

Foster, Bethany

From: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>
Sent: 03 March 2017 11:06
To: ATM, Resource
Cc: Sponsorship Resource; Kearney, Rebecca; ceri.jones@uhcw.nhs.uk
Subject: IRAS 187315. Confirmation of Amendment Categorisation as Category C

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Dr. Joanne O'Beirne-Elliman,

IRAS Project ID:	187315
Short Study Title:	Achilles Tendinopathy Management
Date complete amendment submission received:	22/02/2017
Amendment No./ Sponsor Ref:	6
Amendment Date:	15/02/2017
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 C - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

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

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 Greenfield



Laura Greenfield | Amendments Coordinator
Health Research Authority

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