Subject: IRAS 203355. Amendment confirmation of REC Validation, categorisation and implementation information
From: "NRESCommittee.EastMidlands-Nottingham1@nhs.net" <noreply@harp.org.uk>
Date: 09/10/17 10:02
To: <carl.reynolds@imperial.ac.uk>, <jrco@imperial.ac.uk>
CC: <nhsg.nrspcc@nhs.net>, <research-permissions@wales.nhs.uk>, <jrco@imperial.ac.uk>

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Dr Reynolds,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

Information Specific to Participating NHS Organisations in England

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the HRA website.
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment will be reviewed by the REC, as per the attached letter. In parallel to this, an assessment against HRA standards will take place.
4. Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.
5. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment.** If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.
6. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

Information Specific to Participating NHS/HSC Organisations in Northern Ireland, Scotland and/or Wales

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with the research teams at all participating NHS/HSC organisations in Northern Ireland, Scotland and/or Wales.
2. You do not need to include the R&D offices in this correspondence, as we have separately made it available via their national coordinating functions.
3. The participating NHS/HSC organisations should prepare to implement this amendment.
4. You may implement your amendment at all NHS/HSC participating organisations in Northern Ireland, Scotland and/or Wales on the date provided in the table below (or as soon as the participating NHS/HSC organisation confirm that you may implement, if sooner), so long as you have a REC Favourable Opinion and any other applicable regulatory approvals (e.g. from the MHRA) for your amendment by this date. **NHS/HSC organisations do not have to confirm they are happy with the amendment.** If you receive any applicable regulatory approval subsequent to this date, you may implement once you receive the last relevant approval. Please note that HRA Approval is not required to implement this amendment outside of England.
5. You may not implement the amendments at any participating NHS/HSC organisation that requests additional time to assess, until it confirms that it has concluded its assessment.
6. You may not implement at any participating NHS/HSC organisation that declines to implement the amendment

IRAS Project ID:	203355
Short Study Title:	Idiopathic Pulmonary Fibrosis Job Exposures Study (IPF JES)
Date complete amendment submission received:	03 October 2017
Amendment No./ Sponsor Ref:	1
Amendment Date:	29 September 2017
Amendment Type:	Substantial
Outcome of HRA Assessment	**HRA Approval for the amendment is pending.** The HRA will separately confirm HRA Approval for the amendment by email.
Implementation date in NHS organisations in England	35 days from date amendment information together with this email, is supplied to participating organisations **(provided HRA Approval for the amendment is in place and conditions above are met)**
Implementation date in NHS/HSC organisations in Northern Ireland, Scotland and/or Wales	07/11/2017 **(providing conditions above are met)**
For NHS/HSC R&D Office information	
Amendment Category	A

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

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

Kind regards

Mr George R. Martin
REC Assistant

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Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
E.hra.amendments@nhs.net
W. www.hra.nhs.uk

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Attachments:

203355 17.EM.0021 Substantial Amendment Valid.pdf	130 kB