Health Research Authority

East Midlands - Nottingham 2 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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

04 December 2019

Miss Helen Sisson
Lecturer in Public Health
University of Hull
Faculty of Health Sciences
University of Hull
Cottingham Rd, Hull
HU67RX

Dear Miss Sisson

Study title:	**An investigation to determine if vaccinations are delayed in preterm infants, and the factors associated with vaccination timeliness in preterm infants.**
REC reference:	**19/EM/0351**
Protocol number:	**N/A**
IRAS project ID:	**209347**

The Research Ethics Committee reviewed the above application at the meeting held on 25 November 2019. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

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

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

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register 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/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

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/

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

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 taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS 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 documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]	n/a	24 September 2019
IRAS Application Form [IRAS_Form_08112019]		08 November 2019
IRAS Application Form XML file [IRAS_Form_08112019]		08 November 2019
IRAS Checklist XML [Checklist_08112019]		08 November 2019
IRAS Checklist XML [Checklist_12112019]		12 November 2019
Letter from sponsor [Sponsorship agreement]		19 July 2019
Research protocol or project proposal [Study protocol]	3	23 July 2019
Summary CV for Chief Investigator (CI) [CV]	1	23 July 2019
Summary CV for supervisor (student research) [Supervisor CV]	1	12 November 2019
Summary CV for supervisor (student research) [Supervisor CV]	1	12 November 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Data flow diagram]	v3	29 October 2019

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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/

19/EM/0351	**Please quote this number on all correspondence**

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

Yours sincerely

PP

Ms Bernadette Roberts
Chair

E-mail: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" [SL-AR2 for other studies]

Copy to: Dr Danielle Smith
Confidentiality Advise Team

Lead Nation England: HRA.Approval@nhs.net

East Midlands - Nottingham 2 Research Ethics Committee

Attendance at Committee meeting on 25 November 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Krishnan Anantharamakrishnan	Consultant Urological Surgeon	Yes	
Dr Joanne Cooper	Assistant Director of Nursing (Research, Innovation and Professional Regulation)	No	
Mr Daniel (Ben) Kennedy	Consultant Haematologist/Honorary Associate Professor	Yes	
Mr Jon Merrills	Barrister/Pharmacist	Yes	
Mrs Carla Richardson	Senior Clinical Trials Researcher	Yes	
Ms Bernadette Roberts	Retired Finance Manager	Yes	
Dr Ian Ross	Retired Consultant Physician	Yes	
Mr Nirav Shah	Trailblazer Muscular Dystrophy UK Volunteer	Yes	
Dr John Shaw	Retired Patent Licensing Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Danielle Bromage	Approvals Administrator
Mr David Parr	Approvals Officer
Ms Kelly Rowe	Approvals Manager