**Executive Summary**

IRB XXX-XX

**Title of this Research Study**

A phase III, double blind stud**Y** of ABC123 vs treprontinil for patients with WHO group I P**U**lmonary Arterial Hypertension Functional **C**lass II or III (YUCk-123)

**Description**

You are being invited to be in this research study because you have pulmonary hypertension. You are being treated with treprontinil but still have symptoms.

This research study is voluntary. You do not have to participate.

**Purpose**

The purpose of this research is to see if an experimental drug ABC123 works better than an approved drug treprontinil. You are already getting this standard drug.

**Methods**

You will have some tests done to see if you are eligible. These tests include blood tests, a 6 minute walking test and a right heart catheterization. You will only have the right heart test if you haven’t had one in the last 12 months. After these tests the research doctor will tell you if you can join the study.

If you are eligible you will be randomly assigned (like the flip of a coin) to get the experimental drug or to get the standard drug. You will continue all your other medicines.

You will come to see the research doctor and have the walk test and the blood tests every 6 months. You will also complete some surveys about your Quality of Life. You will keep a diary at home and record your symptoms.

After two years you will have another right heart test. If you got the experimental drug and it made you better, you can continue getting it as long as it works for you.

**Risks and Side Effects**

**Common side effects of the experimental drug are headache, diarrhea, and nausea. Serious but rare side effects are** bleeding, infection, heart attack, and death.

If you get the experimental drug, and it doesn’t work, you could get worse (have more symptoms).

Side effects of the standard drug are nausea, dizziness, belly pain. Serious but rare side effects are low blood pressure, lung damage, heart attack and death.

**Potential Benefits**

If you get the experimental drug and it works you may feel better.

If you get the standard drug you would not benefit, because you are already getting the drug.

The information from this study may help researchers decide which drug is better.

**Alternatives**

Instead of being in this research study, you can continue to get the standard drug.

Talk to the research doctor (or your heart doctor) about your choices before you decide if you will be in this study.

**Additional Information**

Your investigator will review the main consent with you. The main consent has a complete description of this study.

Note: Flesch-Kincaid Reading level 6.8; Flesch Reading Ease 71.0 (excluding study title)