Overview: Consent process

INITIAL ELIGIBILITY CHECK BY CLINICIAN FROM MEDICAL RECORDS:

Potentially eligible if YES to ALL of the following:

- Woman in hospital giving birth by CS
- Adult (≥18 years old)
- Has history of at least one risk factor for PPH.

Not potentially eligible if YES to any of the following:

- Giving birth vaginally
- Women with current antepartum haemorrhage
- Women known to have received TXA within 48 hours prior to randomisation
- Women with known renal impairment
- Women with any known blood clotting disorder
- Women with a known allergy to TXA or its excipients

Potentially Eligible?

YES

NO

- Full information given to woman by researcher
- Woman competent to give consent?

NO

If unwilling or not fully competent to consent, do not include

YES

Willing to be considered for inclusion in the trial?

NO

YES

Able to read and write?

NO

- Explain the trial in the presence of an independent witness
- Obtain mark (e.g. thumbprint) from woman
- Independent witness must sign the relevant section of the form

NOTE: (Independent witness is someone not involved in the organization or conduct of the trial)

YES

Obtain written consent from woman using forms provided.

NOTE: In all cases:

- Researcher/Clinician obtaining consent must also sign the relevant section of the consent form
- File original signed consent form in Investigator's Site File
- Give copy of signed form to woman
- File one signed copy in the woman's medical notes
- Document consent process used in woman's medical notes