HORIZONS

From: LANCASTER, NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY) <nrescommittee.northwest-lancaster@nhs.net>
Sent: 15 March 2017 10:18
To: Foster C.L.; HORIZONS; NRSPCC, Nhsg (NHS GRAMPIAN)
Cc: sharon.davies-dear@uhs.nhs.uk
Subject: IRAS 202342. Confirmation of REC Validation and Categorisation of Amendment
Attachments: 16.NW.0425 ack amend 4.pdf

Dear Professor Foster,

IRAS Project ID:	**202342**
REC Reference:	**16/NW/0425**
Short Study Title:	**HORIZONS: Understanding the impact of cancer diagnosis and treatment**
Date complete amendment submission received:	**10 March 2017**
Amendment No./ Sponsor Ref:	**4**
Amendment Date:	**27 February 2017**
Amendment Type:	**Substantial**

Thank you for submitting the above referenced amendment. I am pleased to confirm that this amendment has been submitted to the REC for ethical review. Please find attached a copy of the validation letter.

Categorisation of Amendment

In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category A -** An amendment that has implications for, or affects, ALL participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the three conditions below, you will be able to implement the amendment at your participating NHS organisations in England **35 days after you notify them of the amendment.** A template email to notify participating NHS organisations in England is provided here.

Subject to the same three conditions, you will be able to implement your amendment at participating NHS organisations in Northern Ireland, Scotland or Wales on 14 April 2017.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion, (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England, plus to local research teams at any participating NHS organisations in Northern Ireland, Scotland or Wales*.

- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.

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

If you receive required regulatory approvals (for participating organisations in England, this includes confirmation that the amendment has been granted HRA Approval) after the 35 days have passed, you may then immediately implement this amendment at all participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study.

There is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

* Where the study involves NHS organisations in Northern Ireland, Scotland or Wales, the HRA will forward regulatory approvals to the relevant national coordinating function to distribute to their research management support offices.

BW

Carol

Carol Ebenezer | REC Manager
Health Research Authority
3rd Floor

Barlow House

4 Minshull St

Manchester

M1 3HY
E: nrescommittee.northwest-preston@nhs.net | T: 02071048008 | www.hra.nhs.uk

IMPORTANT – **Click here** for the latest details of the roll-out of HRA Approval in England

The HRA is keen to know your views on the service you received – our short feedback form is available **here**