOPD app will be used by the trial team to ensure that the trial is suitable for you.

You do not have to take part in the trial. It is entirely up to you to decide whether or not to take part.

You have been approached to participate in the trial because you are a user of the myCOPD app.

To be eligible for the trial, you must:

1. Be an adult over 18 years of age and able to give informed consent

2. Have a clinical diagnosis of chronic obstructive pulmonary disease (COPD)

3. Be a registered and activated user of the myCOPD app

4. Have one or more COPD Assessment Test (CAT) questionnaire completed on the myCOPD app in the last 12 months

5. Have one or more exacerbation form completed on the myCOPD app in the last 12 months

6. Have one or more COPD medication diary completed on the myCOPD app in the last 12 months

7. Be classified appropriately into one of 3 CAT groups based on your reporting into the myCOPD app:

(A) Few symptoms,

(B), Many symptoms or

(C) Exacerbators

In addition to the above, you will be ineligible for the trial if:

8. You cannot read or write in English as required to understand the trial materials and provide the trial data.

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| **More about the Algorithm** |
| The algorithm has been built by my mhealth Ltd and tested by the University of Southampton. It is designed to use your reported symptoms, COPD Assessment Test (CAT) results, medication entries and prescriptions, and flare-ups (exacerbations) to calculate whether you are taking the right medication. The algorithm will compare your data to the standard guidelines for COPD medication. If the algorithm calculates that you may not on the best medication, you will receive a Medication Alert message asking you to book a COPD medication review with your usual healthcare team (such as nurse or GP). There is also a message for your healthcare team explaining the algorithm information so they can discuss with you whether your regular COPD medication should be changed. **It is important that you do NOT stop taking your usual medication, even if you receive a message asking you to have a review.**The algorithm is only in the app called MMH-LAB1, not the myCOPD app. The MMH-LAB1 app is only for the mySmartCOPD trial and is not available to anyone not taking part in this trial. You should continue to use the myCOPD app as usual to self-manage your COPD.In the trial app, MMH-LAB1, there are two groups: MMH-LAB\_Test\_1 has the algorithm; and MMH-LAB\_Control\_1 does not have the algorithm.  |
| **If I join the** **trial, will I have access to the algorithm?** |
| This trial is a ‘randomised trial’. This means we put people into groups randomly, with one group using the algorithm and the other group without the algorithm. The results are then compared to see if one is better. If you join the trial, you will randomly be put into one of these two groups for the duration of the trial.  |

9. Have not opted in to the research agreement via myCOPD.

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| **What will happen to me if I take part?** |
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You will be asked to use the MMH-LAB1 app for the next 6 months, but please do not stop using myCOPD as usual. This is because the MMH-LAB1 app does not contain all the information to help you to stay well with your COPD. You will need to Activate the MMH-LAB1 app exactly the same way you did for myCOPD. It is a separate app so you can download it from Google Play or App Store or access it via your usual web browser.

In the MMH-LAB1 app we ask that you complete some questionnaires and if you have the algorithm, contact your healthcare team if you receive a Medication Alert message.

Joining the trial

1. **Consent** - You will be asked to provide your consent to take part in the research being conducted. This will be done via the University of Southampton electronic consent system. We will also collect your month and year of birth and ethnicity to help us understand the characteristics of the people taking part in the trial.
2. **Eligibility** - Once your consent is received, a trial clinician will double check your data from the myCOPD app to make sure the trial is suitable for you. Some of the information you have entered into the myCOPD app will be copied to the MMH-LAB1 app.
3. **Randomisation** - If you can take part, you will then be assigned (or “randomised”) to either receive the MMHLAB-Test\_1 system within the MMHLAB1 app; or be in the control group MMHLAB-Control\_1. The MMHLAB1 app will tell you which group you are in and provide further instructions to help you through the trial.

During the trial

1. **COPD Symptom Scores** – You will be asked to enter your COPD symptom scores daily.
2. **COPD Medication** – You will be asked to update your regular COPD medication if the medication changes.
3. **Questionnaires** – You will be asked to complete:
	* Short in-app trial questionnaires to see if there are any changes in your health since the start of the trial. These include the COPD Assessment Test (CAT test) (monthly), a quality-of-life questionnaire called EQ5D-5L (monthly), a smoking questionnaire, and an exacerbation (flare-up) questionnaire at the beginning of the trial.
	* An additional University of Southampton questionnaire to ask if you have seen your healthcare professional about your COPD; visited hospital; or feel that taking part in the trial has made you unwell.
4. Prescription Assessment – if you are randomised to receive the algorithm, we will ask you to:
* Read the Medication Alert message if you receive one in the app. It will tell you if your medication is out of guidance. If you receive a Medication Alert message, you should:
	+ Contact your usual doctor or nurse and if possible show them the message. There is a message there for them too
	+ Contact the Patient Advocate if you need support or are worried about the message
	+ Keep taking your usual medication even if the message says you might not be on the best medication for your symptoms
	+ Once you have spoken, or seen your usual doctor or nurse, please update the app so that we know you have had your medicine checked
	+ If your doctor decides to change your medication, please make sure you enter the new medication in the MMH-LAB1 app and also in the myCOPD app

End of trial

After 6 months on the trial, you will be asked to complete the final trial questionnaires and then your participation on the trial will be completed and you will be returned to the myCOPD app. You will no longer have access to the MMH-LAB1 app.

