Study Consent Form

Name of Principal Investigator: {First name} {Last name} {Centre Name}
Tel: {Number} **Email:** {Email}

Title of Project: Timing of Stoma Closure in Neonates (ToSCiN)

Name of Chief Investigator: Mr Nick Lansdale

Infant's details

Name **Date of Birth** D D / M M / Y Y

Infant's study number

Part 1: Patient Data Collection	Tick	Initial
1. I confirm that I have read and understood the information sheet (v3.0, 14 January 2021) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.		
2. I understand that their participation is voluntary and that I am free to withdraw my baby from the ToSCiN study at any time, without giving a reason.		
3. I understand this will not affect my baby's care in any way.		
4. I understand that relevant sections of my baby's medical notes and data collected during the study, may be looked at by individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to them taking part in this research. I give permission for these individuals to have access to these records.		
5. I agree to this information being stored by the study team for at least 25 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.		
6. I agree to my baby being involved in this part of the study.		

Part 2: Parental Interview	Tick	Initial
1. I confirm that I have read and understood the information sheet (v3.0, 14 January 2021) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.		
2. I agree to take part in an interview.		
3. I agree to the interview being audio recorded.		
4. I understand that my participation is voluntary and that I am free to withdraw from the ToSCiN study at any time, without giving a reason.		
5. I understand that brief quotations from some interviews may be included in study reports. I understand that nobody will be able to identify me or my child in these reports.		
6. I agree to data from my interview being stored by the study team for up to 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.		

Part 3: Future Correspondence	Tick	Initial
7. I would like to receive a summary of the findings at the end of the study.		
8. I would like to be contacted about any future related studies.		

Contact details (required to arrange interview and/or future correspondence)

Telephone number **Email address**

Parent Full Name: *Parent Signature:* D D / M M / Y Y

To be completed by Researcher once the parent has provided consent:

Researcher Full Name: *Researcher Signature:* D D / M M / Y Y

When completed, 1 (original) to be kept on record at the University of Oxford; 1 copy to be filed in the patient's notes; 1 copy to be given to the participant; and 1 copy to be filed in researcher site file

This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (project reference NIHR 128617). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Participant Consent Form

{Add researcher contact details) or Dr Kerry Woolfall
University of Liverpool, Block B, Waterhouse Building, Liverpool, L69 3GL
Tel: (ADD RA number) and 07872 963676
Email: K.Woolfall@liv.ac.uk

Title of Project: Timing of Stoma Closure in Neonates (ToSCiN)

Explain to the participant: **I will read 8 statements to you in order to obtain your consent for the study. Please answer yes or no to each statement. I will then complete the form and send you a copy for your records. Is that ok? (Researcher tick (✓) AND initial when participant says yes; if they do not agree leave blank).**

Is it ok with you if I audio record this consent taking for our records? **If Yes,** continue. **If No,** explain that we will not be able to proceed with the interview without recorded consent. (Thank the participant for their time – interview end)

	Tick	Initial
1. I confirm that I have read and understood the information sheet (v2.0, 03 December 2020) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐	
2. I agree to take part in an interview.	☐	
3. I agree to the interview being audio recorded.	☐	
4. I understand that my participation is voluntary and that I am free to withdraw from the ToSCiN study at any time, without giving a reason.	☐	
5. I understand that brief quotations from some interviews may be included in study reports. I understand that nobody will be able to identify me or my child in these reports.	☐	
6. I agree to data from my interview being stored by the study team for up to 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.	☐	
7. I would like to receive a summary of the findings at the end of the study.	☐	
8. I would like to be contacted about any future related studies.	☐	

Contact details (only needed if you have ticked and initialled statements 7 and/or 8)

Telephone number ☐☐☐☐☐☐☐☐☐☐☐ **Email address**

To be completed by the Researcher:

When was the participant sent the PIS? D D / M M / Y Y

I confirm this consent was taken verbally with the participant not physically present.	☐	
I confirm the participant is eligible for this involvement in the study.	☐	
I confirm that the participant has had the chance to ask questions and have these answered to their satisfaction.	☐	

Participant Full Name:

Today's date D D / M M / Y Y

To be completed by Researcher once the participant has provided consent:

Researcher Full Name: | *Researcher Signature:* | D D / M M / Y Y

When completed, 1 (original) to be kept on record at the University of Liverpool, 1 copy to be sent to the participant after the interview

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FUNDED BY NIHR | National Institute for Health Research

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Email: K.Woolfall@liv.ac.uk

Title of Project: Timing of Stoma Closure in Neonates (ToSCiN)

For online focus groups: please complete the consent form and return to the researcher before the scheduled focus group. Thank you.

For interviews only: **I will read 6 statements to you in order to obtain your consent for the study. Please answer yes or no to each statement. I will then complete the form and send you a copy for your records. Is that ok? (Researcher tick (✓) AND initial when participant says yes; if they do not agree leave blank). Is it ok with you if I audio record this consent taking for our records?**
If Yes, continue. **If No,** explain that we will not be able to proceed with the interview without recorded consent. (Thank the participant for their time – interview end)

	Tick	Initial
1. I confirm that I have read and understood the information sheet (v2.0, 03 December 2020) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	☐	
2. I agree to take part in an interview or focus group.	☐	
3. I agree to the interview/focus group being audio recorded.	☐	
4. I understand that my participation is voluntary and that I am free to withdraw from the ToSCiN study at any time, without giving a reason.	☐	
5. I understand that brief quotations from some interviews/focus groups may be included in study reports. I understand that nobody will be able to identify me in these reports.	☐	
6. I agree to data from my interview being stored by the study team for up to 10 years after the end of this study for checking purposes. I understand that these will be stored securely in compliance with the Data Protection Act 2018.	☐	

Participant Full Name:	*Participant Signature:*	D D / M M / Y Y

To be completed by Researcher once the participant has provided consent:

Researcher Full Name:	*Researcher Signature:*	D D / M M / Y Y

When completed, 1 (original) to be kept on record at the University of Liverpool, 1 copy to be sent to the participant after the interview

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