

HORIZONS

From: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)
<hra.amendments@nhs.net>
Sent: 29 March 2017 16:00
To: HORIZONS
Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.
Subject: RE: HORIZONS SA4 16/NW/0425 202342 - Amendment assessment outcome

Dear Becci,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

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

Yours sincerely,
Simon



Simon Connolly | Senior Assessor

Health Research Authority

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E: simon.connolly1@nhs.net | T: 020 7972 2552

Would you like to receive the latest updates on HRA work? Sign up [here](#)

For more information on the HRA Approval process [Click here](#)

From: LANCASTER, NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
Sent: 16 March 2017 11:30
To: 'HORIZONS'; 'nhsg.NRSPCC@nhs.net'
Cc: 'Sharon Davies-Dear (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.
Subject: RE: HORIZONS SA4 16/NW/0425 202342

Dear Becci,

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

I am pleased to confirm that this amendment has been reviewed by the REC and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that this amendment will be assessed by the HRA to confirm that it meets the expected criteria and standards. An Assessor from the HRA will contact you, and you will receive separate notification that the HRA Assessment is complete. You should not implement this amendment at participating NHS organisations in England until the outcome of the HRA assessment is confirmed, and the conditions detailed in the categorisation section above have been met.

If you require further information, please contact hra.amendments@nhs.net


Carol



Carol Ebenezer | REC Manager

Health Research Authority

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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](#)

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

Sent: 10 March 2017 12:06

To: LANCASTER, NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)

Cc: HORIZONS; 'Sharon Davies-Deer (sharon.davies-dear@uhs.nhs.uk)'; Foster C.L.

Subject: HORIZONS SA4 16/NW/0425 202342

Dear Carol,

Please find attached the documents relating to substantial amendment 4 for HORIZONS 16/NW/0425 which the North West Lancaster REC gave favourable opinion to on 20/06/2016.

Documents submitted for substantial amendment 4;

Contents of HORIZONS Baseline Questionnaires

HORIZONS 202342 baseline Q v1.0 BREAST [tracked] 07/07/2016

HORIZONS 202342 baseline Q v2.0 BREAST [clean] 27/02/2017

HORIZONS 202342 baseline Q v1.0 CERVICAL [tracked from gynae v1.0] 07/07/2016

HORIZONS 202342 baseline Q v2.0 CERVICAL [clean] 27/02/2017

HORIZONS 202342 baseline Q v1.0 ENDOMETRIAL [tracked from gynae v1.0] 07/07/2016

HORIZONS 202342 baseline Q v2.0 ENDOMETRIAL [clean] 27/02/2017

HORIZONS 202342 baseline Q v1.0 OVARIAN [tracked from gynae v1.0] 07/07/2016

HORIZONS 202342 baseline Q v2.0 OVARIAN [clean] 27/02/2017

HORIZONS 202342 baseline Q v1.0 NHL [tracked] 07/07/2016

HORIZONS 202342 baseline Q v2.0 NHL [clean] 27/02/2017

Contents of HORIZONS 3month Questionnaires

- HORIZONS 202342 3 mo Q v1.0 BREAST [tracked] 21/09/2016
- HORIZONS 202342 3 mo Q v2.0 BREAST [clean] 27/02/2017
- HORIZONS 202342 3 mo Q v1.0 CERVICAL [tracked] 21/09/2016
- HORIZONS 202342 3 mo Q v2.0 CERVICAL [clean] 27/02/2017
- HORIZONS 202342 3 mo Q v1.0 ENDOMETRIAL [tracked] 21/09/2016
- HORIZONS 202342 3 mo Q v2.0 ENDOMETRIAL [clean] 27/02/2017
- HORIZONS 202342 3 mo Q v1.0 OVARIAN [tracked] 21/09/2016
- HORIZONS 202342 3 mo Q v2.0 OVARIAN [clean] 21/09/2016
- HORIZONS 202342 3 mo Q v2.0 NHL [clean] 27/02/2017
- HORIZONS 202342 3 mo Q v1.0 NHL [tracked] 21/09/2016

Contents of HORIZONS 9month Questionnaires

- HORIZONS 202342 9 mo Q v1.0 BREAST
- HORIZONS 202342 9 mo Q v1.0 CERVICAL
- HORIZONS 202342 9 mo Q v1.0 ENDOMETRIAL
- HORIZONS 202342 9 mo Q v1.0 OVARIAN
- HORIZONS 202342 9 mo Q v1.0 NHL

- HORIZONS flyer for online completion of questionnaires v1.0 270217
- HORIZONS - Online questionnaire email text V1.0 23.02.2017
- HORIZONS 202342 SA 4 Notification of amendment form
- HORIZONS IRAS Form 202342 SA4 additional sites
- HORIZONS IRAS Form 202342 SA4 London sites

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

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