sth.asthmabreathmasterylhs@nhs.net
Local Investigator Contact:
Sarah Cameron – 07792 40334

Sheffield Teaching Hospitals NHS Foundation Trust

Asthma & Breath Mastery
Learning Health System

Asthma & Breath Mastery: Developing a Learning Health System (LHS) and Trials within Cohorts (TwiCs) platform

Short Title: Asthma & Breath Mastery LHS

Participant Information Sheet

Invitation

We would like to invite you to take part in a long-term project in asthma care. Before you decide, we would like you to understand why the research is being done and what it will involve. Please read the following information sheet carefully before you decide whether you wish to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Why have I been invited?

You have been invited because you are aged 16 years or over and have been referred to the severe asthma service or respiratory medicine department at Sheffield Teaching Hospitals NHS Foundation Trust for asthma or persistent (chronic) breathlessness.

What is the purpose of the study?

People referred to a hospital asthma service have persistent breathlessness despite treatment in primary care. Many people find that being short of breath is frightening and has a negative impact on their quality of life. We are running a research study ('Asthma & Breath Mastery: Developing a Learning Health System (LHS) and Trials within Cohorts (TwiCs) platform') to understand the causes of this breathlessness and how best to help people living with breathlessness to master it.

Typically, a healthcare professional (e.g. doctor) will have attributed the breathlessness to a medical condition called asthma. People might be given asthma drugs (treatments) to help improve their symptoms. However, for some people, these treatments do not make their symptoms of breathlessness any better. Some people also have breathlessness that is worse than expected given their clinical markers of asthma (e.g. blood results). This suggests there may be other factors contributing to their breathlessness.

One reason why people might have breathlessness that does not improve with asthma treatment is because the breathlessness is not entirely caused by asthma. Causes of breathlessness other than asthma may include breathing pattern changes, increased alarm symptoms associated with breath awareness, deconditioning, or other health conditions.

We are developing a learning health system to collect data to measure success of the Sheffield adult severe asthma service in helping people to master their breathlessness. A **learning health system** is like a smart hospital or healthcare system that learns and improves over time. It collects information from patients (like test results, treatments, and outcomes), learns what works best, and then uses that knowledge to help other patients. A learning health system:

- **observes** what happens when patients are treated (data in, knowledge out). Every patient's experience teaches the system something new.
- **learns** from that data and adapts quickly - what treatments help most, etc.
- **improves** how healthcare workers (e.g. doctors) care for future patients, using those lessons.

We will use patient medical records to look at things like asthma treatments prescribed and details of symptoms of breathlessness. As part of standard clinical care, healthcare workers (e.g. doctors) or members of the study team may perform a number of different tests to help understand your breathlessness - the results of these will also be collected. Some of these will be research-specific activities. We will also ask people to complete questionnaires about their asthma/breathlessness, and physical and mental health, at different time points throughout the study. We want to develop and ultimately test an approach, using the learning health system, that helps people to master their breathlessness, whatever its cause.

People with asthma or persistent (chronic) breathlessness within the asthma service will be given the option to contribute their health data to future research studies. This could result in being offered new treatments or interventions. The data may be used as part of normal care and lead to changes in how the asthma team supports people living with breathlessness.

What would I be asked to do if I took part?

1.	Give consent/ agree to take part in the study.
2.	Agree that we can collect data relevant to the study from your medical records.
3.	Provide information about your asthma/breathlessness and physical and mental health by completing some questionnaires.
4.	Complete some of the questionnaires again at different timepoints throughout the study. Depending on the questionnaire, some will be completed once or as a one-off; some may be completed once a year; and some may be completed at each clinic appointment or every quarter (three months).
5.	You will be asked if we can contact you for future research, and if we can share your data with other approved projects, to help get the best use out of the data we collect. This could result in being offered new treatments or interventions. This part is optional and is explained in more detail below.

Further information

If you decide to take part in this research study, first we will check with you that you have read this information sheet and the consent form and whether you have any questions. Once you have had all your questions answered satisfactorily, we will then ask you to formally agree or consent to take part in the study. You can choose how you would like to give your consent:

- via a web link or email
- a paper consent form that you can hand to a researcher or member of the asthma clinical team if meeting in person
- verbal consent where a researcher will read out each statement from the consent form and ask you to verbally agree 'yes' or disagree 'no' with each statement.

