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08 February 2021

Dear Mr Lansdale

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Timing of Stoma Closure in Neonates (ToSCiN)**
IRAS project ID:	**278331**
REC reference:	**20/LO/1227**
Sponsor	**Manchester University NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **278331**. Please quote this on all correspondence.

Yours sincerely,

Georgia Copeland

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Ms Emma Columbine*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [ToSCiN interview social media ad]	1.0	04 November 2020
Initial Assessment for REC [Version 1]		10 November 2020
Interview schedules or topic guides for participants [Distress protocol for qualitative interviews]	1.0	18 August 2020
Interview schedules or topic guides for participants [Interview telephone number card]	1.0	06 October 2020
Interview schedules or topic guides for participants [ToSCiN Parent interview topic guide version 1.0 28.10.2020.pdf]	1.0	28 October 2020
Interview schedules or topic guides for participants [Parent interview topic guide]	2.0	20 November 2020
IRAS Application Form [IRAS_Form_11122020]		11 December 2020
IRAS Application Form XML file [IRAS_Form_11122020]		11 December 2020
IRAS Checklist XML [Checklist_19012021]		19 January 2021
Letter from funder [Letter from funder to CI - start-up letter]	1.0	02 September 2019
Letter from statistician [Letter from Statistician]	1.0	11 July 2020
Organisation Information Document [ToSCiN OID]	1.0	05 October 2020
Organisation Information Document [ToSCiN Organisation Information Document (Non-Commercial) v1.0 appendices completed.docx]		
Other [FW IRAS 278331 - response to VUC queries.msg]		28 October 2020
Other [ToSCiN Protocol TRACKED CHANGES]	2.0	03 December 2020
Other [Response to REC]	1.0	04 December 2020
Other [Chief Investigator Nick Lansdale GCP certificate]	1.0	15 September 2020
Other [Response to REC - revised application]	1.0	18 January 2021
Other [ToSCiN website content v2.0 - additional info for participants]	2.0	18 January 2021
Participant consent form [ToSCIN Study Interview Consent Form v1.0 - 07-Oct-2020 CHANGES COMMENTED]	1.0	07 October 2020
Participant consent form [ToSCiN consent form (main)]	2.0	03 December 2020
Participant consent form [ToSCiN consent form - main CHANGES COMMENTED]	1.0	07 October 2020
Participant consent form [ToSCiN consent form (interview only)]	2.0	03 December 2020
Participant consent form [ToSCiN consent form (practitioner)]	2.0	03 December 2020
Participant consent form [ToSCiN practitioner consent form - main CHANGES COMMENTED]	1.0	07 October 2020
Participant information sheet (PIS) [ToSCiN PIS (practitioner)]	2.0	03 December 2020
Participant information sheet (PIS) [ToSCiN Practitioner PIS - main CHANGES COMMENTED]	1.0	07 October 2020
Participant information sheet (PIS) [ToSCiN PIS (social media recruitment)]	2.0	03 December 2020
Participant information sheet (PIS) [ToSCiN PIS (social media recruitment) - CHANGES COMMENTED]	1.0	07 October 2020
Participant information sheet (PIS) [ToSCiN PIS (main)]	3.0	14 January 2021
Participant information sheet (PIS) [ToSCiN PIS - main v2.0 CHANGES COMMENTED]	2.0	03 December 2020
Research protocol or project proposal [ToSCiN Protocol]	2.0	03 December 2020

Schedule of Events or SoECAT [ToSCiN SOECAT]	1.0	26 March 2019
Summary CV for Chief Investigator (CI) [Nick Lansdale Curriculum Vitae]	1.0	01 July 2020

IRAS project ID	278331

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Please note that although the SoECAT submitted for this study has been authorised by an AcoRD Expert , HRA or HCRW sign off is for versioning only. This sign off does not constitute authorisation of the content of the SoECAT or confirmation that the cost attribution is appropriate.	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement

					checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.