Form 1: Confirmation of Eligibility

Please complete in black ballpoint pen

Hospital name: ____________________________

Points to remember:

• This form should be completed prior to randomisation.
• In order to proceed to randomisation the woman must meet all of the inclusion criteria and none of the exclusion criteria.
• If you make a mistake when completing this form, please strike through once and initial and date the correction.
• Please ensure all questions on this form are answered.
• On completion the signed and dated form should be returned to the allocated ANODE tray/folder.

LRM when data entry is complete, send a copy of this form to the Trial Co-ordinating Centre using a FREEPOST envelope from the ANODE Documentation Box.

If you have any questions please contact the Co-ordinating Centre on: 01865 289 750

For NPEU office use

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Woman’s Details

Last name: ____________________________

First name(s): ____________________________

NHS or CHI number (if known): ____________________________

Woman's hospital ID number in this hospital: ____________________________

ANODE is funded by the National Institute for Health Research HTA Programme (project number 13/96/07).
Section A: Eligibility

Please complete this section **BEFORE** taking an ANODE pack to randomise this woman

**Inclusion criteria**

A1. Has the woman given informed consent?  
   Yes ☐  No ☐  **Must be Yes**  
   **If Yes**, please indicate the initial type of consent given:  
   Verbal ☐  Written ☐  
   You must obtain a **WRITTEN consent** from the woman prior to discharge

A2. What was the expected date of delivery (EDD)?  
   Use the best estimate (ultrasound scan or date of last menstrual period)  
   based on a 40 week gestation

A3. What was the actual date and time of delivery?  

A4. Is the woman ≥ 36+0 weeks of gestation  
   Yes ☐  No ☐  **Must be Yes**

A5. What is the woman’s date of birth?  

A6. Is the woman aged 16 years or over?  
   Yes ☐  No ☐  **Must be Yes**

A7. Has the woman undergone an operative vaginal delivery?  
   Yes ☐  No ☐  **Must be Yes**

**Exclusion criteria**

A8. Has the woman got a known allergy to penicillin or to any of the components of co-amoxiclav, as documented in hospital notes?  
   Yes ☐  No ☐  **Must be No**

A9. Has the woman got a clinical indication for **ongoing** antibiotic administration post-delivery e.g. due to confirmed antenatal infection, 3rd or 4th degree tears?  
   Yes ☐  No ☐  **Must be No**  
   **Note that receiving antenatal antibiotics e.g. for maternal Group B Streptococcal carriage or prolonged rupture of membranes, is not a reason for exclusion if there is no indication for ongoing antibiotic prescription post-delivery.**

A10. Has the woman got a history of anaphylaxis to another β-lactam agent, as documented in hospital notes (e.g. cephalosporin, carbapenem or monobactam)?  
   Yes ☐  No ☐  **Must be No**

To be eligible a woman must meet all of the inclusion criteria and none of the exclusion criteria. If the woman is not eligible DO NOT randomise

A11. This woman meets all of the inclusion criteria and none of the exclusion criteria:  
   **Name**: _______________________________  
   **Date**: ___/___/___
   **Signature**: _______________________________  
   **Role**: _______________________________
   * This person MUST be on the ANODE Delegation Log with appropriate delegated duties