CONSENT OVERVIEW

PATIENT FULFILS ELIGIBILITY CRITERIAS?

**YES**

Patient **competent** to give valid written consent considering the urgency of the situation and their mental state?

**NO**

Relative or friend **present and willing** to act as the patient’s Personal Representative (PeR)?

**NO**

Professional Representative (PrR) present?

**NO**

Patient **able** to give agreement for participation?

**NO**

Two clinical personnel, one independent of the trial, both agree to enrol patient into the trial? (waiver of prior written consent)

**NO**

**DO NOT INCLUDE IN TRIAL**

**YES**

Patient given information sheet

Consent form completed and signed by patient

**NO**

PeR able to give valid consent considering the urgency of the situation and their mental state?

**YES**

PeR given information sheet

Consent form completed and signed by PeR

Give patient information to level of capacity

If patient regains capacity, obtain consent for continuation in the trial

**NO**

Give PeR brief information about the trial and obtain agreement for patient’s participation

Obtain written consent from patient (if capacity returns) or from representative for continuation in the trial

If patient or representative is unable to read or write:

- Explain the trial in the presence of an independent witness
- Patient/representative places mark (eg thumbprint) on consent form
- Independent witness completes the consent form

**YES**

Give patient brief information about the trial and obtain agreement for participation

Obtain written consent from patient (if capacity returns) or from representative for continuation in the trial

**NO**

Write in medical records why written consent could not be obtained

Obtain written consent from patient (if capacity returns) or from representative for continuation in the trial