

## RANDOMISATION INSTRUCTIONS

## **Randomisation Process**

After participant eligibility has been confirmed and informed consent has been received, the participant can be randomised into the trial.

Randomisation will be by telephone via an automated secure system developed by the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. Eligibility will be confirmed as part of the recruitment process and checked by the automated telephone randomisation system. It is anticipated that the task of randomising a woman will typically be delegated to a Midwife, but it can be conducted by an Obstetrician.

Randomisation will be available 24 hours a day. Participants will be randomised at the level of the individual in a 1:1 ratio to either standard dose regimen oxytocin or high dose regimen oxytocin. Full instructions are available on the **iHOLDS Trial Entry Form**.

Randomisation Line: 0800 2802 307

(See separate Telephone Randomisation Service User Guide in section 18 of the ISF for further details if required)

## **Randomisation Records**

Following randomisation, a confirmatory email will be sent to the randomiser, local Research Midwife, local PI, local Pharmacist, Chief Investigator and the iHOLDS Trial Office (iHOLDS@trials.bham.ac.uk).

Investigators will keep their own log which links participants with their allocated Trial Number in the **iHOLDS Participant Recruitment and Identification Log**. The Investigator must maintain this document, which is <u>not</u> for submission to the iHOLDS Trials Office. The iHOLDS Participant Recruitment and Identification Log should be held in strict confidence.