

IRAS 92703. Amendment confirmation of REC Validation, categorisation and implementation information (Reissued with correct IRAS ID)

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Fri 10/08/2018 10:08

To:REGISTRYTEAM, Uk-Itp (BARTS HEALTH NHS TRUST) <uk-ity.registryteam@nhs.net>;

Cc:NRSPCC, Nhsg (NHS GRAMPIAN) <nhsgr.nrspcc@nhs.net>; research.amendments@hscni.net <research.amendments@hscni.net>;

Categories: Green Category

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear ,

IRAS Project ID:	92703
Short Study Title:	United Kingdom Adult ITP Registry
Date complete amendment submission received:	13 July 2018
Amendment No./ Sponsor Ref:	Substantial Amendment 6
Amendment Date:	18 May 2018
Amendment Type:	Substantial
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment will be separately confirmed by email.
Implementation date in NHS organisations in England and/or Wales	35 days from date amendment information together with this email, is supplied to participating organisations (provided HRA and HCRW Approval for the amendment is in place and conditions are met)
Implementation date in NHS/HSC organisations in Northern Ireland and/or Scotland	17 August 2018 (providing conditions are met)
For NHS/HSC R&D Office information	
Amendment Category	A

Thank you for submitting an amendment to your project. We have now categorised your amendment and please find this, as well as other relevant information, in the table above.

What should I do next?

Please read the information in [IRAS](#), which provides you with information on how and when you can implement your amendment at NHS/HSC sites in each nation, and [what actions you should take now](#).

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment please note that **we will** forward the amendment submission to the relevant national coordinating function(s).

If not already provided, please email to us any regulatory approvals (where applicable) once available. Your amendment will be reviewed by the REC, as per the attached letter.

When can I implement this amendment?

You may implement this amendment in line with the information in [IRAS](#). Please note that you may only implement changes described in the amendment notice.

Who should I contact if I have further questions about this amendment?

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any other questions about this amendment please contact the relevant national coordinating centre for advice:

- England – hra.amendments@nhs.net
- Northern Ireland – research.gateway@hscni.net
- Scotland – nhsg.NRSPCC@nhs.net
- Wales – research-permissions@wales.nhs.uk

Additional information on the management of amendments can be found in the [IRAS guidance](#).

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

Kind regards

Ashley Totenhofer

Technical Assurance Officer

Health Research Authority

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E. hra.amendments@nhs.net

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