The SUNRRISE Trial
CONSENT PROCESS OVERVIEW

Has the patient got capacity to consent?

NO

Is this due to long-term incapacity?

NO

Patients that have short-term temporary) incapacity due to the acute illness or analgesia etc. are not excluded from **SUNRRISE**.

Is a Personal Consultee (relative/carer) available?

NO

Patient is **ineligible** for enrolment in **SUNRRISE.**

YES

The trial MUST be discussed with a relative/carer (Personal Consultee), who is given the '**Consultee / Representative Information Sheet**' (in England & Wales). The Personal Consultee is asked to complete the '**Consultee Declaration Form**' (in England & Wales).

Where possible, give the patient the '**Summary Patient Information Sheet**'.

After surgery and when the patient has regained capacity, give them the '**Patient Information Sheet (Delayed Consent)**' and consent them using the '**Informed Consent Form (Delayed)**'.

YES

Give the patient the '**Patient Information Sheet (Standard Consent)**' and consent them using the '**Informed Consent Form (Standard)**'.

Please Note: Consent for research is separate to the patient's consent for their operation. A surgical consent form for a patient lacking capacity (aka "Consent Form 4") does not cover a patient being included into SUNRRISE.

If there is any doubt about a patient's eligibility or consent, the patient should not be randomised.

- Written, informed consent from a patient (or assent/consent from a patient's personal consultee/legal representative) must be obtained for all patients:
    - Prior to Randomisation
    - By a suitably trained, delegated investigator who is listed on delegation the log
        - the investigator must have been trained and authorised by the PI before undertaking any study-specific activities and procedures
    - If necessary, translators should be provided for patients unable to understand English
    - A full verbal explanation of the trial and the Patient (or consultee) Information Sheet must be provided

Patients with capacity to give consent…

- **Process for approach and consent:**

1. Patient is given the Patient Information Sheet (Standard) and the opportunity to discuss the trial with a member of the research team
2. Patient then completes Informed Consent Form (Standard) and the form is countersigned by the person taking consent, checking that the patient has completed the form correctly (initialled all boxes, correct date given)

Patients temporarily lacking capacity to give consent…

- In the emergency setting, patients may not have capacity to provide informed consent as a result of the condition for which they require surgery
- Such patients can still be enrolled if they have a **Personal Consultee (PC)** (England & Wales only)

  A person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity

  If a PC is unavailable, the patient cannot be entered into the study
- **Process for approach and consent:**
    - Where possible, the patient is given the Summary Patient Information Sheet
    - PC is given the Consultee or Representative Information Sheet (England & Wales) and opportunity to discuss trial with a member of the research team
    - PC then provide assent using the Consultee Declaration Form (England & Wales) and the form is countersigned by the person taking consent, checking that the PC has completed the form correctly (initialled all boxes, correct date given)
    - Once patient regains capacity, consent is to be sought using the Patient Information Sheet (Delayed) & Informed Consent Form (Delayed)

Patients lacking capacity long-term…

- If a patient's lack of capacity to consent is not temporary, they cannot be entered into the study
  i.e. ineligible for enrolment in the trial