



# Participant Information Sheet

## Asthma Research Study: IMP<sup>2</sup>ART-E

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

### What is the purpose of the study?

Looking after yourself helps people with asthma feel better every day, miss less school or work, and avoid asthma attacks. Having a plan that guides you if you have symptoms, and talking to a doctor or nurse, is part of looking after yourself. But not many people have or use these plans.

The IMP<sup>2</sup>ART study has designed a new way to help practices support asthma patients currently being tested in 144 practices in England and Scotland. Our trial is testing if IMP<sup>2</sup>ART works overall, but will not tell us if it helps all groups of people equally. We want to make sure all people are getting the same benefit by, for example, giving extra support to practices that need it.

In this study, IMP<sup>2</sup>ART-E, we want to understand how people manage their asthma day-to-day, the factors that influence asthma and asthma management, and if the way people manage their asthma varies between groups.

We are talking to people living with asthma and professionals who work in asthma care. We hope this research will help us to better understand how we can support people to manage their asthma and support health professionals in delivering high-quality care.

### Can I take part?

We would like to talk with people living with asthma. You can take part if you are:

- Live in the UK
- Aged 18 years and over
- Have an active asthma diagnosis
- Do **not** have another respiratory diagnosis (for example asthma and COPD)
- Are able to consent to take part.

### Do I have to take part?



No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

## What will happen if I take part?

We want to hear from people living with asthma about their experiences. We are asking you to join an interview. It will be a one-off informal chat with a researcher about your thoughts and experiences of asthma and asthma management. You do not have to answer any questions that you do not want to. With your permission we will record the interview with an encrypted digital recorder.

We will also send you a short questionnaire before the interview to learn a few a little about you before the interview. These questions are optional. The questions will help us to understand a little about you (for example, your age and gender) and your experience of asthma. The questions also make sure our work is inclusive and help make sure we speak with a range of different people. You can fill in the questionnaire on your own before the interview or the researcher will go through the questions with you at the start of the interview.

The interview will be about one hour long and will be at a time that is good for you. We can talk online in a video or audio call, on the phone, or in person. The location for in person interviews will be agreed with you in advance. You will not be expected to travel to Edinburgh. The researcher will travel to you.

Interviews will typically be just between you and the researcher. You can choose to have someone you trust, such as a family or friend, join the interview. If you would prefer to speak as part of a group you may be able to join an interview with a small group of people who are also living with asthma.

With your permission we will record the interview with an encrypted digital recorder and have the interview transcribed by an external professional transcriber. Professional transcribers and translators will have a confidentially agreement in place with the research team at the University of Edinburgh before any data is shared with them.

Before starting the interview, the researcher will go through this information with you and answer any questions you have. They will then ask for your consent to include you in the study and use the information you provide in the research. A copy of the consent form is given at the end of this information sheet.

You can sign the consent form and return a copy to the researcher by email, post or in person. You can also give verbal consent at the start of the interview. The researcher will read through the consent form with you and ask you to give verbal consent to each point if



you agree with it. The researcher will record this verbal consent using an encrypted digital recorder.

We will reimburse you for reasonable costs associated with you taking part. This might include travel costs to attend an in person interview, costs associated with arranging cover for caring responsibilities whilst taking part. This will be discussed and agreed with the researcher before your interview. Where possible we will arrange and pay for travel upfront (for example, buying a bus or train ticket for you).

### What are the possible benefits of taking part?

There are no direct benefits to you taking part in this study, but you might find the opportunity to share your experiences enjoyable, and the results from this study might help to improve the healthcare of patients in the future.

### What are the possible disadvantages of taking part?

The risks of joining this study are very small. You might find that discussing some topics, such as health, make you feel upset or worried. You do not have to talk about anything you don't want to, and you can pause or stop the interview at any time. You can also choose to have someone you trust, such as a family or friend, join the interview to support you.

The researchers carry out interviews have had a Disclosure Scotland checks. If you would feel more comfortable you can choose to have someone you trust come along to the interview. We will take steps to reduce the risk of someone identifying you as a participant in this study by removing information that could identify you.

### What if there are any problems?

If you have a concern about any aspect of this study please contact Hilary Pinnock ([Hilary.Pinnock@ed.ac.uk](mailto:Hilary.Pinnock@ed.ac.uk)) who will do their best to answer your questions.

In the unlikely event that something goes wrong, and you are harmed during the research, then you may have grounds for a legal action for compensation against The University of Edinburgh, but you may have to pay your legal costs.

