Guidance Sheet 3:

Randomisation

Randomisation

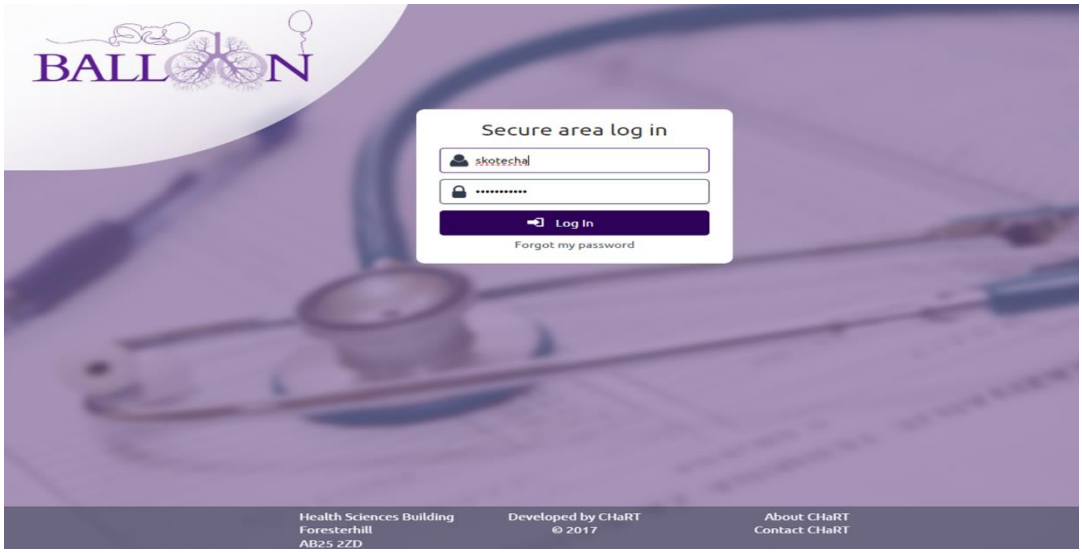
Randomisation must be **carried** out prior to administering or prescribing the IMP

▪ Confirm that written informed consent from the parents has been taken by someone who has received suitable training and is named on the Delegation Log.

▪ Confirm the baby still meets all of the eligibility criteria and ensure a medically qualified person (who is delegated this duty on the Delegation Log) has documented clinical assessment of eligibility within the medical notes.

