Consent

Approaching Parents

Once an infant is identified as potentially eligible, their parent(s)/carer(s) may be approached to introduce TOAST Study. A Parent Information Leaflet (PIL) should be provided to parent(s)/carer(s) and they should be given the opportunity to consider the information, and ask questions to decide whether they would like to participate in the study. Study videos are also available on the TOAST website, which can be accessed via the QR code in the TOAST PIL. We recommend using your hospital translation and interpreting services to aid communication about the study where required.

Antenatal Approach

Parents may be given information about the study, but confirmation of eligibility and consent must be taken **after** the infant's first operative intervention.

Who can take consent?

Staff who have evidence of full GCP training, TOAST Study training, and are listed on the TOAST Delegation Log may take consent.

Who can give consent?

Where possible, both parents should be involved in the consent process. A parent with legal parental responsibility must sign the consent form in order for the infant to take part in TOAST Study.
Legal parental responsibility is currently defined as:

- the child's birth mother
- married or in a civil partnership with the child's birth mother
- listed on the birth certificate, has a parental responsibility agreement with the mother, or has a parental responsibility order from a court

Maternal Questionnaires

There is a separate section of the consent form for biological mothers to consent to complete maternal questionnaires. The baby may be recruited into the study before this separate section has been completed by the biological mother. The mother may decline participation for herself in the maternal questionnaires without this impacting consent for the baby's participation to the main study. The maternal questionnaires are sent at 6-month intervals, within the TOAST parent questionnaires.

When to consent?

In order to take part in the TOAST Study, consent must be given within 3 days of surgery (where day of surgery is day 0). Ideally, consent will be taken as soon as possible following surgery, while being mindful of the parent(s)/carer(s) emotional wellbeing.

How to consent?

Parent(s)/carer(s) should be aware that participation is voluntary and that they may withdraw consent at any time without giving a reason, and without this affecting the quality of their or their child's care. If they choose to discontinue the TOAST medication, they will be asked to continue providing data for the study – though they may choose to withdraw from this aspect too. Where available, parents can be directed to TOAST videos to aid understanding of the study.

GUIDANCE SHEET 4

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Consent

What if…

…parent(s)/carer(s) don't have a good understanding of English?

You can use your hospital translation and interpreting services to aid communication about the study. The study involves parents completing questionnaires at home, so it is important to ascertain whether the parent(s)/carer(s) have adequate support (e.g. from a family member who speaks English) to complete these questionnaires at home.

…the birth mother is under 16?

Birth mothers under 16 years of age may be approached for consent if determined to be competent according to the Gillick Guidelines.

…capacity to consent is in doubt?

Do not proceed with consent if the capacity of the consent-giver is in doubt. Discuss the case with your PI and/or local research team.

…there is disagreement between parents about their baby participating?

We would advise against proceeding with study enrolment where this is causing significant disagreement between parents.

…the infant is already enrolled in another trial?

Co-recruitment to other research studies must be agreed by the Chief Investigator(s). Studies that have been reviewed already can be found at www.npeu.ox.ac.uk/toast/clinicians/faqs. For all other studies please contact the TOAST Study team prior to consent for confirmation.

…a correction is needed on the consent form?

Any changes or corrections to the completed consent form must be completed according to GCP guidance. If unsure, speak to your local research team or contact the TOAST Study team.

Completing Consent Form

Please see the annotated consent form on page 3.

What next?

Once informed consent has been obtained, the infant can be randomised (please refer to **TOAST Guidance Sheet 5: Randomisation)**. The TOAST Randomisation website will issue a study ID number, which should then be written on the consent form. File a digital copy of the consent form in the electronic Investigator Site File, one copy in the infant's medical notes, give one copy to the consenting parent(s)/carer(s), and send one copy via secure document transfer to the TOAST Study team.

