

Department of Neonatology
Simpson Centre for Reproductive Health
51 Little France Crescent
Edinburgh EH16 4SA

Tel: 0131 242 1665
[date]

Dr [name]
[address]

Dear Dr [name]

**Re: Patient participation in the COLLABORATE Study and Imaging Sub-Study
(REC Ref: XXXXX) (Lead Investigator: Professor James Boardman)**

I am writing to inform you that your patient, [child's name, DOB], has been recruited to the COLLABORATE study, a UK-wide randomised controlled trial that addresses two uncertainties in the care of extremely preterm infants; first, whether pasteurised human donor milk or preterm formula is the optimum supplement when there is a shortfall in own mother's milk; and second whether human milk feeds require routine macronutrient fortification. The primary outcome is survival without requiring surgery for necrotising enterocolitis at 34 weeks. We are recruiting preterm infants born at less than 29 weeks gestational age.

Your patient's parents consented for [him/her] to join the imaging sub-study while participating in COLLABORATE. Participation involves a brain MRI close to their due date to determine whether brain development is affected by the type of milk a baby receives when there is a shortfall in own mother's milk. More details can be found in the enclosed participant information sheet.

For the purpose of the study, the MRI primary outcome is computational and interpretable at group level. However, individual scans are reported by a paediatric radiologist. I am writing with reference to [child's name's] MRI results.

{delete paragraphs that are not applicable}

[Child's name] brain MRI shows a pattern of brain development that is common in preterm infants at term equivalent age and of unknown clinical significance. There were no incidental findings. There is no need for further action over and above the routine neurodevelopmental follow-up offered to all babies born at less than 29 weeks' gestation.

OR

[Child's name] brain MRI confirms features of preterm brain injury that were known about from cranial ultrasound scans carried out during routine care in the neonatal unit, which [his/her] parents are aware of. [Child's name] will be invited for neurodevelopmental follow-up, which is offered to all babies born at less than 29 weeks' gestation.

OR

[Child's name] brain MRI showed [INSERT]. This is a new incidental finding. It requires a further scan OR referral to [paediatric NHS services - specify] for further assessment. The research team has made this referral. [Child's name] parents have been informed about the incidental finding [and about referral to paediatric services - specify]. [Child's name] will be invited for neurodevelopmental follow-up, which is offered to all babies born at less than 29 weeks' gestation.

Please contact me if you have any questions about [child's name]'s participation in the research.

Yours sincerely,

Professor James Boardman