

Wales REC 3

Health and Care Research Wales Support and Delivery
Centre
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09 October 2018

Professor Julia Sanders
School of Healthcare Sciences,
College of
Biomedical and Life Sciences,
Cardiff University,
Room 1.7, Ty Dewi Sant
Heath Park
Cardiff CF14 4XN

Dear Professor Sanders

Study title: The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.

REC reference: 18/WA/0291

Protocol number: SPON1682-18

IRAS project ID: 238743

I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 September 2018

Documents received

The documents received were as follows:

Document	Version	Date
IRAS Checklist XML [Checklist_04102018]		04 October 2018
Other [POOL Poster]	1.0	03 October 2018
Other [POOL Leaflet]	1.0	03 October 2018
Other [Discussion group advert women]	1.0	01 October 2018
Other [Discussion group advert - Obstetricians]	1.0	01 October 2018
Other [Discussion group advert - Neonatologists and Paediatricians]	1.0	01 October 2018
Other [Discussion group advert - Midwives]	1.0	01 October 2018
Other [Screenshot of webpage with support weblinks]	1.0	02 October 2018
Participant information sheet (PIS) [Participant information sheet]	1.2	01 October 2018

Approved documents

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

Document	Version	Date
Contract/Study Agreement template [Model Non Commercial Agreement]	1	14 August 2018

Copies of advertisement materials for research participants [Opt Out Strategy]	0.2	06 June 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]	1	15 July 2017
Initial Assessment for REC		05 September 2018
IRAS Application Form [IRAS_Form_02082018]		02 August 2018
IRAS Checklist XML [Checklist_02082018]		02 August 2018
IRAS Checklist XML [Checklist_16082018]		16 August 2018
IRAS Checklist XML [Checklist_04102018]		04 October 2018
Letter from funder [Letter from funder]		03 January 2018
Letter from sponsor [Sponsorship Approval Letter]		06 July 2018
Other [Discussion group advert women]	1.0	01 October 2018
Other [Discussion group advert - Obstetricians]	1.0	01 October 2018
Other [Discussion group advert - Neonatologists and Paediatricians]	1.0	01 October 2018
Other [Discussion group advert - Midwives]	1.0	01 October 2018
Other [Screenshot of webpage with support weblinks]	1.0	02 October 2018
Other [POOL Poster]	1.0	03 October 2018
Other [POOL Leaflet]	1.0	03 October 2018
Participant consent form [Consent form]	1	18 May 2018
Participant information sheet (PIS) [Participant information sheet]	1.2	01 October 2018
Research protocol or project proposal [Protocol]	1	18 July 2018
Summary CV for Chief Investigator (CI) [CI Summary CV]		18 July 2018
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Sponsor Insurance]	1	15 July 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Lay Summary]	1	02 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.

18/WA/0291

Please quote this number on all correspondence

Yours sincerely

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