REFRESH
Consent Process

Patient meets study enrolment criteria

Yes

Competent to Consent

No

Initial explanation & verbal consent

Enrol under Waiver of Consent

RANDOMISE

Person responsible present

Obtain written consent from participant to continue in trial

Person responsible available by telephone

Obtain written consent from person responsible

Obtain verbal consent from person responsible

Person responsible unavailable

Continue in trial under waiver of consent

REFRESH Study Protocol v3 25 October 2016