FLOWCHART: GUIDANCE FOR OBTAINING INFORMED CONSENT

FULFILS ELIGIBILITY CRITERIA FOR WOMAN TRIAL?

FULLY COMPETENT TO CONSENT?

- Yes
  - Written Informed consent obtained by the researcher;
  - Researcher and PI must both sign consent (if not the same person);
  - Woman can now be randomised

- No
  - Written consent obtained from PeR by Researcher;
  - Woman can now be randomised;
  - If/when woman regains capacity, inform of participation and obtain written consent for continuing in the study

Relative/Friend present & willing to take on the role of Personal Representative (PeR)

- Yes
  - PrR not connected with the conduct of the study to be identified in advance;
  - Researcher to discuss woman with PrR;
  - Written consent obtained from PrR by researcher;
  - Woman can now be randomised;
  - If/when woman regains capacity, inform of participation and obtain consent for continuing in the study

- No
  - Professional Representative (PrR) present
    - Yes
      - Randomise woman to TRIAL and commence treatment;
      - Document in medical records why consent could not be obtained;
      - If/when relative arrives, obtain written consent from PeR;
      - If no relative available, obtain written consent from PrR;
      - Researcher to discuss woman with PrR;
      - Written consent obtained from PrR by researcher;
      - Woman can now be randomised;
      - If/when woman regains capacity, inform of participation and obtain consent for continuing in the study
    - No
      - If woman or relative unable to read or write or verbal consent required for another reason:
        - Explain trial in the presence of independent witness
        - Obtain mark (thumbprint or other mark) from woman/relative
        - Independent witness to provide complete signature

If written consent cannot be obtained from Patient, PeR or PrR reason to be documented in medical records (i.e. why prior written consent procedure has been waived).

- Recruiting doctor and PI must both sign consent form (if not the same person) – PI can sign after randomisation
- 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 woman / legal representative
- Copy to be filed in medical records

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Version 1.0_ Consent FLOWCHART

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