**Optional** – mySmartCOPD Trial Discussions and the EQUATE trial

If you optionally consent, we would like to contact you between 3 to 12 months after starting the trial to talk about your experience using the system.

We are also working with researchers from the **University of Southampton EQUATE trial**, who are investigating how technology can help or make it more difficult to take part in health research. You can optionally consent for us to securely share your contact details and some information about yourself (age, gender, ethnicity) with the EQUATE team, who will then contact you and provide more details about the EQUATE trial.

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| **Help with the Algorithm - Patient Advocates** |
| If you are assigned to the algorithm group and require help with understanding the medication message and what to do next, a team of non-medical advisers (called ’Patient Advocates’) working on the trial can support you. This is optional and it is completely up to you whether you want them to help.These advisers are employed by my mhealth to help patients with new healthcare services and technologies. You can learn more about the patient advocates on page 4 of this information sheet. |

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| **Are there any benefits in my taking part?** |
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The data you provide as part of the trial will help us understand the best ways of getting people with COPD onto the treatment that is right for them. We hope that this will improve the day-to-day symptoms of COPD patients and reduce the risk of hospitalisation due to COPD

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| **What are the possible disadvantages and risks of taking part?** |
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The MMH-LAB1 algorithm has been fully tested prior to the trial and will recommend the guideline-compliant medication for your symptoms. However, all medication decisions will be made between you and your healthcare team. The MMH-LAB1 app cannot make any changes to your medication on its own.

If you receive a message that tells you to have a review of your medication, it is very important that you do NOT stop taking your usual medication. This is only a decision for your healthcare team to make.

All data will kept on University of Southampton or my mhealth servers. Data will be transferred between University of Southampton and my mhealth via an encrypted email delivery system called SafeSend.

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| **What data will be collected?** |

The MMH-LAB1 algorithm has been fully tested prior to the trial and will recommend the guideline-compliant medication for your symptoms. However, all medication decisions will be made between you and your healthcare team. The MMH-LAB1 app cannot make any changes to your medication on its own.

If you receive a message that tells you to have a review of your medication, it is very important that you do NOT stop taking your usual medication. This is only a decision for your healthcare team to make.

For us to conduct the trial, we will need to collect certain information about you, such as:

* Your name
* Your contact details (telephone number, email address)
* Your demographics (age, gender, ethnicity)
* Information about your GP practice

We will use some of the data you have already entered into the myCOPD app.

The MMH-LAB1 app contains trial questionnaires (COPD Assessment test, EQ5D-5L quality of life, flare-up (exacerbation) and smoking questionnaires) which we will ask you to complete during the trial.

We will also ask you to complete other questionnaires about your health and what healthcare you have used in the preceding month, e.g. visits to the GP, hospital etc.

We will let your GP know that you are taking part in this trial. Other than that, your participation and the information we collect about you during the course of the research will be kept strictly confidential.

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| **Will my participation be confidential?** |

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton and my mhealth, who run the MMH-LAB1 app may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

All data used for analysis will be de-identified. This means that any data that could identify you is replaced with a code or number. No identifiable data such as your name and contact information will be shared outside of those staff who require it to conduct the trial unless you provide your explicit consent for us to do so. De-identified research data will be retained for 20 years in keeping with regulatory requirements.

Any identifiable data collected on the University of Southampton electronic consent system will be stored securely on the University of Southampton servers and will not be stored with any health data received from the myCOPD app or in the trial questionnaires.

Staff from Southampton Clinical Trials Unit and patient advocates working on the trial will see information such as your name, contact details and outcomes of medication reviews, and may contact you to help with trial activities. You do not need to accept this help if you do not want to.

All data will kept on University of Southampton or my mhealth servers. Data will be transferred between University of Southampton and my mhealth via an encrypted email delivery system called SafeSend.

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| **Do I have to take part?** |
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No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

You will receive a notification inviting you to register your interest in participating in the trial.

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| **What happens if I change my mind?** |
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You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights *(or routine care if a patient)* being affected.

You have the right to change your mind and withdraw at any time without giving a reason and without your use of the myCOPD app being affected. To withdraw, contact the trial team on: 02380599130.

If you withdraw from the trial, we will keep the research data we have already obtained for the purposes of achieving the objectives of the trial only, unless you state otherwise. We will also keep a copy of your consent form to confirm your initial consent to take part in the trial. Your withdrawal from the trial will not impact on any other participant.

If you withdraw from the mySmartCOPD trial, you will no longer have access to the MMH-LAB1 app. This means that if you are in the group that has the algorithm, you will no longer have access to the algorithmFor further information on how your data will be used and/or can be removed, please see ‘What are your choices about how your information is used’ section in the Privacy statement.

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| **What will happen to the results of the research?** |
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Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The results will be analysed and presented at national and international meetings; and will also be published in a medical journal. A simple summary of the findings will be sent to all trial participants.

