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11 September 2019 Reissued 20 September 2019

Dear Professor Shennan

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

Study title:	**CRAFT: Cerclarge after full dilatation caesarean section; an investigation into the role of previous in labour caesarean section in future preterm birth risk and potential management strategies**
IRAS project ID:	**261294**
REC reference:	**19/LO/1270**
Sponsor	**Vice President & Vice Principal (Research), King's College London**

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 **261294**. Please quote this on all correspondence.

Yours sincerely,

Katherine Ashley
Approvals Specilaist

Email: hra.approval@nhs.net

Copy to: Elizabeth Bruna (Sponsor Contact), Guy's and St Thomas' Hospital NHS Foundation Trust

List of Documents

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

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [REC corrections]	2.0	10 September 2019
Covering letter on headed paper [HRA Cover letter]	v1.0	01 June 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [KCL Insurance cover]	v1.0	09 July 2018
GP/consultant information sheets or letters [CRAFT-RCT GP letter]	2.0	10 September 2019
GP/consultant information sheets or letters [CRAFT-IMG GP letter]	2.0	10 September 2019
GP/consultant information sheets or letters [CRAFT-OBS GP letter]	2.0	10 September 2019
IRAS Application Form [IRAS_Form_10092019]		10 September 2019
Letter from funder [JP Moulton Charity award letter]	1.0	29 January 2019
Letters of invitation to participant [CRAFT-IMG Consent form]	2.0	10 September 2019
Organisation Information Document [CRAFT Organisation Information Document]	1.0	17 June 2019
Participant consent form [CRAFT-OBS Consent form]	2.0	10 September 2019
Participant consent form [CRAFT-RCT Consent form]	2.0	10 September 2019
Participant information sheet (PIS) [CRAFT-RCT PIS]	2.0	10 September 2019
Participant information sheet (PIS) [CRAFT-OBS PIS]	2.0	10 September 2019
Participant information sheet (PIS) [CRAFT-IMG PIS]	2.0	10 September 2019
Referee's report or other scientific critique report [Letter of support from PPI]	1.0	19 March 2019
Research protocol or project proposal [CRAFT protocol]	2.0	10 September 2019
Schedule of Events or SoECAT	2	23 August 2019
Summary CV for Chief Investigator (CI) [Professor Andrew Shennan CV]	2.0	02 April 2019
Summary CV for student [Dr Agnieszka Glazewska-Hallin CV]		05 July 2019
Summary CV for supervisor (student research) [Dr Lisa Story Supervisor CV]		04 March 2019
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [KCL Employers Liability]	v1.0	01 August 2018

IRAS project ID	261294

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.	No study funding will be provided to sites as per the Organisational Information Document	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, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), 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. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

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.