When you give consent, you will be asked to contribute your data to the Asthma & Breath Mastery Learning Health System. We would like to access your medical records over the course of the study to note down information such as (not limited to) your blood results, lung function and results of other tests, hospital admissions, and number of steroid courses prescribed. To do this, we may need to access information held by NHS England and/or your local Integrated Care Board and to link this to the information we have already

collected from you. Access to this information will only be carried out for the study, and there will be no further access once the study ends.

After you have given consent, we will ask you to provide some more information on questionnaires about your asthma/breathlessness, as well as your physical and mental health. These questionnaires can be completed online, either at home or when you attend the hospital for a clinic appointment with your local asthma team. If you would like support to complete the questionnaires, then a member of the asthma clinical team or an asthma researcher can help you. If you prefer to complete the questionnaires online, a link will be sent to your email address. The questionnaires could also be completed on paper if preferred. We will then ask you to complete some of the questionnaires again at different time points. Depending on the questionnaire, some will be completed once or as a one-off; some may be completed once a year; and some may be completed at each clinic appointment or every quarter (three months). We will also ask you to complete something called a Breath Hold check, to see how long you can hold your breath for. During this, you will be asked to breathe in and hold your breath for as long as is reasonably comfortable. This only takes a few minutes and can be completed over the phone or face-to-face. You will be asked to complete this at the start of the study, and you may be asked to do this again at future timepoints.

As part of standard clinical care, your asthma clinical team or members of the study team may perform a number of different tests to help understand your breathlessness - the results of these will also be collected.

Your asthma clinical team may use your data as part of routine care, for example using the information you provide about your asthma/breathlessness and other physical health complaints in clinics or during inpatient stays, but the answers you give to some questionnaires will be used for the purposes of research only. Members of the clinical team in Sheffield will not contact you to discuss them once you have submitted your answers, so please contact your asthma clinical team in the usual way if you have any concerns about your asthma/breathlessness. Your asthma clinical team will *not* have access to the measures you complete about your mental health. Throughout the questionnaires, there are links to resources/contact details for how you can get any well-being support should you need it.

Although physical and mental health are closely linked, information about both is not often collected together. To address this, our study includes the Core Mental Health Dataset (CMHDS), a tool created between 2020 and 2023 with funding from the National

Institute for Health and Social Care Research (NIHR). It helps us collect mental health information in studies about physical health.

The CMHDS is now being used in a project called DATAMIND - a research hub for mental health funded by the Medical Research Council and Health Data Research UK. DATAMIND will safely store mental health data for use by approved researchers.

We are working with DATAMIND to learn how mental health information can help improve healthcare. As part of this, we will ask for your permission to share your data with DATAMIND. Your name and contact details will be removed. Instead, your data will be **pseudonymised**, meaning it will be given a special code so no-one knows it is yours.

If you indicated on your consent form that you would like to participate in future research, then you may be contacted and be asked whether you would like a new treatment, intervention, or to take part in some additional activity as part of a future approved research study. You can say no if you are not interested, with no impact on your usual treatment or care, chances of being selected for future studies, or involvement in the main study ('Asthma & Breath Mastery: Developing a Learning Health System (LHS) and Trials within Cohorts (TwiCs) platform').

Consent for future research ('Trials within Cohorts')

This research study is set up as a 'Trials within Cohorts' (TwiCs) platform. This means that we can efficiently use the data within this study to support additional studies. These studies may involve you being invited to receive new treatments or interventions. Taking part in the 'Trials within Cohorts' part of this study is optional.

- If you agree to take part in this study, you will have the option to provide 'broad consent' for your pseudonymised data to be used for future research (consent statement 12). This may include being used as a 'control' in future studies, where taking part in the new study does not involve any change to your usual treatment, care, or data collection within the Asthma & Breath Mastery Learning Health System. In this instance, you would not be approached for further consent, and you would not be informed of your participation in the control group. This is an important part of our project which will make asthma research easier, less expensive and ensure that research is less disruptive to patients.
- You will also have the option to agree to be contacted about future research studies (consent statement 13). This includes being invited to receive a new treatment or intervention, or to take part in some additional activity as part of a

future approved research study. Consent to the new study must be provided in order to receive the new intervention, or to take part in the additional research activity. You can decide against participating in the new study without any consequences.

