Health Research Authority

London - Dulwich Research Ethics Committee
Health Research Authority
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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

05 January 2021

Mr Nick Lansdale
Consultant Paediatric and Neonatal Surgeon
Manchester University NHS Foundation Trust
Royal Manchester Children's Hospital
Oxford Road
Manchester
M13 9WL

Dear Mr Lansdale

Study title:	**Timing of Stoma Closure in Neonates (ToSCiN)**
REC reference:	**20/LO/1227**
IRAS project ID:	**278331**

Thank you for your letter of 14 December 2020, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair, Dr Thomas Kabir.

Confirmation of Ethical Opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good Practice Principles and Responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the Favourable Opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Number	Conditions
1	The Committee acknowledged the Consent Form contains a clause regarding regulatory authorities, but emphasised a line stating that regulatory authorities will have access to participant data does need to be included in the Participant Information Sheet so individuals can decide whether to consent or not.
2	The Committee emphasised that a line regarding there being no clinical interventions in the study is required in the Participant Information Sheet as it is not impossible that the children of parents will need medical care.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical Review of Research Sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved Documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [ToSCiN interview social media ad]	1.0	04 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_11122020]		11 December 2020
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
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 [Website content - additional info for participants]	1.0	03 December 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 consent form [ToSCIN Study Interview Consent Form v1.0 - 07-Oct-2020 CHANGES COMMENTED]	1.0	07 October 2020
Participant information sheet (PIS) [ToSCiN PIS (main)]	2.0	03 December 2020
Participant information sheet (PIS) [ToSCiN PIS - 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
Research protocol or project proposal [ToSCiN Protocol]	2.0	03 December 2020
Summary CV for Chief Investigator (CI) [Nick Lansdale Curriculum Vitae]	1.0	01 July 2020

Statement of Compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 278331 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

PP
Dr Thomas Kabir
Chair

Email: dulwich.rec@hra.nhs.uk

Copy to: Ms Emma Columbine