

Griffin, Ryan

From: hra.amendments@nhs.net <noreply@harp.org.uk>
Sent: 24 October 2018 09:53
To: Quenby, Siobhan
Cc: hra.amendments@nhs.net; R&Dsponsorship@uhcw.nhs.uk; Harris, Kirsten
Subject: IRAS Project ID 229163. HRA Approval for the Amendment

Follow Up Flag: Follow up
Flag Status: Completed

Dear Professor Quenby,

IRAS Project ID:	229163
Short Study Title:	The 'Big Baby Trial'
Amendment No./Sponsor Ref:	AM02
Amendment Date:	18 September 2018
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment. The main PIS and Site Investigator Interviews PIS were both updated following the REC Favourable Opinion for this amendment to ensure compliance with the GDPR transparency requirement. Both documents and version 3.1 and dated 15 October 2018.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation email.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Helen Penistone

Assessor

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E. hra.amendments@nhs.net

W. www.hra.nhs.uk

Sign up to receive our newsletter [HRA Latest](#).