Your asthma clinical team may be aware of your participation in the Asthma & Breath Mastery Learning Health System, however, they may not be aware of your participation in future research.

Time commitment/ how long will I be in the study for?

The 'Asthma & Breath Mastery: Developing a Learning Health System (LHS) and Trials within Cohorts (TwiCs) platform' study is an ongoing study planned to be conducted over five years (July 2025 – June 2030).

If you agree to take part in the study, you will be followed up for the duration of the study. This could include being followed up even if you are discharged from the severe asthma service. In this instance, you would still remain in the Asthma & Breath Mastery Learning Health System unless you ask to withdraw from the study.

Questionnaires will not take more than 30-45 minutes in total to complete. Some questionnaires will be completed as a one-off after you have consented to the study. This means that you will likely spend longer completing the questionnaires at the start of the study (but no longer than 30-45 minutes). After this, questionnaires should not take more than 20-30 minutes to complete. You will also have the option to skip questionnaires if you do not wish to complete them.

Do I have to take part?

No, taking part is voluntary. It is up to you to decide to join the project or not.

If you agree to take part, we will follow the process outlined above. You will be asked to sign a consent form or provide verbal consent. Participants will be provided with a copy of their signed consent form.

If you do not wish to take part, you will not be asked to do anything else. This will not affect the quality of care you receive from your hospital asthma service. The asthma team may ask you again whether you'd like to take part again at a later date.

What are the possible benefits of taking part?

Participating in research can be rewarding, and you will be contributing to the development of new knowledge which could benefit other people in the future.

Taking part in this study may provide data which leads to changes and improvements in the care provided by your hospital asthma service.

Participants who are selected to take part in new studies may benefit from the treatment or intervention offered.

What are the possible disadvantages and risks of taking part?

The main disadvantage would be giving up your time to complete the study questionnaires.

In the mental health questionnaires, there are questions about sensitive topics that some people may find offensive or distressing. Further information can be found on the 'Help and Advice' tab within the questionnaire link. You will have the option to skip any questionnaires that you do not feel comfortable completing.

You will be asked whether you are happy to do a Breath Hold check as part of the study. Holding your breath may feel uncomfortable (which is normal), and you will be advised of this before completing the Breath Hold check. You will be advised that if you start to feel *very* uncomfortable during the check, to stop holding your breath and to let the researcher/ healthcare professional know. We will also ask that you are sitting comfortably in an upright position beforehand. Before you do a Breath Hold check, we will check whether you have had any eye surgery within the last 8 weeks or have any eye problems (e.g. a detached retina) which would mean that we would not complete the Breath Hold check at that timepoint.

What to do if you need support with your wellbeing?

Throughout the mental health questionnaires, there are links to resources/contact details for how you can get any well-being support you need. In addition to this:

- You can get in touch with the asthma clinical team as you usually would, either at your next visit or by phone.
- If you feel you are in crisis and need immediate help, you can contact Samaritans (call free 116 123) or Shout (text SHOUT to 85258) 24 hours a day, 7 days a week.

- Alternatively, you can contact Sheffield Health and Social Care NHS Foundation Trust on 0808 196 8281 or, in an emergency, call 999 or go to A&E. If you are not in Sheffield, then please contact your local mental health crisis team.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time, without giving a reason. Participants can withdraw their consent to any part of the study mentioned above. Any data that has been anonymised at the point of withdrawal will be kept for analysis, but no further data will be collected.

What will happen to the results of the research study?

This project will increase the data available at your asthma appointments and has the potential to improve care locally and nationally. The results of the study will be published in research journal articles or be presented at conferences. You will not be identifiable in any results/publications. The results of studies supported through the Asthma & Breath Mastery Learning Health System will be presented separately elsewhere.

Who is conducting the research?

