

Informed Consent Special

We've had two incidents in the last few months regarding consent, which have been reported to the study sponsor as potential serious breaches of GCP and protocol.

In both cases a baby was randomised into the trial before full written consent was taken and we wanted to use this as an opportunity to remind all teams of what counts as informed consent for PREVAIL. The examples below will probably be questions that you get asked quite frequently on your units so please feel free to pass this around your teams. If you have any other queries that we can help with please feel free to let us know! We should also remember that over 650 babies are now taking part in PREVAIL and the vast majority of consent forms have been completed perfectly and returned on time, so thank you once again for your hard work in making sure the consent process runs as smoothly as it has been.

I've spoken to the parents about the trial and they are happy to participate but they are no longer on the unit to sign the consent for and we need to put baby's line in. Can I confirm their verbal consent over the phone and sign the form later when they arrive?

No. Verbal consent is not acceptable for PREVAIL and written consent must be taken from the parent or guardian before entering the baby into the trial.

I've spoken to the parents and they wish for their child to participate but I can't find a consent form. Can I ask them to sign another document/sign elsewhere to confirm that they consent for their child?

No. Consent is only valid if it is recorded on the informed consent form that has been approved by our Ethics Committee.

In both the scenarios above the correct response would have been not to enter the child into the study. If the line required to be inserted urgently and you do not have time to get full consent from the parents then this baby should be recorded as a missed baby on Log B. It is a shame to miss eligible babies and we know that these situations can occur when you are actively trying to recruit as many patients as possible, which is excellent, but the GCP and protocol procedures regarding consent must be followed.

I spoke to the parents and they were interested in the trial. Later, another member of staff spoke with them and the parents signed the consent form, but the colleague speaking to them forgot to sign the researcher section. Can I/they add my/their signature retrospectively?

No. The consent form must be signed by the parent/guardian and a member of staff who is delegated to take consent at the same time. The form should not be signed retrospectively. If you notice that a colleague has forgotten to sign the consent form please let Chloe know ASAP and write a file note explaining the situation. Preventative actions will need to be discussed with the person who took consent.

We've also been made aware of other issues with consenting parents of twins or triplets.

I've spoken to the parents of twins/triplets and they are interested in the study but want their babies to receive the same allocation. Can I ensure the babies receive the same PICC?

No. The parents must understand at the time of consent that there is a chance their babies may not receive the same allocation and that you cannot choose what allocation to give them.

When we took consent the parents were happy with the idea of their twins/triplets receiving different allocations, but once they were randomised to receive different lines the parents over-ruled the doctors and insisted that both babies were given the same type of line. What do we do?

You should always make sure that parents of multiples understand that their babies may receive different lines before taking consent, however it is entirely possible that they may change their mind when faced with this situation even if they agree beforehand. In the scenario above you could still follow-up the infants as usual but make sure to record whether or not they received the correct allocation on Form 3. This situation should be discouraged as it could skew the numbers of babies receiving each allocation and therefore please discuss this possibility thoroughly with parents before randomising their babies.

Recruitment Progress

Site	Opening Date	Recruitment to 08/09/2016	Recruitment rate per week
Bradford Royal Infirmary	10/08/2015	72	1.30
Leicester Royal Infirmary	11/08/2015	68	1.23
The Jessop Wing	01/09/2015	45	0.86
Birmingham Women's Hospital	07/09/2015	50	0.97
Nottingham City Hospital	07/09/2015	24	0.46
Queen's Medical Centre	08/09/2015	22	0.43
The Royal London Hospital	18/09/2015	36	0.72
Royal Oldham Hospital	23/09/2015	41	0.83
Homerton Hospital	02/10/2015	51	1.06
Liverpool Women's Hospital	12/10/2015	46	0.98
Queen's Hospital, Romford	10/11/2015	20	0.47
Royal Preston Hospital	11/11/2015	30	0.70
St Michael's Hospital	01/12/2015	21	0.53
Royal Bolton Hospital	03/12/2015	32	0.81
Leeds General Infirmary	04/12/2015	27	0.69
Newham University Hospital	04/01/2016	8	0.23
St Mary's Hospital, Manchester	20/01/2016	41	1.25
John Radcliffe Hospital, Oxford	08/02/2016	28	0.93
Totals	Sites: 18	Recruitment: 662	Average: 0.80

The weekly recruitment rates are a good way of viewing your successes, and a rate of 0.6 babies per week would see you comfortably reaching the target of 30 per year. Several sites have achieved this milestone early and some 2 have even doubled it which is phenomenal– well done! We are currently recruiting 3 months ahead of target which is a brilliant achievement, so thank you. Please keep up all the hard work and if there is anything affecting your recruitment rate that you would like support with do not hesitate to let us know.