**Widening participation for orphan drug trials study: Participant Information Sheet (Short) – Patients**

**What is it about?**

Orphan drugs are medicines for diagnosis, prevention or treatment of life-threatening or progressive disorders that are rare (affecting less than 1 in 2,000 people). An example is Idiopathic Pulmonary Fibrosis (IPF).

We are approaching a number of people who have Idiopathic Pulmonary Fibrosis (IPF) to learn more about how and why they have or have not been referred to trials of new drugs for IPF and their experiences of participating in any trials of new drugs.

Dr Julia Frost of the University of Exeter, an experienced healthcare researcher, would like to interview people with IPF (by phone or internet) about their experiences of having IPF; referral to and participation in clinical trials of drugs for rare diseases, or non-participation. This study is funded by UK Research and Innovation (Medical Research Council) (MR/W003732/1).

**Why widening participation?**

We know quite a lot about patients who take part in clinical trials of drugs for rare diseases. However, there are gaps in knowledge about the experience of patients in clinical trials of drugs for rare diseases who have trouble being referred to a trial, who do not receive the active treatment (e.g. a placebo), or who experience side effects, and those who drop out of a trial.

**What would taking part involve?**

If you decide to take part in the research, we will interact with you by telephone or internet. A member of the research team will contact you via telephone to talk more about the study. They can answer any questions you have and explain how we collect your permission to take part in the research (this is called “consent”).

With your written consent, and at a time that is convenient for you, you will be asked to take part in an interview (via telephone or the internet) about your experiences IPF.



All information that is collected about you and from you during the course of the study will be kept strictly confidential. Any information about you will be removed and replaced with a code number so that you cannot be identified.

**What are the possible benefits of taking part?**Your participation in an interview will help us understand what happens during referral to, and participation in, clinical trials of drugs for rare diseases.

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

Some people can experience emotional distress when they are asked to think about their health care.

**What is the potential impact?**

This could lead to improvements in future treatment for people with rare conditions, such as IPF.

**Would you like more information?**

Please either:

Contact the Clinical Research Network Nurse who gave you this sheet

[contact details], or:

Return the completed ‘consent to contacted form’ to Dr Frost who is happy to discuss any questions and provide you with additional information.

**Thank you for your interest.**