

**London - Queen Square Research Ethics Committee**

HRA NRES Centre Bristol  
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Bristol  
BS1 2NT

**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**

11 September 2019

Dr Agnieszka Glazewska-Hallin  
Research Fellow and MD student  
King's College London  
Department of Women's and Children's Health  
10th Floor North Wing, St Thomas' Hospital  
Westminster Bridge Road  
SE1 7EH

Dear Dr Glazewska-Hallin

**Study title:** **CRAFT: Cerclage 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**

**REC reference:** **19/LO/1270**

**IRAS project ID:** **261294**

Thank you for your letter of 10/09/2019. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 27 August 2019

**Documents received**

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [REC corrections]	2.0	10 September 2019
GP/consultant information sheets or letters [CRAFT-RCT GP letter]	2.0	10 September 2019

GP/consultant information sheets or letters [CRAFT-OBS GP letter]	2.0	10 September 2019
GP/consultant information sheets or letters [CRAFT-IMG GP letter ]	2.0	10 September 2019
IRAS Application Form [IRAS_Form_10092019]		10 September 2019
Letters of invitation to participant [CRAFT-IMG Consent form]	2.0	10 September 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
Research protocol or project proposal [CRAFT protocol]	2.0	10 September 2019

### Approved documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
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
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

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.

**19/LO/1270**

**Please quote this number on all correspondence**

Yours sincerely

Katherine Ashley  
**Approvals Specialist**

E-mail: [nrescommittee.london-queensquare@nhs.net](mailto:nrescommittee.london-queensquare@nhs.net)

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