



BASE



FAQs for Recruiting Sites

Site set-up

1. Are there any training requirements?

Training will be provided during a Site Initiation Visit (SIV), which will be held virtually on Microsoft Teams.

Site staff will also need to complete the BASE Randomisation website and OpenClinica (study database) training, you can find the training videos here:

www.npeu.ox.ac.uk/base/clinicians/training-materials

2. What is needed to open to recruitment?

Neonatal units across the UK. Please see list of recruiting sites on the 'Sites' page.

The following activities must be completed before we can open your site to recruitment:

- R&D approvals (signed mNCA, confirmation of C&C)
- CVs and GCP certificates sent to the trial team for the PI and lead research nurse
- SIV attended and post-SIV report signed and returned
- Delegation Log completed
- Completion of BASE Randomisation website and OpenClinica (study database) training and Training Log completed
- Receipt of Investigator Site File (ISF) and Document Box
- Local PI Protocol sign off

3. What materials will we receive as a site?

All recruiting sites will receive a document box. The box will include trial documents and guidance sheets. A folder and plastic wallets will be sent to store paper data collection forms in. This will be sent around the time of the SIV.

4. Will a site file be provided?

An electronic site file will be provided to sites after the SIV.

5. How do we complete the delegation log?

The log is provided in the document box. Please add all staff members working on the study, and enter their responsibilities. All staff members must then physically sign the delegation log, which will then be signed off by the PI. Each time the delegation log is updated, please send us a new scanned copy by email.