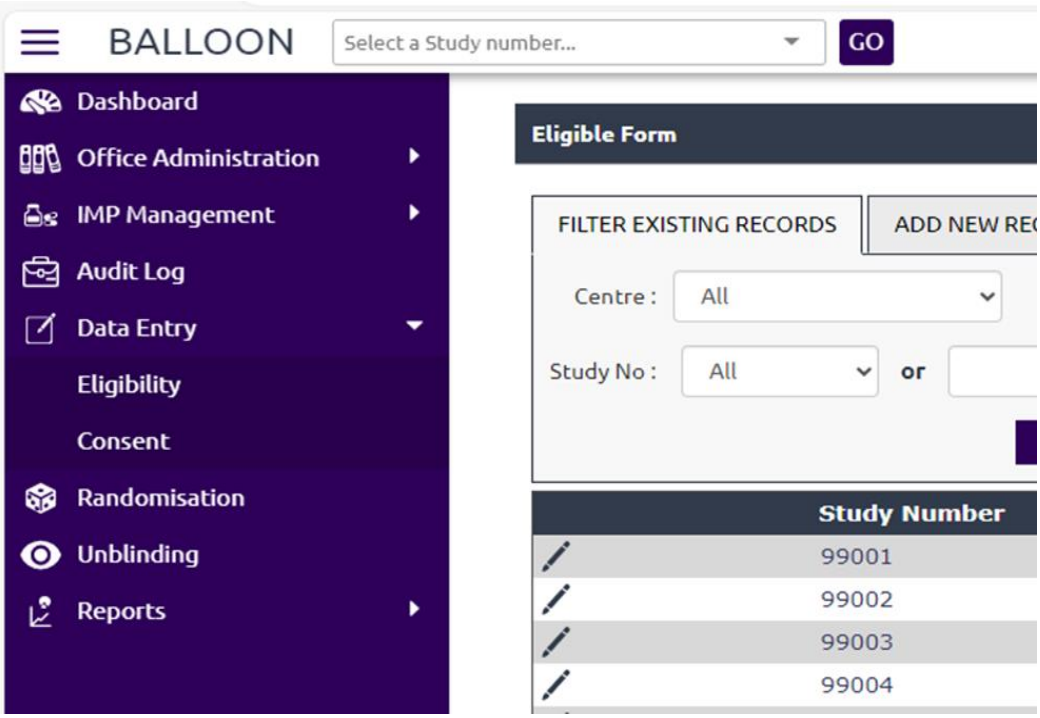
<u>Steps to follow</u>

1. Access the study randomisation program (CHaRT)
   https://w3.abdn.ac.uk/hsru/BALLOON/Login/login.aspx



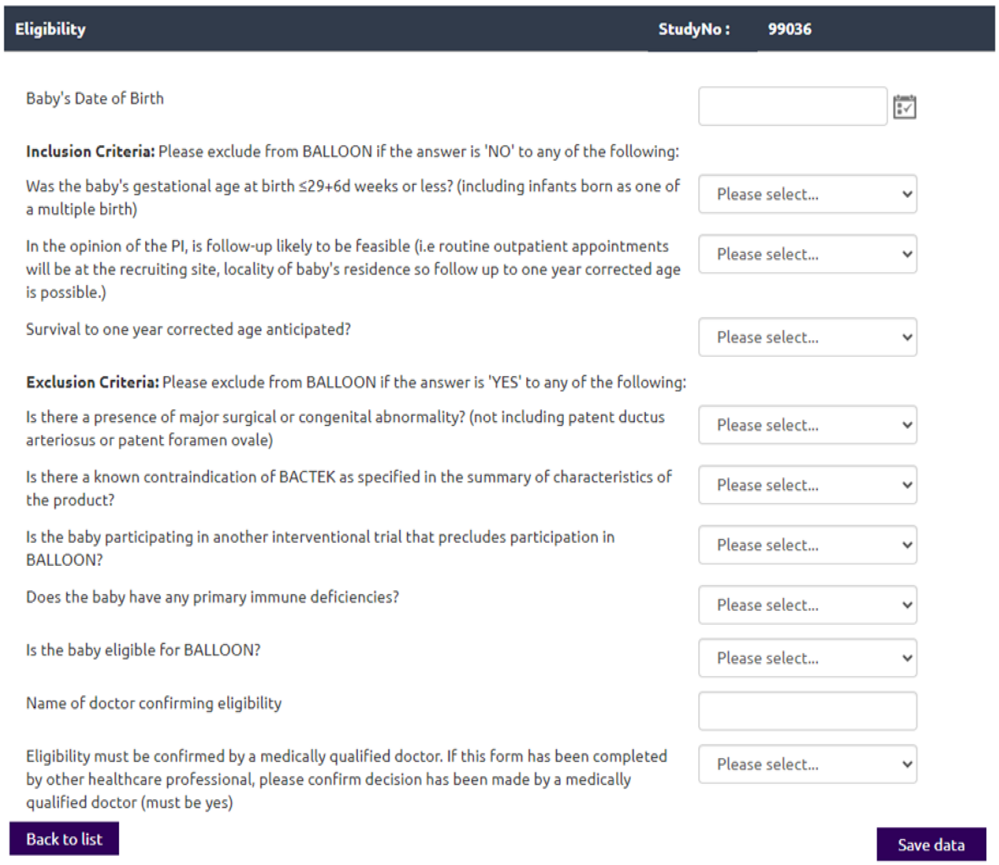
2. Login using your individual credentials as assigned by the CTR team

3. Click on the three lines in the top left corner and then data entry

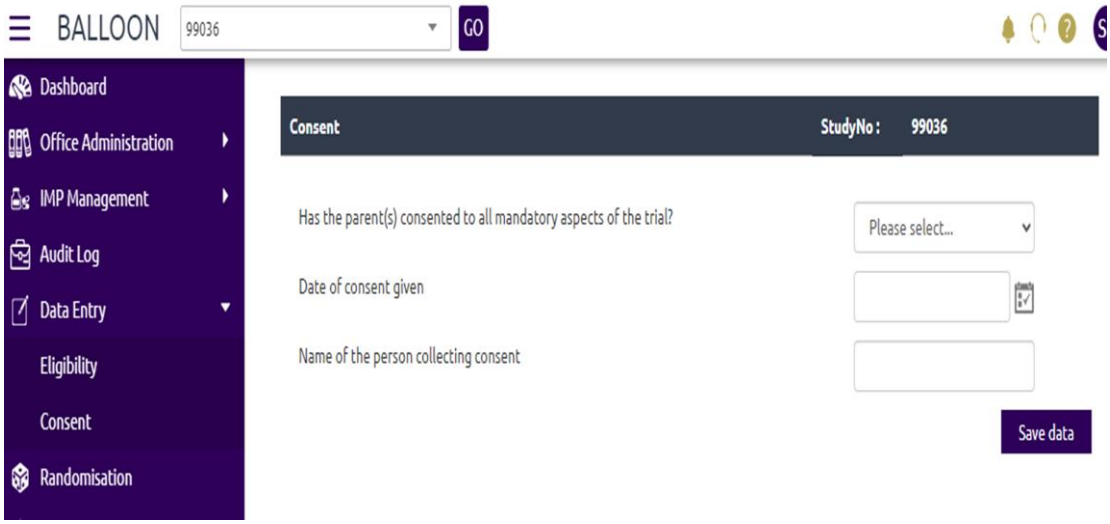


4. Click on eligibility and then add new record
   Select your centre and click add new, this will add a new participant and generate a new CHaRT PID when you say OK to proceed.

