

London - Bloomsbury Research Ethics Committee

HRA RES Centre Manchester
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M1 3DZ

Telephone: 0207 104 8196

**Please note: This is an
acknowledgement letter from
the REC only and does not
allow you to start your study
at NHS sites in England until
you receive HRA Approval**

06 July 2018

Dr Chris Gale
Clinical Senior Lecturer and Consultant Neonatologist
Imperial College London
Section of Neonatal Medicine,
Imperial College London, Chelsea and Westminster Campus,
369 Fulham Road, London
SW10 9NH

Dear Dr Gale

Study title: WithHolding Enteral feeds Around packed red cell
Transfusion to prevent necrotising enterocolitis in
preterm neonates: a multi-centre, electronic patient
record (EPR), randomised controlled point-of-care pilot
trial

REC reference: 18/LO/0900

IRAS project ID: 154432

Thank you for your response. I can confirm the REC has received the documents listed below and

that these comply with the approval conditions detailed in our letter dated 15 June 2018

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other [WHEAT Pilot trial privacy notice]	1.0	05 July 2018
Participant information sheet (PIS) [WHEAT PIL Tracked]	2.0	26 June 2018
Participant information sheet (PIS) [WHEAT PIL]	2.0	26 June 2018

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [WHEAT Parent Poster]	1.0	24 April 2018
Covering letter on headed paper [Covering letter]	N/A	30 April 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [WHEAT sponsorship and insurance confirmation email 24.04.18]	N/A	24 April 2018
IRAS Application Form [IRAS_Form_30042018]		30 April 2018
Letter from funder [C Gale funding letter]	N/A	16 December 2015
Letter from sponsor [Sponsorship confirmation letter]	N/A	24 April 2018
Letter from statistician [Statistician covering letter v1.0 16.04.18]	1.0	16 April 2018
Other [Research ethics committee decision-making efficient neonatal trial BMJ C Gale Sept 16]		14 September 2016
Other [WHEAT screenshots badgerNet]	V1.0	03 April 2018
Other [WHEAT Pilot trial privacy notice]	1.0	05 July 2018
Participant information sheet (PIS) [WHEAT PIL]	2.0	26 June 2018
Participant information sheet (PIS) [WHEAT PIL Tracked]	2.0	26 June 2018
Referee's report or other scientific critique report [Peer Review Certificate C Gale fellowship]	N/A	09 April 2018
Research protocol or project proposal [WHEAT Protocol]	1.0	24 April 2018
Summary CV for Chief Investigator (CI) [Chris Gale CV]		03 April 2018
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Imperial College London Insurance Certificate 2017]	N/A	01 August 2017
Summary, synopsis or diagram (flowchart) of protocol in non-technical language [WHEAT Trial summary]	1.0	12 April 2018

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

18/LO/0900

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'Damilola Odunlami', is centered within a light gray rectangular box.

Damilola Odunlami
REC Assistant

E-mail: nrescommittee.london-bloomsbury@nhs.net

Copy to: Miss Becky Ward
Damon Foster , Chelsea And Westminster NHS Foundation Trust