

Danny Wong

Subject: IRAS 154486. Confirmation of HRA Amendment Assessment

From: "FAIRMAN, Thomas (HEALTH RESEARCH AUTHORITY)"
<thomas.fairman@nhs.net>

Subject: RE: IRAS 154486. Confirmation of HRA Amendment Assessment

Date: 13 December 2016 12:36:50 GMT+03:00

To: Danny Wong <DWong@rcoa.ac.uk>

Cc: "rmoonesinghe@gmail.com" <rmoonesinghe@gmail.com>,
"RandD@uclh.nhs.uk" <RandD@uclh.nhs.uk>

Dear Mr Wong,

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,

Thomas Fairman
HRA Assessor



Thomas Fairman | HRA Assessor

Health Research Authority

Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT

E-mail thomas.fairman@nhs.net | T: 02071 048 112

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From: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Sent: 09 November 2016 10:50

To: 'Danny Wong'

Cc: 'rmoonesinghe@gmail.com'; 'RandD@uclh.nhs.uk'; amendments hra (HEALTH RESEARCH AUTHORITY)
Subject: IRAS 154486. Confirmation of REC Validation and Categorisation of Amendment

Dear Danny Wong,

IRAS Project ID:	154486
REC Reference:	16/SC/0349
Short Study Title:	Epidemiology of Critical Care provision after Surgery (EpiCCS)
Date complete amendment submission received:	03 November 2016
Amendment No./ Sponsor Ref:	V1.5
Amendment Date:	28 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 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 08 December 2016.

- 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.

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

Kind regards

Lucy Roberts
REC Manager (on behalf of)



Helen Sivey / REC Assistant
Health Research Authority

London – Riverside REC and South Central – Berkshire B

Bristol HRA Centre

Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT

E: nrescommittee.london-riverside@nhs.net | T: 0207 104 8204

HRA (Bristol Centre) 0207 104 8056 | 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: Danny Wong [<mailto:DWong@rcoa.ac.uk>]

Sent: 07 November 2016 09:37

To: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Subject: RE: IRAS 154486, REC 16/SC/0349 Substantial amendment - validation under consideration 2

Dear Helen,

I'm just writing to check if there was anything else still outstanding for the amendment application?

Also, do you have any ideas about the timelines of the amendment process? I am worried that because it's taken some time, that the Steering Group and Project Team might suggest further amendments even before this Amendment has gone through.

Kindest regards,
Danny Wong

From: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY) [nrescommittee.southcentral-berkshireb@nhs.net]

Sent: 03 November 2016 13:26

To: Danny Wong

Subject: RE: IRAS 154486, REC 16/SC/0349 Substantial amendment - validation under consideration 2

Dear Danny,

My apologies – I missed a further revision that we need in my previous email: the document title of the revised CRF include a 16th of September date – please could you resubmit this with a date that is consistent with the date on the document itself?

Kind regards,



**Helen Sivey / REC Assistant
Health Research Authority**

London – Riverside REC and South Central – Berkshire B

Bristol HRA Centre

Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT

E: nrescommittee.london-riverside@nhs.net | T: 0207 104 8204

HRA (Bristol Centre) 0207 104 8056 | www.hra.nhs.uk

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

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From: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Sent: 03 November 2016 13:19

To: 'Danny Wong'

Subject: IRAS 154486, REC 16/SC/0349 Substantial amendment - validation under consideration

Dear Danny,

I've withdrawn this as a non-substantial amendment submission and am currently validating it as a substantial amendment. In order that I can complete the validation process and pass this on to the REC, please could you provide the following:

1. A 'tracked changes' version of the protocol.
2. The 'tracked changes' version of the Appendix 1 (CRF) document.
3. Confirmation that the insurance arrangements for this study haven't changed (the removal of the statement that Dr Khondoker is employed by UCL, for whom the insurance is provided, means that I need to double check that the insurance documents provided for this study remain valid).

I'd be grateful for your response by next Wednesday the 9th of November if possible.

Kind regards,



**Helen Sivey / REC Assistant
Health Research Authority**

London – Riverside REC and South Central – Berkshire B

Bristol HRA Centre

Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT

E: nrescommittee.london-riverside@nhs.net | T: 0207 104 8204

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: Danny Wong [<mailto:DWong@rcoa.ac.uk>]

Sent: 28 October 2016 15:30

To: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Helen,

Can I just check if you received my email with the documents attached yesterday? I am just mindful that my email client has recently been suffering problems in terms of reliability.

Kindest regards,
Danny Wong

From: Danny Wong

Sent: 27 October 2016 07:16

To: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Cc: RandD@uclh.nhs.uk; KESHVARA, Rekha (HEALTH RESEARCH AUTHORITY); Ramani

Moonesinghe; Jenise.Davidson@uclh.nhs.uk

Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Helen,

Further to our previous correspondence regarding changing our minor amendment to a substantial amendment, please find attached to this email:

1. The Notification of Substantial Amendment form generated in IRAS and electronically signed by the Chief Investigator and the Sponsor.
2. A zip file containing the supporting documents to the amendment application.

I would be grateful if you could send me an email confirming receipt of the documents. Please do let me know if you require anything else?

Kindest regards,
Danny Wong

From: Danny Wong

Sent: 24 October 2016 11:19

To: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Cc: RandD@uclh.nhs.uk; KESHVARA, Rekha (HEALTH RESEARCH AUTHORITY); Ramani

Moonesinghe; Jenise.Davidson@uclh.nhs.uk

Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Helen,

Thank you very much for your email. I apologise for taking so long to reply as I was away last week.

