Subject	**IRAS 183040. Confirmation of Amendment Categorisation as Category B**
From	AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>
To	PRISM Trial Team <admin@prismtrial.org>
Cc	Amendments Research (BARTS HEALTH NHS TRUST) <Research.Amendments@bartshealth.nhs.uk>, r.pearse@qmul.ac.uk <r.pearse@qmul.ac.uk>, spnsorsrep@bartshealth.nhs.uk <spnsorsrep@bartshealth.nhs.uk>
Date	21/02/2017 10:17

Dear Mari-Liis,

IRAS Project ID:	183040
Short Study Title:	PRISM
Date complete amendment submission received:	10/02/2017
Amendment No./ Sponsor Ref:	Minor Amendment 5
Amendment Date:	10/02/2017
Amendment Type:	**Non-substantial**

Thank you for submitting the above referenced amendment. In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category B** - An amendment that has implications for, or affects, SPECIFIC participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England that are affected by this amendment.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales that are affected by this amendment, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the four conditions below, you will be able to implement the amendment at affected participating NHS organisations in England **35 days after you notify them of the amendment**. A template email to notify participating NHS organisations in England is provided here.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion where applicable, (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England that are affected by this amendment, plus to local research teams at any affected participating NHS organisations in Northern Ireland, Scotland or Wales*.
- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.
- For amendments adding new sites, you may not commence research activities at site until the nation specific processes to allow this are concluded, e.g. NHS Permission in Northern Ireland, Scotland or Wales and Confirmation of capacity and capability in England (if this amendment adds new sites in England, the HRA will shortly provide further information on expectations relating to their formal confirmation of capacity and capability).

Note: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below) after the 35 days have passed you may then immediately implement this amendment at all existing participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study. As above, the 35 days does not apply to opening new sites and nation specific processes should be followed.

For existing participating organisations, there is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards

Laura

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