What do I do now?

If you have decided to take part please complete the enclosed consent form and return it in the reply paid envelope or fax it to *0131 650 6909*

Who can I contact for further information?

Marilyn Kendall or Susan Buckingham
will be pleased to answer any questions.

Tel: *0131 6514152* E-mail: *help.copd@ed.ac.uk*
The study secretary is Cristina Matthews
Centre for Population Health Sciences, The University of Edinburgh
Medical School, Teviot Place, Edinburgh EH8 9AG

http://www.cphs.mvm.ed.ac.uk/projects/help-copd/
ClinicalTrials.gov Identifier: NCT01650480

Thank you for reading this and showing your interest.
Please keep a copy of this information sheet safe for future reference.

HELP-COPD action plan

This is an invitation to help us evaluate the HELP-COPD action plan.

Before you decide, it is important for you to understand why the research is being done and what it will involve. 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.

Thank you for reading this leaflet

What is the purpose of the study?

Chronic Obstructive Pulmonary Disease (COPD) is the third commonest long-term condition in Scotland. People with more severe COPD have a well-recognised burden of disabling physical symptoms (especially breathlessness), compounded by psychological distress and social isolation. Standard models of care, to help and support people with chronic conditions, are often designed for cancer patients and are less helpful for people with COPD. Building on our previous work, published in the BMJ (Pinnock et al BMJ 2011; 342:d142), the HELP-COPD project aims to develop, refine and then pilot a new approach to providing supportive help for people with COPD.

The study is explained in this leaflet.

What will happen in the study?

There are three phases to our programme of work:

- An initial 'modelling' phase when we wish to interview key stakeholders about the design of the HELP-COPD action plan
- A 'refining' phase when we will recruit a few patients to try the intervention and interview the patients and professionals involved to understand how we can refine the intervention
- A pilot trial when we will randomise patients to the intervention or control group in the ratio 3:1.

What is the HELP-COPD action plan?

The action plan is a single page document, designed to prompt and structure a discussion between a healthcare professional and a patient with COPD. Its use is triggered by an admission to hospital with an exacerbation. The document has sections on physical, psychological, social, spiritual and other needs and provides an action plan to manage and track possible actions/referrals.

We are writing to you because you either have patients enrolled in the HELP-COPD action plan trial or a participant in the trial has been referred to you, or your agency. We are very interested in your views on how the HELP-COPD action plan may have affected you and your organisation, what challenges it threw up and ways in which we can improve the intervention.

What are you asking me to do?

We are inviting you to take part in a brief interview lasting about 20 minutes which may be conducted by telephone or face-to-face if you prefer. We will be asking you about how the HELP-COPD action plan affected your workload, how it affected the service you offer and if you felt it benefitted patients. We will also want to know how you think the action plan could be improved in future.

Do I have to take part?

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 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. Your decision will not affect your employment or promotion prospects.

Will the interview be recorded?

Yes. We will, with your permission, record the interview which will then be transcribed for analysis. Your contributions will be identified by a code number, not by name, so that what you say will be anonymous. The recordings will be destroyed after the completion of the project.

Other questions about the study

What information will be needed about me?

The only personal information we will request is your age, gender, professional role and demography of your practice.

Can I be sure that what I say will be kept confidential?

Yes. Everything that you say, and any information about you or your organisation will be kept strictly confidential. Your name and address, and that of your employer or practice, will be removed so that you cannot be recognised.

Are there any risks?

No. We are only asking for your opinions. Any complaints or concerns about this study should be directed to Dr Hilary Pinnock *(help.copd@ed.ac.uk).*

Can I change my mind about taking part?

Yes. You may change your mind at any time and without giving a reason.

What will happen if I decide to take part?

You will be contacted either by Marilyn Kendall or Susan Buckingham to make arrangements for an interview.

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

We will send you a summary of the results. We will also present our findings at professional conferences and publish our results in medical journals. If the intervention is successful, we plan to design a full scale to test the HELP-COPD action plan.

Who is organising and funding the research?

The research is being organised by Dr Hilary Pinnock, a general practitioner and a researcher at the University of Edinburgh. The trial is funded by a grant from the Dunhill Medical Trust.

The **Dunhill Medical Trust** is a UK based charitable company funding research focussing on care of older people, including rehabilitation and palliative care.
Information about the Dunhill Medical Trust is available
http://www.dunhillmedical.org.uk/

Who has reviewed the study?

The study has received ethical approval from the South East Scotland Research Ethics Committee 01 and governance approval has been granted by NHS Lothian Research & Development. This means that your rights will be respected and that any risks to you have been reduced to a minimum and balanced against any possible benefits, and that you have been given sufficient information on which to make an informed decision.