In response to your points:

- 1) Yes, please withdraw the non-substantial amendment and re-create it as a substantial amendment for REC review.
- 2) I will generate a Notification of a Substantial Amendment form via IRAS and get it to you as soon as possible.

I do have a particular question which I would like some clarification on: Do we only need to make a Substantial Amendment notification for the poster? Or do we need to make a Substantial Amendment notification for all the changes we are making? In other words, are we allowed to submit a non-substantial amendment for some aspects and a substantial amendment for others?

Kindest regards,
Danny Wong

From: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY) [nrescommittee.southcentral-berkshireb@nhs.net]

Sent: 20 October 2016 11:11

To: Danny Wong

Cc: RandD@uclh.nhs.uk; KESHVARA, Rekha (HEALTH RESEARCH AUTHORITY); Ramani Moonesinghe

Subject: Re: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Dr Wong,

Thank you for very much for your email. Because the original amendment submission was non-substantial and therefore didn't require REC ethical review), but the inclusion of the poster does need REC review (because it's a patient-facing document that the REC hasn't previously reviewed and approved), please could you provide the following:

1. Confirmation that you're content for me to withdraw the non-substantial amendment and re-create it as a substantial amendment for REC review.
2. A version of the Notification of a Substantial Amendment form. This is generated via IRAS and then emailed to this address, signed electronically by Chief Investigator and study Sponsor named in the IRAS REC application form.

Please don't hesitate to get in touch if you have any questions about the amendment review process.

Kind regards,

Ms Helen Sivey, REC Assistant - Berkshire B

Bristol REC Centre

Health Research Authority

National Research Ethics Service (NRES)

Telephone: 0117 3421382

Bristol REC Centre

Level 3, Block B

Whitefriars


Lewins Mead

Bristol BS1 2NT

Email: nrescommittee.southcentral-berkshireb@nhs.net www.hra.nhs.uk, www.nres.nhs.uk

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From: Danny Wong <DWong@rcoa.ac.uk>

Sent: 17 October 2016 14:22

To: BerkshireB NRESCommittee.SouthCentral- (HEALTH RESEARCH AUTHORITY)

Cc: RandD@uclh.nhs.uk; KESHVARA, Rekha (HEALTH RESEARCH AUTHORITY); Ramani Moonesinghe
Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Ms Cavaliere,

The South Central Berkshire B REC approved our study earlier in July this year. Since then we have had to introduce minor amendments to the study documents, including adding a poster which will be displayed in the hospital department areas where pre-operative patients would be made aware of the study that we are conducting. This was a requirement that the Confidentiality Advisory Group stipulated in order for them to support our study.

We have been advised that the new additional poster will need REC approval, would we be able to submit it to you for it to be assessed by the REC please?

I attach the poster (Appendix 7) in this email.

Kindest regards,
Danny Wong

From: KESHVARA, Rekha (HEALTH RESEARCH AUTHORITY) [rekha.keshvara@nhs.net]
Sent: 17 October 2016 14:00
To: Ramani Moonesinghe
Cc: Danny Wong; RandD@uclh.nhs.uk
Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Dr Moonesinghe,

Hope you're well.

I'm the assessor for the above amendment.

As the amendment is adding an advert poster, the option not included in the original IRAS form/application, I have been advised by a colleague from REC that the amendment would need to be approved by the relevant REC. Therefore, can I please ask you to submit the above amendment to the REC as without this, I will not be able to issue the HRA approval.

Best wishes,
Rekha



Rekha Keshvara | Assessor
Health Research Authority
Nottingham HRA Centre, The Old Chapel,
Royal Standard Court, Nottingham NG1 6FS
E: Rekha.Keshvara@nhs.net | T: 0207 104 8191

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: amendments hra (HEALTH RESEARCH AUTHORITY)
Sent: 12 October 2016 15:48
To: Ramani Moonesinghe
Cc: 'Danny Wong'; RandD@uclh.nhs.uk
Subject: RE: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application - Category A

Dear Dr Moonesinghe,

IRAS Project ID:	154486
Short Study Title:	Epidemiology of Critical Care provision after Surgery (EpiCCS)
Date complete amendment submission received:	04/10/2016
Amendment No./ Sponsor Ref:	16/SC/0349/AM01 - NSA #1
Amendment Date:	04/10/2016
Amendment Type:	Non-substantial

Thank you for submitting the above referenced 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 4 October 2016.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion where applicable, (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below). 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, please see 'Confirmation of Assessment Arrangements' below) 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.

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.

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

Kind regards

Ali Hussain
Amendments Co-ordinator



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: Danny Wong [<mailto:DWong@rcoa.ac.uk>]
Sent: 04 October 2016 17:04
To: amendments hra (HEALTH RESEARCH AUTHORITY)
Cc: Ramani Moonesinghe; RandD@uclh.nhs.uk
Subject: IRAS 154486, REC 16/SC/0349 - Non-substantial / Minor Amendment Application

Dear Sir,

Study title: The Second UK Sprint National Anaesthesia Project: Epidemiology of Critical Care provision after Surgery
IRAS project ID: 154486
REC reference: 16/SC/0349
Sponsor: University College London

Please find enclosed our application for a minor amendment to our study which received HRA approval on 20 September 2016.

Kindest regards,
Danny Wong
SNAP-2 Trainee Lead

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