



Confirmation of amendment 26th March 2018

DALES study IRAS 232512

Please find below the correspondence pertaining to the amendment application made to the HRA relating to the Protocol, Patient Information Leaflet, Waiting Area Poster, patient and anaesthetist survey and additional sites/ PIs added on the 26th March 2018.

The HRA have been contacted about further confirmation that these minor amendments were approved at that time. The HRA has stated that the correspondence below and the letter already available as the HRA amendment letter in the amendments section of the DALES file downloads (found at <https://www.raftrainees.com/dales-files.html>) is the extent of their usual confirmation and are unwilling to provide further written evidence of these amendments having been approved. This is in line with their normal practice.

However, the point of contact at the HRA is happy to be contacted to confirm queries about this. The HRA amendments section of the Dales documents includes the HRA amendment document and the list of sites approved to take part in DALES by the HRA on the 26th March 2018 also appears here. Please note that we will not be publishing lists of PI names.

In addition, please see the below email trail of correspondence pertaining to this amendment application.

1. Email to the HRA detailing the amendment application:

From: SAVIC, Louise (LEEDS TEACHING HOSPITALS NHS TRUST)
Sent: 26 March 2018 14:23
To: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)
Subject: IRAS Study 232512

Dear HRA,

This study has been approved any the REC and HRA previously, but we wish to make some non-substantial amendments. as follows:

1. Minor changes to the Protocol, Patient Information Leaflet and Waiting Area Poster. Most recent versions are now Protocol v3.4, Patient Information Leaflet v2.1, Waiting Area Poster v 2.1.
2. Minor changes to the patient and anaesthetist surveys (these are added as word documents with tracked changes, for ease)

2. Receipt of email by the HRA

From: "AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)"

Date: 26 March 2018 at 15:23:14 CEST

To: "SAVIC, Louise (LEEDS TEACHING HOSPITALS NHS TRUST)"

Subject: Automatic reply: IRAS Study 232512

Thank you for your email to the HRA Amendments team. We acknowledge and confirm receipt of your email.

3. Letter of confirmation from the HRA

Dear Dr Savic

Further to the below, I am pleased to confirm HRA Approval for the referenced amendment. You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

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

Kind regards Maeve Maeve Ip Groot Bluemink Assessor Health Research Authority Bristol HRA

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Subject: IRAS 232512. Amendment categorisation and implementation information