

[PI name]

[Site name & address]

Date: [insert date]

Dr [GP name]

[GP surgery address]

Dear Dr [GP name]

**RE: RSA-PACE study**

**REC Number: [REC reference]**

**Patient name: [patient name]**

**Patient address: [patient address]**

The above patient has kindly agreed to take part in a clinical trial entitled:

*“Respiratory sinus arrhythmia pacing post-CABG surgery in patients with heart failure with reduced ejection fraction (RSA-PACE)”*

This is a first-in-human, randomised controlled trial investigating whether reintroduction of respiratory sinus arrhythmia (RSA) variability to the heart rate will benefit cardiac function in patients with heart failure with reduced ejection fraction (HFrEF). The study, approved by [REC] and the MHRA, is led by:

Chief Investigator: Prof Zaheer Yousef, Consultant  
Cardiologist, Cardiff & Vale University  
Health Board (CVUHB), Cardiff.

The study is Sponsored by a company, Ceryx Medical, and is being managed by CEDAR, a research unit attached to CVUHB.

The purpose of the study is to test whether a new type of heart pacing can restore RSA-like variation in heart rate, and whether this is as safe as normal atrial pacing. This will be done in patients with HFrEF following cardiac artery bypass graft (CABG) surgery. It will also test whether this new pacing could improve the function of the heart. Patients in the study will be randomised to normal, fixed rate atrial pacing, or to atrial pacing modified to restore RSA-like variability. They will be paced during their recovery in hospital using temporary pacing leads (implanted as standard for CABG surgery), and an external pacemaker. They will undergo additional tests in hospital and be closely monitored. They will have an additional visit 1 week following pacing (which may be at home) and a telephone follow-up 1 month after surgery.

A copy of the participant information sheet is enclosed for your information. Should you have any questions regarding this study, please do not hesitate to contact either the Chief Investigator ([Zaheer.Yousef@wales.nhs.uk](mailto:Zaheer.Yousef@wales.nhs.uk) or 029 2074 2972) or Trial Manager ([susan.peirce@wales.nhs.uk](mailto:susan.peirce@wales.nhs.uk) or 029 2184 4771) or the local Principal Investigator/Research Team [local contact details].

Yours sincerely,

[PI details]