Guidance Sheet 2:

Consent

Centre for Trials Research
Canolfan Ymchwil Treialon

Informed Consent

Who can take consent?

Consent may be carried out by any healthcare professional that has received BALLOON training and GCP training and is listed on the Site Delegation Log to take consent. However, please also check with your NHS organisation who may have more specific requirements.

The final assessment of eligibility of the infant for BALLOON must be confirmed by a delegated individual, as per the BALLOON Site Delegation Log, and documented in the infant's medical records.

1. Approach the parents to discuss the trial and provide a Parent Information Leaflet. Ensure they are aware that participation is voluntary, and that consent may be withdrawn at any time without explanation.
2. Allow sufficient time for parent(s) to consider their decision and arrange a follow-up meeting to answer questions. Sometimes several meetings are needed.
3. As soon as the parent(s) decide that their baby may participate in the trial, the Consent Form must be completed. Written consent must be obtained before a baby may be randomised.
4. Written consent must be obtained before a baby may be recruited to BALLOON. Only the mother or father, or person designated formally by legal process, may sign the consent form.
   - In law, unmarried fathers do not automatically have parental responsibility for their child, unless they are named on the birth certificate, or through a court order or parental responsibility agreement, this can be given to them.
   - In the case of twins or triplets, each baby must have a separate signed consent form and please indicate on the form the birth order of the baby (e.g. twin 1, triplet 3).
   - The BALLOON trial involves recording the mother's information, so the mother must provide written consent. The father may sign the consent form (if he is married to the mother, named on the birth certificate/have been granted parental responsibility through a court order or parental responsibility agreement), but the mother must also counter-sign to provide written consent.

- Where the mother is under 16 years of age, they may be approached for consent by the clinical team, if they are determined to be competent according to the Fraser Guidelines.
- If a parent's capacity to give informed, voluntary consent is in doubt, their infant should not be recruited.
- Where there is a disagreement amongst parents regarding the infant's participation, the infant should not be recruited.

Translator

If a translator is used to explain the study and obtain informed consent, this must be an adult who is unrelated to the parent (hospital translation services may be used), and this must be noted on the consent form.

Key points to discuss with parents:

• Ensure parents are aware that participation is voluntary and that they can change their consent at any time without giving a reason. If they decide not to participate, it will not affect their baby's current or future NHS treatment and care.

• Babies born very early have a higher risk of respiratory problems than babies born close to their due date.

• The study aims to find out if giving a daily spray of Bactek under the tongue can decrease the number of visits to the GP, A&E or hospital admissions for chest infections in premature babies when compared to premature babies who get a placebo (dummy) spray.

• The spray contains harmless dead bacteria.

• Bactek has been used in other studies in babies and children, including some who were born early, and does appear helpful, but not enough early babies have yet taken part in studies for us to be certain. We do not believe there are any important risks but like all medicines, there sometimes can be side-effects; these are uncommon, but we know that some babies may develop some tummy soreness or loose stools.

• Whilst there may not be any direct benefit in taking part, participation may help improve future care for babies.

Taking part

• Their baby will have an equal chance of being in either study group; treatment spray or dummy spray. Parents cannot choose which group they are in.

• Joining the study involves parents giving the spray daily to their baby until 12 months post estimated date of delivery.

• Parents will be asked to complete an App or paper diary.

• Parents are asked to provide information about whether they have given the spray or not. This can be done using the study app or by completing a paper diary.

• Parents are asked to take swabs when their baby has a viral illness.

Completion of Consent Form

As soon as the parent(s) decide that their baby may participate in the trial, the Consent Form should be completed, and the baby randomised. Whenever the baby's father signs the consent form, please ensure that the mother countersigns, as we need the mother's agreement to access her medical records. If mother signs the consent form first, there is no obligation to collect the father's signature, although the 2nd signature space provided can be used for this purpose.

