

PIROUETTE

Wythenshawe Hospital
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Double-blind randomised controlled trial of pirfenidone in patients with heart failure and preserved ejection fraction

0161 998 7070

Consent form

Version 3.0: 7 December 2016

Participant study number: _____ Participant date of birth: _____

Instructions on completing this form:

Please read the following statements carefully, and **initial the box** if you agree.

<i>e.g.</i> I confirm that I have read and understand the Participant Information Sheet.	JB
1. I confirm that I have read and understood the Participant Information Sheet (Version 3.0, Dated 07/12/16) for this study. I have had the opportunity to consider the information and ask questions, which have been answered satisfactorily.	<input type="checkbox"/>
2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving a reason and without it affecting my medical treatment.	<input type="checkbox"/>
3. I understand that my data will be retained for a maximum of 15 years at the hospital and at the Clinical Trials Research Centre (which is managing the study), and that they will be stored in a confidential and secure manner.	<input type="checkbox"/>
4. I understand that relevant sections of my medical notes and any data collected during the study may be looked at by authorised individuals from the research team, NHS Trust and Regulatory Authorities (* see 'additional information' section on information sheet) I give permission for these individuals to have access to my records.	<input type="checkbox"/>
5. I agree to my GP being informed of my participation in the study.	<input type="checkbox"/>
6. I give permission for a copy of this consent form, which will include my name and date of birth, to be sent to the Clinical Trials Unit (where will be kept in a secure location), to allow confirmation that my consent was given.	<input type="checkbox"/>
7. I agree to my anonymised safety data being sent to Roche and entered onto their safety information database.	<input type="checkbox"/>
8. I agree to take part in the study.	<input type="checkbox"/>
9. OPTIONAL I agree to gift a blood sample of up to a maximum of 20 mls (or 4 teaspoons) for use in future ethical approved research, including DNA analysis	<input type="checkbox"/>

Full Name (please print)		Today's date	dd-mm-yy
Your signature			

To be completed by the researcher:

Researcher name (print)			
Researcher signature	Date		