Date:

Belfast Health and Social Care Trust

Regional Pulmonary Hypertension Centre

Pharmacy Department
Royal Victoria Hospital
Grosvenor Road
Belfast
BT12 6BJ

Telephone: 028 90634674
Email: michael.jackson@belfasttrust.hscni.net

PARTICIPANT INFORMATION SHEET

The use of personalised interventions to improve patients' ability to take Pulmonary Hypertension medicines.

You are being invited to take part in a research study. Before you decide 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take the time you need to decide whether or not you wish to take part. *Thank you for reading this.*

1. What is the purpose of the study?

Taking medicines on a regular basis can be difficult. It is known that many people do not take their medicines as instructed due to a variety of reasons. Forgetfulness, significant side effects, and the thought that the medicine may be doing harm are examples of such reasons.

Whilst it is known that at least half of patients do not take their medicines correctly, the consequences are often poorly understood or unknown. It is thought that the medicine may not reach its full potential, leading to the doctor changing to a stronger medicine with greater potential for side effects. There is also the financial cost of wasted medicines.

Pulmonary Hypertension is a condition with a limited number of medicines. Examples of these medicines are sildenafil, tadalafil, bosentan, ambrisentan, macitentan, iloprost and epoprostenol. It is important that gain the maximum benefit from these medicines.

The study understands that patients' have different needs in their ability to take medicines. It is thought that providing personalised recommendations to improve or maintain good medication taking behaviours could have positive outcomes.

The goal of this project is to produce an individualised set of recommendations (termed 'ACTION PLAN') that is aimed to improve how you take your medicines. This study will test how effective these recommendations are over the course of 12 months.

The study will also capture your thoughts and feelings about taking Pulmonary Hypertension medicines. This is a unique perspective that is not often recorded in studies.

2. Why have I been chosen?

You have been chosen because you are attending a doctor at the Pulmonary Hypertension Clinic and have been diagnosed with Pulmonary Hypertension. All patients with your condition will have their medical records checked and asked to participate. Even if you are already good at

taking medicines, you may find the knowledge gained beneficial in preparing you for future treatments.

3. 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 should contact one of the researchers (details in section 19) who will answer any questions and ask you to sign a consent form. If you decide to take part, you are free to withdraw at any time and without giving a reason.
If you do not want to take part then this will not affect your care or relationship with the clinic staff.

4. What will happen to me if I take part?

If you decide to take part you will meet with a researcher at your next clinic visit. The researcher for this study has expertise in pulmonary hypertension, and may already be known to you.

As usual, you will be asked to attend the Nurse/Pharmacist-led Pulmonary Hypertension clinic every 3 months for 12 months. This is a standard clinic and not unique to the study. The clinic is designed to provide advice on your condition and medicines. It will also review your progress, providing an opportunity for you to ask both a specialist nurse and pharmacist questions.

The study will assess your progress in the following areas:

- **Your ability to take the pulmonary hypertension medicines**. This is additional to usual care and will be undertaken by asking you to complete a simple questionnaire at home every month for 12 months.

- **Your mood every month**. It is known that depression, anxiety and stress can impact on physical abilities. You will be asked to complete a simple questionnaire at home every month for 12 months. This is additional to usual care.

- **Your quality of life**. Living with Pulmonary Hypertension can be difficult. Two questionnaires will be completed by you at each 3 monthly clinic visit. The nurse and pharmacist will be there to help you with this. This will assess your quality of life score. This is usual clinical care and will be undertaken even if you do not take part in the study.

- **The total amount of medicines you have to take**. This is often referred to as ‘treatment or drug burden’. It takes into account all the medicines you have to take, number of doses per day as well as how complex the medicine is. This will be assessed by a researcher at the 3 monthly clinic visit. This is additional to usual care.

The study will also assess you previous beliefs about medicines to understand how you take medicines and what can be improved. This will be assessed by the researcher speaking to you for up to 60 minutes at month 3 and also at the end of the study. The interview will be audio recorded with your consent to ensure accuracy of information. The recording will be deleted once it is typed and made anonymous. You will not be identified in the typed information. If you wish, you can bring a companion with you to the interview.

The researcher will arrange a time with you that is convenient. This can be undertaken at the hospital clinic, in your home, or elsewhere if that is more convenient. If this is undertaken in the hospital then you will not have to pay for any car parking.

The diagram at the end of this leaflet shows the different stages of the study.

5. What do I have to do?

You will not have to take any additional medicines or have any additional blood tests. Your involvement will be to attend the Nurse/Pharmacist-led Pulmonary Hypertension clinic every 3 months and complete the required questionnaires.

If you decide not to consent to the study it would not have any influence on your involvement in any future research study and will not affect any standard of care that you receive.