The pack ID number issued by the TOAST Randomisation website will refer to a pack of medication that you have in stock at your hospital (please refer to **TOAST Guidance Sheet 6: Pack Management and Pharmacy).**

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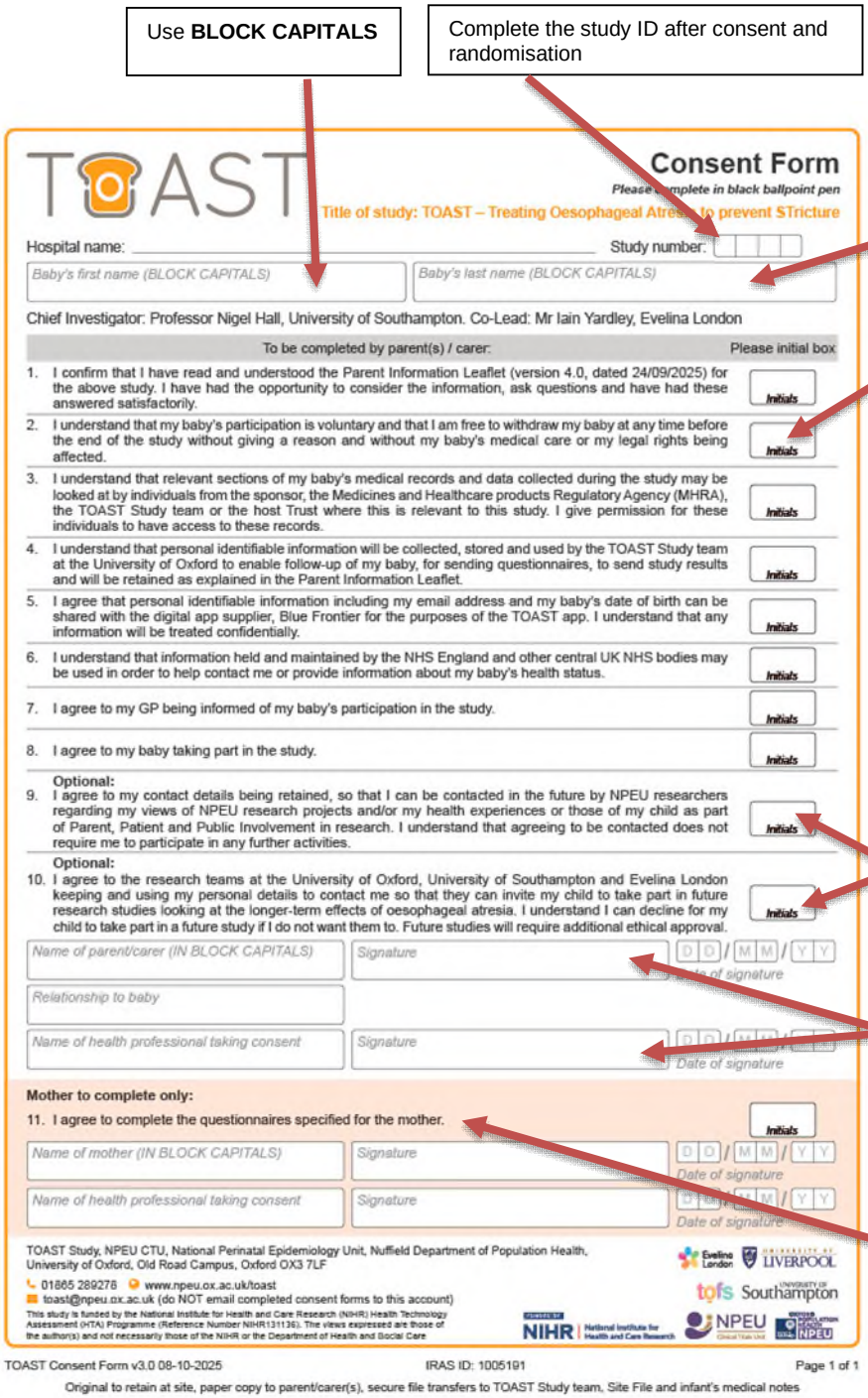
Consent