Important points on completing the consent form

1) Add participant's Study ID from REDCap and NHS/CHI number to the consent form. Please ensure it is the baby's NHS/CHI number not the mother's

2) Please ensure the Parent initials all applicable boxes (not ticks) and then Prints, Signs and Dates the 'Name of Parent/Guardian' section. NOTE: The date section should NOT be pre-populated for the parent

3) The person taking the consent should also Print, Sign and Date in the 'Name of person taking consent' boxes

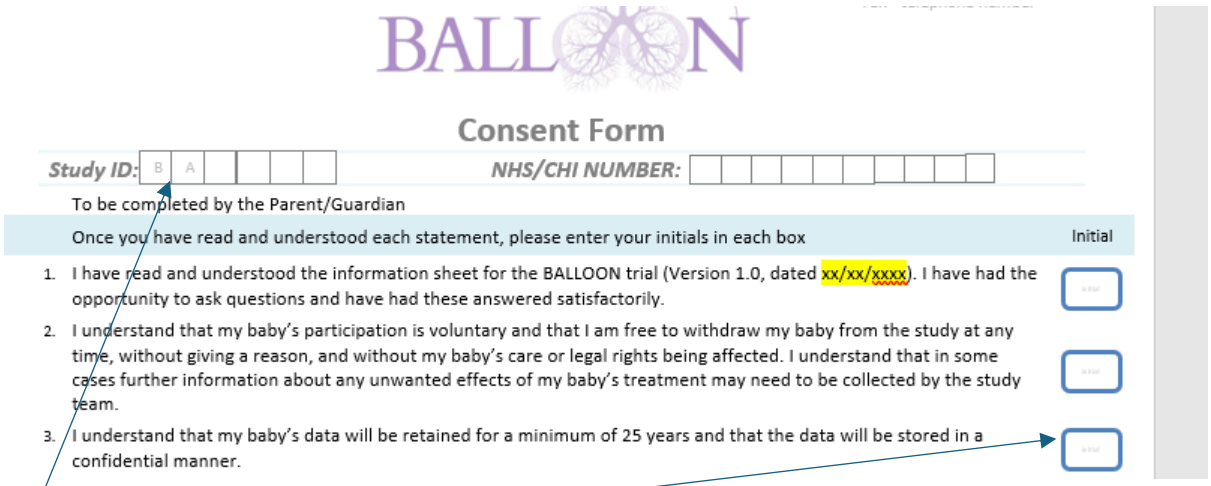
4) There are optional points on the BALLOON Consent Form, which relate to the optional sub studies and longer term follow up and also gifting samples. Whilst we would like parents to agree due to their importance, they are not mandatory for taking part in the BALLOON study. Please note not all sites will be undertaking the optional sub studies.

5) Please make two copies of the consent form after adding the Study ID and NHS/CHI number:

a. Email a copy to BALLOON@Cardiff.ac.uk. Please use an encrypted message as provided by your NHS organisation. Then, place a copy in the baby's clinical notes together with a copy of the Parent Information Leaflet.

b. a copy to the Investigator Site File

c. a copy to a parent



Consent Form

Study ID: B A NHS/CHI NUMBER:

To be completed by the Parent/Guardian

Once you have read and understood each statement, please enter your initials in each box	Initial
1. I have read and understood the information sheet for the BALLOON trial (Version 1.0, dated xx/xx/xxxx). I have had the opportunity to ask questions and have had these answered satisfactorily.	
2. I understand that my baby's participation is voluntary and that I am free to withdraw my baby from the study at any time, without giving a reason, and without my baby's care or legal rights being affected. I understand that in some cases further information about any unwanted effects of my baby's treatment may need to be collected by the study team.	
3. I understand that my baby's data will be retained for a minimum of 25 years and that the data will be stored in a confidential manner.	

Initial the boxes not tick

After consent obtain the study number from REDCap and write study number here.

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Below are optional statements:

10. <<OPTIONAL STATEMENT FOR CENTRES IN ANCILLIARY STUDIES>> I agree for my baby to have blood samples taken as part of the study for use in further research to find out how the Bactek worked.
11. I agree for my baby to have their lung function measured during the study.
12. I agree for my baby's follow up data on applicable databases (at this hospital, NHS digital/NHS Wales Informatics Service/ISD Scotland) to be reviewed by Cardiff University researchers.
13. I agree for me and my baby's GP to be contacted by Cardiff University for the purposes of following up when my baby

These optional statements can be left blank

Baby's name (please print): _____

Name of parent/guardian (please print): _____ Your signature: _____

Relationship to baby: _____ Date: _____

2nd Parent name, (please print): _____ Your signature: _____ Date: _____

Researcher name (please print): _____ Signature: _____ Date: _____

Differentiate between twins e.g. by writing BABY ONE