University of East Anglia

Our vision The best care for every patient

NHS Norfolk and Norwich University Hospitals NHS Foundation Trust

SOP 316 Distance (remote) Consenting for Children and Neonates in Research Studies

For Use in:	Jenny Lind Children's Hospital (including the Neonatal Intensive Care Unit), Research
By:	Consultant staff
For:	All staff involved in the conduct of research
Division responsible for document:	Paediatrics and Research & Development
Key words:	Distance (remote) consenting for children and neonates in research studies
Name of document author:	Kristian Bowles
Job title of document author:	Associate Medical Director for Research and Development, NNUH
Name of document author's Line Manager:	Bernard Brett
Job title of author's Line Manager:	Medical Director
Supported by:	Julie Dawson, Research Services Manager NNUH Paul Clarke, Consultant Neonatologist, NNUH
Assessed and approved by:	Julie Dawson, Research Services Manager NNUH Sarah Ruthven, Research Services Manager, UEA
Date of approval:	23/10/2023
To be reviewed before: This document remains current after this date but will be under review	23/10/2026 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	17534
Version No:	2

Version and Document Control:

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
2	October 2023	NA	Scheduled review Authors / signatories updated to reflect input into current version Rules - NHS to NHS emailing clarified Section 7 Consent form to be returned via secure email	Amy Nichols / Paul Clarke

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies downloaded from the website are only valid on the day of printing

SOP 316 Distance (remote) Consenting for Children and Neonates in Research Studies

1. Contents

2. Definitions of Terms Used / Glossary

GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
Neonate	New-born Child
NNUH	Norfolk and Norwich University Hospital
Parent(s)	Parents / Legal Guardians
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure

3. Objectives

Our standard practice is to consent parents / legal guardians (hereafter collectively referred to as 'parents') of children and neonates for entry into clinical studies following a face-to-face interview, discussion and question answering meeting, and with written consent taken in person by the local principal investigator or delegate following a suitable period of private consideration of the research and study information by parents.

On rare occasions, neonates and children are transferred to our tertiary care paediatric / neonatal departments but the parents are not physically able to travel to be with them or reach the hospital in time to meet trial recruitment deadlines. In order not to deprive those neonates, children, and their parents of the opportunities of clinical trial entry, we have developed a process for discussion and, where appropriate, taking informed consent of parents using the Trust approved method.

4. Scope

This SOP describes the process for seeking informed consent for a neonate or child to potentially enter a clinical trial, in circumstances where it is **not** possible for parents/legal guardians to come to the Norfolk and Norwich University Hospital to meet the

clinical/research team in person and in time to allow the usual face-to-face consenting discussions.

5. Purpose

This SOP describes the process by which we may potentially obtain valid written informed consent from the parents of a neonate or child, to allow their entry into a clinical study when the neonate / child is currently in or being transferred to our Hospital but one or both parents are at another hospital and cannot physically be with them in Norwich for a timely face-to-face meeting with the clinical / research team.

6. Rules

It is always preferable to arrange for the parents to come to the Hospital to discuss clinical trial entry and where appropriate sign consent on behalf of their child.

- This SOP is to be enacted ONLY when the NNUH Consultant Paediatrician/Neonatologist deems this to be not possible in a clinically relevant time frame.
- Justification for enacting this SOP MUST be documented in patients' medical and study notes.
- The person taking consent MUST have up to date GCP training and MUST have consenting recorded as a responsibility on the study delegation log.
- The video link MUST be via the Trust approved secure method; **AttendAnywhere** Refer to Trust Docs ID 17312 Guidelines for Video Consultation
- NHS.uk and NHS.net to NHS email MUST be used when sending e-mail communications that contain personal or patient identifying information.

7. Procedure

- NNUH consultant paediatrician / neonatologist has considered all possibilities to make arrangements for parents to come to the hospital for trial discussion +/- consent but has decided that the distance (remote) consent process covered in this SOP is necessary.

- Discussion and the decision to follow this SOP must be documented in the patient's medical and study notes. This must include the names of all personnel involved in the process

SOP 316 Distance (remote) Consenting for Children and Neonates in Research Studies

- Parent(s) will be sent all necessary trial documentation electronically (including patient information sheet and consent forms and any GDPR leaflet) and given sufficient time to consider these before the discussion.

- NNUH consultant paediatrician / neonatologist will then conduct the interview and discussion with the parent/s by video link, in lieu of a face-to-face interview.
- For the parent(s) presently in another hospital, a local consultant paediatrician or senior paediatric/neonatology specialty trainee with GCP training should also be present for the interview and discussion.

- Following the video discussion, the parent/s will then be given sufficient time in private to consider the trial and read the written information, before a scheduled follow-up video link.

- If trial entry is considered appropriate and the parent/s wish to proceed then they should sign the consent form in the presence of the witnessing local consultant paediatrician / senior paediatric / neonatology specialty trainee with GCP training.

- The local paediatrician / senior paediatric / neonatology specialty trainee must countersign as witness to confirm that in their view the parents have understood the details of the discussion.

- Both the witness and the remote PI conducting the consent discussions shall make and record their assessment of parental competence and mental capacity to make an informed decision.

- The local paediatrician/delegated person will then scan the consent form and return it to the NNUH consultant paediatrician/neonatologist via secure NHS to NHS email addresses.

- The remote local paediatrician / registrar will be asked to retain a copy of the signed form and send the original to the PI at NNUH as soon as possible.

- On receipt, the original partially signed consent form must then be completed with the PI's signature, and a copy of the fully signed form will be given to the parents at the earliest opportunity.

- Reaffirmation of consent to participation will also be obtained at the time of this first face-to-face meeting between PI (or delegate) and parents.

- All other processes will remain the same e.g. patient information sheet, storage of consent forms, adherence to latest version of the Trial protocol.

- In all cases of remote consenting conducted under the guidance of this SOP, full and detailed documentation of the process including names of all personnel involved must be recorded in the source documentation.

8. References and Related Documents

References	
Trust Docs ID 17312 Guidelines for Video Consultation	
SOP No.	**SOP Title**
SOP 310	Development of Participant Information Sheet and Informed Consent Form
SOP 315	Obtaining Written Informed Consent from Competent Adults in Clinical Trials

9. Approval

Author	Kristian Bowles
Role	Associate Medical Director for Research
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	24 October 2023 | 12:15 BST
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 50D5F3BEE2F04C1...
Date	13 November 2023 | 3:36 GMT

10. Training Implication

Training Implication	**Yes**
Actions required	• Additional training may be required • Matrix to be updated