6. What is the drug or procedure that is being tested?

There are no drugs being tested in this study. Your views and opinions on medicines will lead to a personalised intervention at month six to improve and reinforce your ability to take medicines. How effective this intervention is will be assessed.

7. What are the side effects of any treatment received when taking part?

No additional treatment is being given.

8. What are the possible disadvantages and risks of taking part?

There are no major disadvantages and risks of taking part in this study. The need to attend a 3 monthly Pulmonary Hypertension clinic could be more frequent than you are currently attending. There is a possibility that you may become upset or distressed when discussing your condition with the researcher, and whilst completing the questionnaires. You may find that having someone you know with you can help.

9. What are the possible benefits of taking part?

The study has been designed to understand how you take medicines, and your thoughts and views on medicines. The potential benefits to you are:

- You will receive more dedicated time with a researcher and nurse with expertise in Pulmonary Hypertension to discuss all issues.

- You will receive more information on your medicines and be able to discuss your expectations of medicines.

- You will gain the opportunity to discuss your beliefs about medicines with a researcher. This will help identify any difficulties you may have with taking medicines as instructed. The researcher will not be judgemental. It is to help you gain full potential from taking medicines.

- You will be provided with a personalised set of recommendations (known as the ‘ACTION PLAN’) to further improve how you take medicines. This is planned to improve not only your understanding of Pulmonary Hypertension medicines but all your medicines. This may help you become more confident in reducing the burden of future treatments.

- Your participation will enable the study to answer its research question. The outcome will provide important information on medicine taking behaviours in Pulmonary Hypertension. This may lead to beneficial changes in future medication regimens and changes in services.

10. **What happens when the research study stops?**
After the 12 months, you will have completed your participation in the study. You will still be asked to attend the 3 monthly Nurse/Pharmacist-led clinics, as this is now standard practice in the clinic. All recorded details will not identify you in any way. Any quotes in publications will use a made-up name.

11. **What if there is a problem?**
Complaints: If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If a satisfactory explanation is not provided, then you should contact the chief investigator, Professor Tim Palmer, Head of Pharmacology and Experimental Therapeutics, Bradford University, Bradford (see contact details on next page).

Harm: If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

12. **Will my taking part in this study be kept confidential?**
All information which is collected about you during the course of the research study will be kept strictly confidential. With your consent, your GP will be informed of your participation in the study. This is important in case you attend your GP for other reasons. Information may be looked at by responsible individuals from the Belfast hospitals, from regulatory authorities or from HSC trust and retained on University and HSC trust premises.

13. **Research training**
This study forms part of an academic qualification (Doctorate in Pharmacy) for the lead researcher, Michael Jackson. He will be involved in the 3 monthly clinic, the delivery of recommendations and analysis of the results.

14. **What will happen if I do not wish to carry on with the study?**
If you decide to withdraw from the study and with your consent, any questionnaires which you have already completed will be used in the final analysis, but no further study questionnaires will be collected.

If you lose the capacity to consent during the study, data already taken would be retained and used but no further data would be collected.

15. **What will happen to the results of the research study?**
In any publications/reports that arise from this study, volunteers will be acknowledged for their participation. Names of volunteers, however, will not be published in any of these releases. Any information published will be anonymised.

16. Who is organising and funding the research?

The research is funded by the Heart Trust Fund, Royal Victoria Hospital. The study is being sponsored by the University of Bradford, England. The members of the research team will not receive any payments for including you in this study.

17. Who has reviewed the study?

This study has been reviewed by the Office for Research Ethics Committees Northern Ireland and by the supervisors at the University of Bradford, England.

18. Summary

The researchers wish to thank you for taking time to read this Information Sheet. If you decide to participate, you should contact one of the researchers below who will give you a copy of the Information Sheet and Consent Form for your own records.

19. Contact for Further Information

(a) Mr Michael Jackson (Lead Cardiology Pharmacist), Doctoral Researcher, Pharmacy Department, Royal Victoria Hospital, Grosvenor Road, Belfast. BT12 6BJ.

E-mail: michael.jackson@belfasttrust.hscni.net

(b) Mrs Louise Campbell (Specialist Pulmonary Hypertension Nurse), Royal Victoria Hospital, Grosvenor Road, Belfast, BT12 6BJ.

Mobile: 07846364448

E-mail: louise.campbell@belfasttrust.hscni.net

(c) Dr Damian McCall (Consultant Cardiologist), Belfast City Hospital, Lisburn Road, Belfast, BT9 7AB.

E-mail: damian.mccall@belfasttrust.hscni.net

(d) Professor Tim Palmer (Chief Investigator / Head of Pharmacology and Experimental Therapeutics), University of Bradford School of Pharmacy, 2.16b Norcroft Building, Bradford, BD7 1DP

E-mail: t.palmer1@bradford.ac.uk

Overview of Study