

From: Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
<nrescommittee.northwest-lancaster@nhs.net>
Sent: 11 October 2016 14:36
To: Horizons
Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.
Subject: RE: HORIZONS SA2 16/NW/0425 202342
Attachments: 16.NW.0425 fav Amend 2.pdf

Categories: Actioned, Amber, To print

Please find below the re-categorisation email.

Best Wishes

Zainab



Zainab Ahmed | REC Assistant
NRES Committee North West – Lancaster
NRES Committee North West – Liverpool Central
NRES Committee North West – Preston

Health Research Authority- HRA NRES Centre Manchester
3rd Floor, Barlow House
Minshull Street
Manchester M1 3DZ
Email: Zainab.Ahmed@nhs.net | T: 0207 104 8019
www.hra.nhs.uk

IMPORTANT – [Click here](#) for details of significant changes in Spring 2014 to the REC booking and submission process

The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

From: Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
Sent: 11 October 2016 14:35
To: 'Horizons'
Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.
Subject: RE: HORIZONS SA2 16/NW/0425 202342

Dear Prof 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:	23 rd September 2016
Amendment No./ Sponsor Ref:	2
Amendment Date:	23 rd September 2016
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 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, this includes receiving confirmation of HRA Approval for the amendment).

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.

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

Kind regards

NAME: Person undertaking categorisation

JOB TITLE



Health Research Authority

HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH

E: hra.amendments@nhs.net

www.hra.nhs.uk

The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

From: Horizons [<mailto:horizons@soton.ac.uk>]

Sent: 11 October 2016 14:27

To: amendments hra (HEALTH RESEARCH AUTHORITY)

Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.; Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)

Subject: RE: HORIZONS SA2 16/NW/0425 202342

Dear HRA amendments team,

As below and attached I have requested consideration of a re-categorisation of our amendment to HORIZONS 202342 by the REC assistant, but have not had a response. The documents covered in this amendment will be sent directly from the Coordinating Centre to participants, so will not involve sites. we therefore would like to request this amendment is categorised as C, rather than A. please could you advise if this will be reviewed.

With many thanks and best wishes,

Becci Petch

Macmillan Survivorship Research Group Trial Coordinator,

Faculty of Health Science, Building 67, Room 2011, University of Southampton, Southampton, SO17 1BJ

Email R.A.Petch@soton.ac.uk WEB: www.southampton.ac.uk/msrg

MSRG

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From: Horizons

Sent: 03 October 2016 11:18

To: 'Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)'

<nrescommittee.northwest-lancaster@nhs.net>

Cc: 'Sharon Davies-Deard (sharon.davies-dear@uhs.nhs.uk)' <sharon.davies-dear@uhs.nhs.uk>; Foster C.L. <C.L.Foster@soton.ac.uk>

Subject: RE: HORIZONS SA2 16/NW/0425 202342

Dear Zainab,

Thank you for sending through the favourable opinion for SA2 from the REC. I wondered if you would be able to let me know whether our re-categorisation request, sent 27th September and attached for reference, from A to C is being considered?

Best wishes,

Becci Petch

Macmillan Survivorship Research Group Trial Coordinator,
Faculty of Health Science, Building 67, Room 2011, University of Southampton, Southampton, SO17 1BJ
Email R.A.Petch@soton.ac.uk WEB: www.southampton.ac.uk/msrg



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From: Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
[<mailto:nrescommittee.northwest-lancaster@nhs.net>]

Sent: 03 October 2016 10:17

To: Horizons <horizons@soton.ac.uk>

Cc: 'Sharon Davies-Deard (sharon.davies-dear@uhs.nhs.uk)' <sharon.davies-dear@uhs.nhs.uk>; Foster C.L. <C.L.Foster@soton.ac.uk>

Subject: RE: HORIZONS SA2 16/NW/0425 202342

Please find attached the committees decision to your substantial amendment.

Kind Regards

Zainab



Zainab Ahmed | REC Assistant
NRES Committee North West – Lancaster
NRES Committee North West – Liverpool Central
NRES Committee North West – Preston

Health Research Authority- HRA NRES Centre Manchester
3rd Floor, Barlow House
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Manchester M1 3DZ
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From: Horizons [<mailto:horizons@soton.ac.uk>]
Sent: 23 September 2016 08:52
To: Lancaster NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.; Horizons
Subject: HORIZONS SA2 16/NW/0425 202342

Dear Carol,

Please find attached the documents relating to substantial amendment 2 for HORIZONS 16/NW/0425 which the North West Lancaster REC gave favourable opinion to on 20/06/2016.

- HORIZONS 202342 REC 16.NW.0425 amendment 2 cover letter
- HORIZONS 202342 3 month questionnaire v1.0 BREAST
- HORIZONS 202342 3 month questionnaire v1.0 CERVICAL
- HORIZONS 202342 3 month questionnaire v1.0 ENDOMETRIAL
- HORIZONS 202342 3 month questionnaire v1.0 NHL
- HORIZONS 202342 3 month questionnaire v1.0 OVARIAN
- HORIZONS 202342 SA 2 Notification of amendment form
- HORIZONS 202342 Matrix of measures used v1.0

We look hearing the response from the REC and if you have any queries please don't hesitate to contact us.

Best wishes,

Becci Petch

Macmillan Survivorship Research Group Trial Coordinator,
Faculty of Health Science, Building 67, Room 2011, University of Southampton, Southampton, SO17 1BJ
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