**OPTIMISE II Trial - Summary of changes in patient information sheet (version 3.0, dated 18th September 2017)**

We have made a change to the **What are the possible risks and benefits of taking part?** section of the Patient information sheet referring to the ‘very small risk of a minor heart attack for some patients’.

The change includes the revised sentence ‘Previous research suggests that the treatment we are investigating is very safe and should benefit most patients. However we would like to collect additional safety information, and you will be closely monitored throughout the study period, to ensure the treatment is safe.’

This is a result of the concerns we have received from several of our local investigators that this statement on minor heart attack is preventing patients from enrolling into the trial. It appears that the original statement is misleading, as it suggests that it is the intervention treatment which increases this risk. In fact based on clinical evidence the risk of cardiac events is often related to the type of major surgery patients are undergoing rather than the treatment intervention itself. Additionally the work by Gillies et al published in the British Journal of Anaesthesia 115 (2): 227–33 (2015) evaluated the incidence of cardiac events in goal directed therapy in combination with low-dose inotropic therapy compared with usual care as part of a substudy from the OPTIMISE trial. The main finding of the paper was that dopexamine-based goal-directed therapy was not associated with any biochemical or clinical evidence of myocardial injury and that the occurrence of myocardial injury was more associated with major surgery.