UNBLINDING INSTRUCTIONS

Unblinding of participants as an emergency will not be required as the management of these women will not change in the light of this information. Any adverse event that occurs from whichever dose the woman is randomised to should be managed by the clinical team caring for the woman as per local protocols. The plasma half-life of oxytocin is approximately five minutes, so should any cause for concern be identified, stopping the oxytocin is the recommended course of action regardless of randomised allocation.

Should unblinding be required as part of any investigation, access to unblinding will be through the Trial Office who will be able to unblind during normal working hours. Unblinding at a site may trigger an additional monitoring visit in accordance with the iHOLDS Monitoring Plan.

If unblinding is required:

The Principal Investigator (or an individual delegated this responsibility on the Site Signature and Delegation Log) should call the iHOLDS Trial Office at the BCTU on **0121 415 8298** during office hours (Monday – Friday 9:00 – 17:00) and speak to the (Senior) Trial Manager.

The following information will need to be provided:

- Participant Number
- Treatment Pack number(s)
- Name and contact details of person requesting unblinding
- Occupation (Consultant, registrar, nurse etc.) and department of person requesting the unblinding
- Hospital details (location and contact details)
- Primary reason for the unblinding request

Following unblinding:

- The circumstances surrounding the decision to unblind should be documented in the medical notes but not the results themselves
- Treatment allocation must be placed within a sealed envelope with the Participant Number written on, together with “unblinded treatment allocation – do not open”
- The confirmation of treatment allocation envelope should be filed in the Investigator Site File section 15: Trial Medication