

Dear Amber,

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](mailto:hra.amendments@nhs.net) for any queries relating to the assessment of this amendment.

Yours sincerely,  
HRA Amendments

**Helen Penistone**

**Assessor**

**Health Research Authority**

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

**Sent:** 30 June 2017 14:58

**To:** Horizons ([horizons@soton.ac.uk](mailto:horizons@soton.ac.uk)); Cole A.B. ([A.B.Cole@soton.ac.uk](mailto:A.B.Cole@soton.ac.uk)); [C.L.Foster@soton.ac.uk](mailto:C.L.Foster@soton.ac.uk)

**Subject:** RE: HORIZONS SA5 16/NW/0425 202342

Dear Amber,

<b>IRAS Project ID:</b>	<b>202342</b>
<b>REC Reference:</b>	<b>16/NW/0425</b>
<b>Short Study Title:</b>	<b>HORIZONS: Understanding the impact of cancer diagnosis and treatment</b>
<b>Date complete amendment submission received:</b>	<b>29 June 2017</b>
<b>Amendment No./ Sponsor Ref:</b>	<b>5</b>
<b>Amendment Date:</b>	<b>23 June 2017</b>
<b>Amendment Type:</b>	<b>Substantial</b>

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](mailto:hra.amendments@nhs.net)

  
*Carol*



Carol Ebenezer | REC Manager  
**Health Research Authority**

3<sup>rd</sup> Floor  
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E: [nrescommittee.northwest-preston@nhs.net](mailto:nrescommittee.northwest-preston@nhs.net) | T: 02071048008 |  
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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:** 29 June 2017 09:55

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

**Cc:** Horizons

**Subject:** HORIZONS SA5 16/NW/0425 202342

Dear Carol,

Please find attached the documents relating to substantial amendment 5 for HORIZONS 16/NW/0425 which the North West Lancaster REC gave favourable opinion to on 20/06/2016.

**Documents submitted for substantial amendment 5;**

HORIZONS Protocol V3 19.06.2017 Clean.pdf

HORIZONS Protocol V3 19.06.2017 Tracked Changes.pdf

HORIZONS - PIS V2.0 19.06.2017.pdf

HORIZONS - PIS V2.0 19.06.2017 Tracked Changes.pdf

HORIZONS – Full Consent Form V2.0 19.06.2017.pdf

HORIZONS – Full Consent Form V2 19.06.2017 Tracked changes.pdf

HORIZONS Participant Letter Questionnaire Timepoints V1.0 19.06.2017.pdf  
HORIZONS Participant Letter Reduced Consent V1.0 19.06.2017.pdf  
HORIZONS Follow up online questionnaire letter V1.0 09.06.2017.pdf  
HORIZONS - Patient Invitation Letter V2.0 19.06.2017.pdf  
HORIZONS - Patient Invitation Letter V2.0 19.06.2017 Tracked.pdf  
HORIZONS GP Letter V2.0 19.06.2017.pdf  
HORIZONS GP Letter V2.0 19.06.2017 Tracked Changes.pdf  
HORIZONS Flyer for waiting room V2.0 19.06.2017 Clean.pdf  
HORIZONS Flyer for waiting room V2.0 19.06.2017 Tracked Changes.pdf  
HORIZONS Flyer for patient pack V2.0 19.06.2017 Clean.pdf  
HORIZONS Flyer for patient pack V2.0 19.06.2017 Tracked Changes.pdf  
HORIZONS Decliners Log NHL V1.0 19.06.2017.pdf (for reference regarding the removal of the demographic form however this will not be a patient facing document)

HORIZONS 202342 12 Month Questionnaire Breast V1.0.pdf  
HORIZONS 202342 12 Month Questionnaire NHL V1.0.pdf  
HORIZONS 202342 12 Month Questionnaire Cervical V1.0.pdf  
HORIZONS 202342 12 Month Questionnaire Endometrial V1.0.pdf  
HORIZONS 202342 12 Month Questionnaire Ovarian V1.0.pdf  
Contents of HORIZONS 12 month Questionnaires.pdf  
HORIZONS 202342 SA 5 Notification of amendment form.pdf  
HORIZONS 202342 SA 5 REC Cover Letter

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

Best wishes,

**Amber Cole**

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Some of our research in film: [www.southampton.ac.uk/crewfilm](http://www.southampton.ac.uk/crewfilm)

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