Standard Operating Procedure (SOP)			
Surgery Delayed or Cancelled Post-Randomisation			
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Scope:

- To outline the procedures for when a patient has been randomised into the trial, but their surgery has been delayed or permanently cancelled.
- To provide guidance on data collection and case report form (CRF) completion for patients with delayed or cancelled surgery post-randomisation.

Background:

- Patients should only be randomised when it has been confirmed the surgery will be going ahead i.e. once the patient is in the anaesthetic room.
- In the unavoidable circumstance where a patient is randomised, but their surgery is then cancelled, this SOP outlines the procedures to follow.

Surgery delay:

- After randomisation, if a patient's surgery is delayed, please find out the reason for cancellation and whether there is a new surgery date booked for the patient.
- Within 48 hours of the original surgery date please notify the trial coordinating centre via email (admin@optimiseii.org) with the following information:
    - Patient ID
    - The reason for surgery cancellation
    - New surgery date. If a new surgery date has not been booked, continue to monitor the patient's medical records for a new date.
- A copy of this email correspondence should be filed in the investigator site file (ISF).
- When the patient comes in for their rebooked surgery, verbally confirm if they are happy to continue the trial and please document this in the medical notes. The patient **does not need to be randomised again**, please use their originally allocated randomisation treatment arm.

Permanent surgery cancellation:

- If the surgery is cancelled and there are no surgery dates booked for the foreseeable future, notify the trial coordinating centre via email.

- If a patient does not have surgery at all, they do not meet the trial eligibility criteria and will not be included in the final analysis. The data collected up to that point will be kept i.e. randomisation and baseline data. No further data collection is required for these patients. The participant ID will not be reused.

Randomisation in error:

- If a patient withdraws consent after randomisation but before surgery, this is regarded as randomisation in error. Notify the trial coordinating centre via email as soon as possible. The patient does not meet the trial eligibility criteria and will not be included in the final analysis. Follow-ups do not need to be completed for these patients. The participant ID will not be reused.

Patient follow-up and CRF completion following surgery cancellations:

- The patient's 24-hour, 30-day and 180-day follow-ups are to be collected from the **DATE OF SURGERY**.
- For any clinical outcomes documented in the CRF, ensure the date of outcome is recorded accurately. This will help the trial coordinating team determine if the outcomes occurred within 30 days of randomisation for the final analysis.
- On the OPTIMISE II database (https://trials3.pctu.qmul.ac.uk/), under the 'sign record' tab, there is a free text box available. Enter the reason for surgery delay in this text box.