The **MABEL** study:

A study about the use of morphine for the relief of chronic breathlessness.

Can you help?

(<<INSERT LOCAL TRUST LOGO>>)

We invite you to take part in a study

- Before you decide whether 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.
- Ask 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.
- If you have any questions, please contact us.
- Thank you for reading this information sheet.

Contact details

If you require further information about this study, you can contact one of the following:

Principal Investigator:
(<<Insert local PI details>>)

Research Nurse:
(<<Insert RN details>>)

What is the purpose of the MABEL study?

Many people with heart and lung disease have chronic breathlessness. In other illnesses small doses of morphine medication can be safely used to help breathing. We are not sure whether it helps people with heart or lung disease. The main aim of the study is to test whether low dose morphine is better than a placebo (dummy medicine) at relieving breathlessness. We plan to compare morphine with placebo for 8 weeks. As part of this study, we are also interested to learn how caring for someone with chronic breathlessness affects the carer, and whether the study medicine helps or hinders this experience.

What does "low dose" mean?

The daily study morphine dose is 10mg with the option of going up to 20mg for some. This is less than the dose given by other painkillers such as codeine, commonly used for e.g. arthritis (codeine is converted into morphine by the body): 2 tablets of Co-Codamol strong four times daily will give 24mg of morphine per day.

Why am I being asked to take part?

You are helping to care for someone who has persistent daily breathlessness due to lung or heart disease who has agreed to participate.

Do I have to take part?

No, taking part is entirely voluntary. If you decide not to participate, it will not affect the treatment you receive now or in the future or whether the person you care for can participate in the study. If you do take part and change your mind once it has started, you can withdraw at any time without having to give a reason.

1 What do I have to do if I take part?

The study will last for 8 weeks and you will be required to:

- Complete one questionnaire on three occasions (study start, at week 4 and at week 8).
- The research nurse will be available to help you complete the questionnaire over the phone.

2 What will be measured?

Effect of providing care

The short questionnaire (6 questions) asks about how your life is affected by providing help for the person you care for.

3 What will happen after the study

- If in the unlikely event that the person you care for should die whilst on the study, we may wish to contact you a few months after the study has ended to find out how you are and to complete a short questionnaire about your views on his/her healthcare. We appreciate this would be a difficult time for you and we emphasise that you would be free to decline if you preferred.

4 What are the possible benefits and disadvantages of taking part in the study?

- Although this study may not directly benefit you, it may improve future support for other people providing help to those living with chronic breathlessness.
- The questionnaires may bring to mind things that are difficult in providing help to the person you care for. If so, you would be able to talk about your concerns to a member of the clinical team.

5 More information about taking part

Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything and there will not be any payment for taking part. Reasonable expenses will be reimbursed for clinic visits.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer all your questions: contact your local research team [INSERT *name / telephone number*]

If you have any concerns or complaints about the way the researcher has carried out this study, or any other aspects of your care, you may contact: [INSERT *local information, e.g. Patient Advice and Liaison Service contact details*]

In the unlikely event that something does go wrong and you are harmed as a result of the research study the normal NHS complaints mechanism will still be available to you if appropriate.

Will my taking part in the study be kept confidential?

Any identifiable information that is collected about you with this study will be kept confidential and secure, disclosed only with your permission, or except as required by law. Your name will not appear on any materials produced from this study.

Anonymised data only will be entered onto a secure web-based database held at Hull Health Trials Unit or by other relevant third parties for the delivery of the trial.

What will happen to the data collected in the study?

The results of this study may be published or presented at scientific meetings and in journals so other doctors caring for similar patients can learn from your experience. The costs of treatment will also be explored to see if morphine is a cost-effective treatment for breathlessness. If you would like a copy of the results summary, let your study nurse know.

Anonymised data that you provide may be used by authorised researchers studying other relevant research projects. Please let us know if you do not agree to this. For more detail, see Section 2 at the end of this leaflet.

Who is organising and funding the research?
The Hull University Teaching Hospitals NHS Trust is taking overall responsibility for the study. It is funded by the National Institute for Health Research Health Technology Assessment programme (grant number 17/34/01).

The research team is led by Prof Miriam Johnson, Professor in Palliative Medicine at Hull York Medical School, the University of Hull. The trial is conducted by the Hull Health Trials Unit at the University of Hull.

Who has reviewed the study?
Before any research goes ahead it is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by an NHS Research Ethics Committee and Hull York Medical School Ethics Committee. It has also been reviewed by your local hospital Trust Research and Development Department, as well as by the Funders.

What do I do now?

If you do not wish to take part then there is no need to do anything else. If you would like to take part, or feel you need more information, then please speak to the research nurse, the member of staff who gave you this leaflet or one of the contacts on page one of this leaflet.

mabel trial

Section 2 – General Data Protection Regulation (GDPR) 2018

All information collected about you in the course of this study is confidential and will be held in accordance with the General Data Protection Regulation (GDPR 2018).

Hull University Teaching Hospitals NHS Trust is the sponsor for this study. This study is organised and managed by the Hull Health Trials Unit (HHTU), University of Hull. HHTU will be using information from you and / or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your local NHS / hospice sites will collect information from you and your medical records for this research study in accordance with our instructions. They will keep your name, NHS number and contact details confidential and will not pass this information to Hull University Teaching Hospitals NHS Trust.

Your local NHS / hospice sites will use this information as needed, to contact you about the research study and make sure that relevant information about the study is recorded for your care. A copy of your consent form with your name on it will be sent via the secure web based database to the HHTU to ensure quality and accuracy. Only designated research team members will see the consent form. This will be the only information sent to the HHTU with identifiable personal data on it.

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Research monitors from Hull University Teaching Hospitals NHS Trust, HHTU and regulatory organisations may look at your medical and research records to oversee the quality and accuracy of the research study. All will have a duty of confidentiality to you as a research participant, and nothing that could reveal your identity will be disclosed outside the agreed use of the research data. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Hull University Teaching Hospitals NHS Trust will keep identifiable information about you for 15 years after the closure of the research database. Datasets will be made available for longer periods of time for research purposes as described in other sections of this information sheet.

More information about health care research can be found using the following link:
https://www.hra.nhs.uk/information-about-patients/

You can find out more about how we will use your information by contacting:
hhtuenquiries@hyms.ac.uk or telephone 01482 463444.