GUIDANCE FOR OBTAINING INFORMED CONSENT: CONSENT PROCESS OVERVIEW
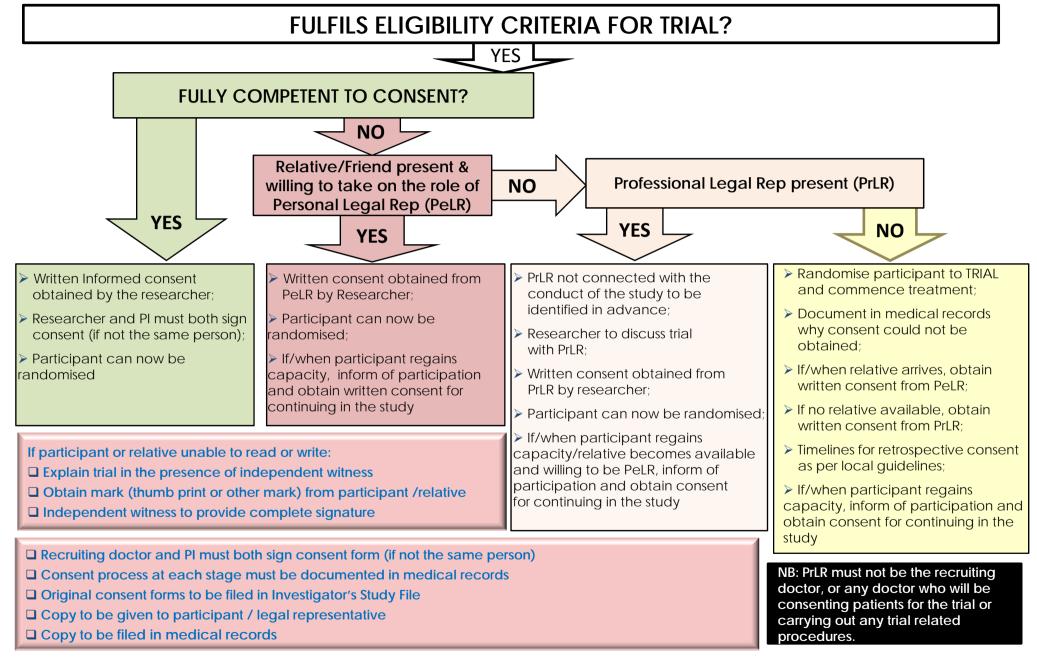
FULFILS ELIGIBILITY CRITERIA FOR TRIAL?

YES

FULLY COMPETENT TO CONSENT?

NO

Relative/Friend present & willing to take on the role of Personal Legal Rep (PeLR)

NO → **Professional Legal Rep present (PrLR)**

YES

YES

YES

NO

YES branch (Fully competent):
- Written Informed consent obtained by the researcher;
- Researcher and PI must both sign consent (if not the same person);
- Participant can now be randomised

PeLR branch:
- Written consent obtained from PeLR by Researcher;
- Participant can now be randomised;
- If/when participant regains capacity, inform of participation and obtain written consent for continuing in the study

PrLR branch:
- PrLR not connected with the conduct of the study to be identified in advance;
- Researcher to discuss trial with PrLR;
- Written consent obtained from PrLR by researcher;
- Participant can now be randomised;
- If/when participant regains capacity/relative becomes available and willing to be PeLR, inform of participation and obtain consent for continuing in the study

NO (no PrLR) branch:
- Randomise participant to TRIAL and commence treatment;
- Document in medical records why consent could not be obtained;
- If/when relative arrives, obtain written consent from PeLR;
- If no relative available, obtain written consent from PrLR;
- Timelines for retrospective consent as per local guidelines;
- If/when participant regains capacity, inform of participation and obtain consent for continuing in the study

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If participant or relative unable to read or write:
- ❑ Explain trial in the presence of independent witness
- ❑ Obtain mark (thumb print or other mark) from participant /relative
- ❑ Independent witness to provide complete signature

- ❑ Recruiting doctor and PI must both sign consent form (if not the same person)
- ❑ Consent process at each stage must be documented in medical records
- ❑ Original consent forms to be filed in Investigator's Study File
- ❑ Copy to be given to participant / legal representative
- ❑ Copy to be filed in medical records

NB: PrLR must not be the recruiting doctor, or any doctor who will be consenting patients for the trial or carrying out any trial related procedures.