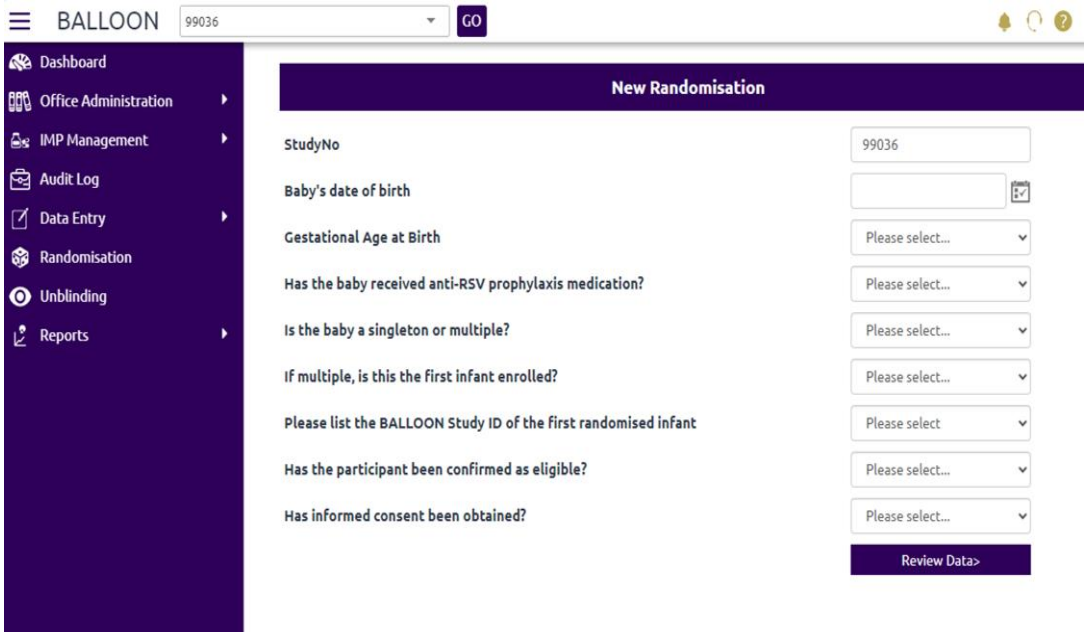
5. The following screen will open, please complete and then save data.



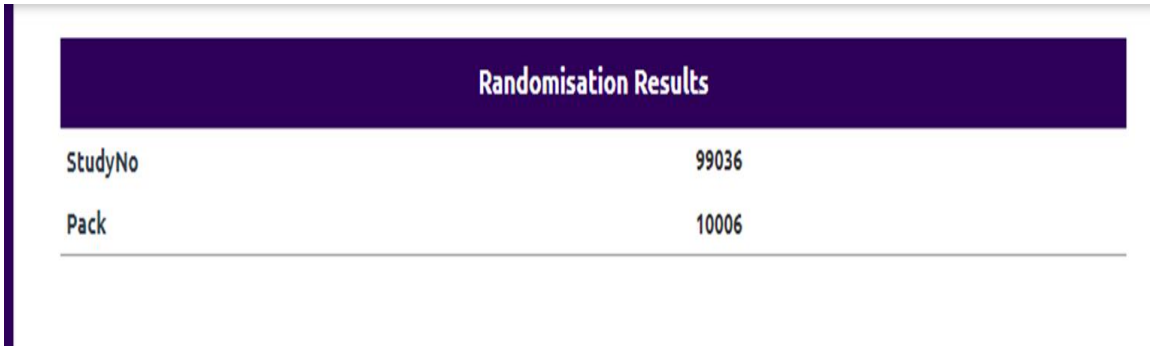
6. Click on the three lines in the top left corner and then consent, please complete the form and then save data.



7. Click on the three lines in the top left corner and then randomisation, please complete the form. The Date of birth and eligibility and consent answers will be populated from the previous forms. Click review data, please check it carefully and then click randomise



8. You will see the results and will also get an email with the randomisation results. Please print the email for the baby's notes



Randomisation Results	
StudyNo	99036
Pack	10006

9. If you are randomising a baby from a multiple birth you will need to enter the mother's date of birth.

   If you are randomising a baby from a multiple birth and it is the second or third baby to be randomised you will need the CHaRT ID number of the first baby to be randomised

10. If the correct Pack ID cannot be located, or the package is open, please report this to the trial manager, kotechasj@cardiff.ac.uk

11. Finally, please ensure the following:

- CHaRT ID will need to be recorded in the REDCap database. Please put the PID generated by REDCap on the consent form
- Screening log updated with the PID generated by REDCap

12. If CHaRT cannont be accessed pease email BALLOON@cardiff.ac.uk