The information collected about you may be used to support other ethically-approved research in the future and may be shared in a de-identified form with other researchers.

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| **Where can I get more information?** |
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If you have questions about any aspect of the Patient Information Sheet, please contact the trial team on mysmartcopd@soton.ac.uk or 02380599130

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| **Who has reviewed this trial?** |
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All research is looked at by a Research Ethics Committee, to protect your interests. This trial has been reviewed and given a favourable opinion by REC West Midlands - South Birmingham Research Ethics Committee, REC ID: 25/WM/0050. This trial has also been reviewed bythe MHRA (Medicines & Healthcare products Regulatory Agency) – this is the agency in the UK that regulates medicines and medical devices.

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| **What happens if there is a problem?** |
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This trial has been reviewed and given a favourable opinion by REC South Birmingham, REC ID: 25/WM/0050.

Furthermore, this trial has received Professional Indemnity and Clinical Trials Insurance from the University of Southampton, should something go wrong.

If you have a concern about this trial, please contact the researchers via telephone 02380599130 or email (mysmartcopd@soton.ac.uk). If you have a complaint, please contact the University of Southampton Research Governance Office (023 8059 5058, rgoinfo@soton.ac.uk). If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay legal costs.

* If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.
* If you remain unhappy or have a complaint about any aspect of this study, please contact the Head of Research Ethics and Governance (023 8059 5058, rgoinfo@soton.ac.uk), University of Southampton.

**Thank you for taking the time to read this Patient Information Sheet**

If you have questions about any aspect of the Patient Information Sheet, please contact the trial team on: 02380599130

**Additional Information**

**Description of Patient Advocate role in the mySmartCOPD Trial**

**Who are patient advocates?**

Patient advocates are employees of my mhealth Ltd, which is the company behind the myCOPD and MMH-LAB1 apps. The Patient Advocates will not be able to give you any medical advice. For this trial, patient advocates will only support you if you are assigned to use the algorithm.

**How can patient advocates help?**

Patient advocates are there to support you with the trial, but only if you decide that you would like their support. In the trial, if you are assigned to use the algorithm, you may receive messages from the app telling you the outcome of the medication review that the algorithm performs for you. The outcome of this will be for you book an appointment with a healthcare team to discuss your medication. The patient advocate can help you to understand this message and what you need to do once you receive it.

**What will the patient advocates know about me?**

Patient advocates will have access to:

1. Patients’ names
2. Patients’ email address and phone number
3. Patients’ GOLD grouping (this explains how severe patients’ COPD symptoms are for the medication review)
4. The outcomes of the medication reviews that the app has performed for patients
5. Whether patients have already discussed the medication review with their healthcare team and, if so, when this was.

**What contact will I have with the patient advocate?**

The patient advocates are able to support you with understanding the algorithm message but i**t is up to you if you would like this support, as we understand that you may prefer to do this yourself.** **You may choose to not have their involvement.**

If any of the above information isn’t clear or you have any questions, please contact the trial team for more information on 02380599130

# **Data Protection Privacy Notice**

**How will we use information about you?**

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, we will need to use information from you and from what you input onto the MMH-LAB1 application and from data provided by my mhealth relevant to this trial.

This information will include your initials, name, year and month of birth, and email address***.***  People will use this information to do the research or to check your records to make sure that the research is being done properly.

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.

The University of Southampton is the sponsor of this research and is responsible for looking after your information.

We will keep all information about you safe and secure by:

We will generate a trial ID so that your data will be connected to that

We will keep your data on servers designed to store data and only relevant personnel from the University will have access. Only relevant personnel from my mhealth will have access to data on the MMHLAB1 app

We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the [Information Commissioner's Office (ICO) website](https://ico.org.uk/for-organisations/report-a-breach)

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 20 years*.* The study data will then be fully anonymized and securely archived or destroyed.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

* Human Regulatory Authority (HRA) protects and promotes the interests of patients and the public in health and social care research, more information can be found at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* the leaflet available from [[**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch)]
* by sending an email to University’s Data Protection Officer (data.protection@soton.ac.uk).
* by asking one of the research team or from our [general privacy policy](https://www.southampton.ac.uk/about/governance/policies/privacy-policy.page).
* by sending an email to mysmartcopd@soton.ac.uk, or by ringing us on 02380599130.

**my mHealth Privacy Information**

my mHealth who have developed the MMH-LAB1 app also have responsibilities with the University of Southampton to keep your information safe. Their privacy policy can be found here: <https://mymhealth.com/privacy>

This policy outlines that information from the MMHLAB1 app and will only be available under specific research-related and lawful purposes. This includes only sharing the minimal amount of information necessary for research purposes and my mhealth will not sell or share any personal or sensitive personal to third parties, including for marketing purposes.

For the purposes of data protection law, the University of Southampton and my mhealth Ltd are joint ‘Data Controllers’ for this trial, which means that they are responsible for looking after your information and using it properly. The University of Southampton and my mhealth will keep identifiable information about you for 20 years after the trial has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research trial objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage which is located on (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

**Thank you.**

Thank you for taking the time to read the information sheet and considering taking part in the research.