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

You are free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

You can stop an interview at any point during the interview session. You can also withdraw your data at any point from the point it is recorded up until the point where we have published the data. To withdraw your data please contact the research team by email on [IMP2ART@ed.ac.uk](mailto:IMP2ART@ed.ac.uk), by phone on 07391860644, or by writing to IMP2ART-E, Centre for



Population Health Sciences, Usher Institute, Usher Building, The University of Edinburgh, 5-7 Little France Road, Edinburgh BioQuarter – Gate 3, EDINBURGH, EH16 4UX.

## What happens when the study is finished?

The information you provide will be stored safely at the University of Edinburgh on the University of Edinburgh's DataStore account (a network file storage service located in the UK). Only the IMP<sup>2</sup>ART and IMP<sup>2</sup>ART-E research team will be able to see it.

Any electronic data containing personal identifying information will be stored in encrypted folders and all physical data in a locked unit in a secure room. We will label all documents with participant identifiers. Consent forms or consent recordings, which contain both your participant identifier and name will be held separately from your other data in encrypted folders on the University of Edinburgh's DataStore account.

Information you give us, including quotes from your interview, will be used in presentations, to write reports, articles, and grant applications, and may be used in future ethically approved research studies. Personal information will be removed so that it will not be possible to identify you in any of the above.

All study documentation will be kept for a minimum of 3 years from the end of study on DataVault, the University of Edinburgh's secure archiving service after which it will be destroyed.

At the end of the study pseudonymised transcripts, where identifying information about you has been removed, will be made available open access on the online digital repository - Edinburgh DataShare. For more information on Edinburgh DataShare please visit: <https://datashare.ed.ac.uk/> Personal identifiable data will not be stored in the digital repository.

## Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

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

You can find out more about how we use your information

- by sending an email to [IMP2ART@ed.ac.uk](mailto:IMP2ART@ed.ac.uk),
- by ringing us on 07391860644, or
- by writing to us at IMP2ART-E, Centre for Population Health Sciences, Usher Institute, Usher Building, The University of Edinburgh, 5-7 Little France Road, Edinburgh BioQuarter – Gate 3, EDINBURGH, EH16 4UX.



- For further information about how the University of Edinburgh will use your personal data please see [www.ed.ac.uk/data-protection/privacy-notice-research](http://www.ed.ac.uk/data-protection/privacy-notice-research)

## What will happen to the results of the study?

We hope this research will help us to better understand how we can support people to manage their asthma and support health professionals in delivering high-quality care. This study will be presented at academic conferences and stakeholder meetings, published in written reports and international journal articles, used to write grant applications, and may be used in future ethically approved research studies.

You will not be identifiable from any published results.

We would like to let you know about what we find in this study. Please let us know if you would like to receive a summary of the findings.

## Who is organising and funding the research?

This piece of work is being led by researchers at the University of Edinburgh, alongside researchers at University College London, and Swansea University.

The study is sponsored by the University of Edinburgh and NHS Lothian.

The study is paid for by a National Institute for Health and Care Research Programme Development Grant (NIHR 208908).

## Who has reviewed the study?

The study proposal has been reviewed by the NHS Health Research Authority.

All research is looked at by an independent group of people called an Ethics Committee. A favourable ethical opinion has been obtained from the East Midlands - Derby Research Ethics Committee.

## Researcher Contact Details

If you have any further questions about the study please contact Catherine MacLeod on 07391860644 or email on [IMP2ART@ed.ac.uk](mailto:IMP2ART@ed.ac.uk).

## Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dominique Balharry ([D.Balharry@ed.ac.uk](mailto:D.Balharry@ed.ac.uk)).

## Complaints

If you wish to make a complaint about the study please contact: [resgov@accord.scot](mailto:resgov@accord.scot)

**Participant ID:**

# CONSENT FORM

## Asthma Research Study: IMP<sup>2</sup>ART-E

Please **initial** box

1. I confirm that I have read and understand the information sheet for the above study.

*Date (DD MMM YYYY)	*Version Number

*\*complete during consent process*

2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected.

4. I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and NHS Lothian), from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.

5. I give permission for my personal information (including initials, name, age, gender, sex, ethnicity, address, postcode, telephone number, email address, and consent form) to be retained on University of Edinburgh servers for administration of the study.

6. I understand that data collected about me during the study may be converted to pseudonymised data - where information which could identify me has been removed.



Please **initial** box

7. I agree to my interview being audio recorded and the use of pseudonymised quotes in research reports, publications, and presentations.

8. I agree to my audio recorded interview being transcribed by a third party contractor.

9. I agree to my pseudonymised data being store in the open access online digital repository - Edinburgh DataShare and used for future ethically approved studies.

Yes

No

10. If applicable, I agree to my interview transcript being translated into English by a third party contractor.

Yes

Not Applicable

11. I agree to take part in the above study.

\_\_\_\_\_  
Name of Person Giving Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person Receiving Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

I would like to be sent a summary of the findings from this research

Yes – By Email

Yes – By Post

No