TOAST

Consent Form

Please complete in black ballpoint pen

Title of study: TOAST – Treating Oesophageal Atresia to prevent STricture

Hospital name: _____ Study number:

Baby's first name (BLOCK CAPITALS) | *Baby's last name (BLOCK CAPITALS)*

Chief Investigator: Professor Nigel Hall, University of Southampton. Co-Lead: Mr Iain Yardley, Evelina London

To be completed by parent(s) / carer:	Please initial box
1. I confirm that I have read and understood the Parent Information Leaflet (version 4.0, dated 24/09/2025) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Initials
2. I understand that my baby's participation is voluntary and that I am free to withdraw my baby at any time before the end of the study without giving a reason and without my baby's medical care or my legal rights being affected.	Initials
3. I understand that relevant sections of my baby's medical records and data collected during the study may be looked at by individuals from the sponsor, the Medicines and Healthcare products Regulatory Agency (MHRA), the TOAST Study team or the host Trust where this is relevant to this study. I give permission for these individuals to have access to these records.	Initials
4. I understand that personal identifiable information will be collected, stored and used by the TOAST Study team at the University of Oxford to enable follow-up of my baby, for sending questionnaires, to send study results and will be retained as explained in the Parent Information Leaflet.	Initials
5. I agree that personal identifiable information including my email address and my baby's date of birth can be shared with the digital app supplier, Blue Frontier for the purposes of the TOAST app. I understand that any information will be treated confidentially.	Initials
6. I understand that information held and maintained by the NHS England and other central UK NHS bodies may be used in order to help contact me or provide information about my baby's health status.	Initials
7. I agree to my GP being informed of my baby's participation in the study.	Initials
8. I agree to my baby taking part in the study.	Initials
Optional: 9. I agree to my contact details being retained, so that I can be contacted in the future by NPEU researchers regarding my views of NPEU research projects and/or my health experiences or those of my child as part of Parent, Patient and Public Involvement in research. I understand that agreeing to be contacted does not require me to participate in any further activities.	Initials
Optional: 10. I agree to the research teams at the University of Oxford, University of Southampton and Evelina London keeping and using my personal details to contact me so that they can invite my child to take part in future research studies looking at the longer-term effects of oesophageal atresia. I understand I can decline for my child to take part in a future study if I do not want them to. Future studies will require additional ethical approval.	Initials

Name of parent/carer (IN BLOCK CAPITALS) | *Signature* | D D / M M / Y Y *Date of signature*

Relationship to baby

Name of health professional taking consent | *Signature* | D D / M M / Y Y *Date of signature*

Mother to complete only:

11. I agree to complete the questionnaires specified for the mother. Initials

Name of mother (IN BLOCK CAPITALS) | *Signature* | D D / M M / Y Y *Date of signature*

Name of health professional taking consent | *Signature* | D D / M M / Y Y *Date of signature*

TOAST Study, NPEU CTU, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Old Road Campus, Oxford OX3 7LF

01865 289278 www.npeu.ox.ac.uk/toast

toast@npeu.ox.ac.uk (do NOT email completed consent forms to this account)

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Original to retain at site, paper copy to parent/carer(s), secure file transfers to TOAST Study team, Site File and infant's medical notes

Use **BLOCK CAPITALS**

Complete the study ID after consent and randomisation

Ensure all writing is legible, and details have transferred through all carbon copies of the form.

Read through the consent form with the parent and ask them to **initial** each statement.

Ensure all relevant boxes are initialled (**NOT TICKED**)

Statements 9 and 10 are optional in addition to the baby's participation in the main study.

Parent and professional sign and date the fields at the time of consent.

The professional must not pre-populate their details before consent is signed by the parent.

Only the biological birth mother can consent to statement 11, this can be completed at a later date.

GUIDANCE SHEET 4

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