

FW: IRAS PROJECT ID 183040, REC Reference 15/LO/1595 : Amendment acknowledgement and implementation information

Pakats, Mari-Liis

Mon 09/04/2018 10:25

To: Mari-Liis Pakats <m.pakats@qmul.ac.uk>

From: hra.amendments@nhs.net [mailto:noreply@harp.org.uk]
Sent: 02 March 2018 17:05
To: r.pearse@qmul.ac.uk; admin@prismtrial.org
Cc: spnsorsrep@bartshealth.nhs.uk
Subject: IRAS PROJECT ID 183040, REC Reference 15/LO/1595 : Amendment acknowledgement and implementation information

New Site Amendment, Implementation Information

Dear Professor Pearse

Thank you for submitting an amendment to add one or more new sites to your project

If you have listed new sites in any other UK nations we will forward the information to the national coordinating function(s) for nations where the new site(s) are being added. In Northern Ireland, Scotland and Wales, NHS/HSC R&D offices will be informed.

What Happens Next?

Please set up the new site(s) as per the guidance found within [IRAS](#). **Please note** that processes change from time to time so please use the most up to date guidance about site set up.

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

IRAS Project ID:	183040
Short Study Title:	PRISM
Date complete amendment submission received:	27/02/2018
Sponsor Amendment Reference Number:	Minor amendment 11
Sponsor Amendment Date:	15 February 2018
Amendment Type:	Non-substantial
For new sites in Northern Ireland, Scotland and/or Wales only:	Please start to set up your new sites. Sites may not open until NHS management permission is in place.
For new sites in England only:	<p>For studies which already have HRA Approval: This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).</p> <p>For studies which do not yet have HRA Approval: HRA Approval is pending and you will receive confirmation of HRA Approval. You can start the process of setting up the new site</p>

but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).

If you have any questions relating to setting up sites in England, please direct these to hra_approval@nhs.net.

If you have any questions relating to setting up sites in Northern Ireland, Scotland or Wales, please direct these to the relevant [national coordinating function](#).

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

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

Kind regards

Mr Ali Hussain
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