The project is being carried out by a multi-institution team of clinicians and researchers from Sheffield Teaching Hospitals NHS Foundation Trust and the University of Manchester. Sheffield Teaching Hospitals NHS Trust is the Sponsor and Data Controller of this research and manages the project on a day-to-day basis. The University of Manchester hosts the secure web-based database system (REDCap) used in the study and will be involved in analysing the data.

How is the study funded and who has reviewed the study?

The 'Asthma & Breath Mastery: Developing a Learning Health System (LHS) and Trials within Cohorts (TwiCs) platform' study is supported by funding from multiple sources, including research funding from Sheffield Teaching Hospitals NHS Foundation Trust, and DATAMIND, The Hub for Mental Health Informatics Research Development, which is funded by The Medical Research Council (MRC) and Health Data Research (HDR) UK. This study has been reviewed and approved by the North East - Newcastle & North Tyneside 1 Research Ethics Committee (Reference number: 25/NE/0130).

How will we use information about you?

We will need to use information from you, from your medical records, from clinician assessments, and from external sources (e.g. UK Severe Asthma Registry; NHS England and/or your local Integrated Care Board (ICB)) for this research project.

This information will include your:

- Personal details like your name, NHS number and contact details (e.g. home address, email address, contact number(s));
- Demographic information like your age, date of birth (DOB), sex, ethnicity, and education;
- Record of consent (e.g. online, paper, verbal);
- Medical history and information (e.g. height, weight, lung function, steroids prescribed, GP attendances, hospital admissions, other health conditions etc.);
- Your responses to the study questionnaires.

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.

Sheffield Teaching Hospitals NHS Trust is the Sponsor of this research.

Sheffield Teaching Hospitals NHS Trust is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Universities and other academic institutions
- Healthcare organisations
- Research charities
- Linked research projects, e.g. DATAMIND

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

- ensuring that the study is undertaken according to Good Clinical Practice (GCP) and information governance (IG) guidelines and standard operating procedures;
- collecting and retaining data in accordance with the Data Protection Act and General Data Protection Regulations;

- using a secure web-based database system hosted on University of Manchester servers (REDCap) to enter contact details and study data;
- restricting access to the REDCap database to members of the project or clinical team, using an in-built secure system to grant access and data management privileges that will be authorised by the project Chief Investigator (CI), or as otherwise stated on the delegation log;
- ensuring that any data transferred from Sheffield Teaching Hospitals NHS Trust to the University of Manchester for analysis is pseudonymised and is managed via REDCap, or an alternative safe data transfer system approved by the Sponsor;
- ensuring that any data from the CMHDS measures shared with DATAMIND is pseudonymised and is managed via REDCap, or an alternative safe data transfer system approved by the Sponsor;
- sharing data with the UK Severe Asthma Registry for only those who have consented to the UK Severe Asthma Registry.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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 five years. The study data will then be fully anonymised 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 access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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 agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Please see the 'Consent for future research ('Trials within Cohorts')' section above for more information.

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

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

- our leaflet - How is your information handled in research - Sheffield Clinical Research
- by asking one of the research team
- by sending an email to sarah.cameron7@nhs.net
- or via *www.hra.nhs.uk/patientdataandresearch*

How will my data be kept confidential?

In this research study, we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

What if I wish to complain about the way in which this study has been conducted?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during this study, the normal National Health Service (NHS) complaints mechanisms are available to you. You are not compromised in any way because you have taken part in a research study.

If you have any complaints about anything you experience as a result of being in the study that cannot be addressed by the study team, or if you have any queries that you would like to be dealt with independently, please contact the Patient Advice and Liaison Service (PALS). Your complaint will be treated confidentially and will not affect your current or future care and treatment in any way.

PALS can be contacted Monday to Friday 9.30am and 4pm (excluding Bank Holidays). The team can be contacted in the following ways:

- Telephone on 0114 271 2400
- Via email on sth.pals@nhs.net
- By writing to us at the PALS Office, B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF

Who do I contact about the study?

Asthma & Breath Mastery Study Team	
sth.asthmabreathmasterylhs@nhs.net	
Asthma Learning Health System Researcher	
Sarah Cameron	sarah.cameron7@nhs.net
Study Programme Manager	
Dr Sophie Dawson	sophie.dawson20@nhs.net

Thank you for taking the time to read this information sheet.