Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Idiopathic Pulmonary Fibrosis Job Exposures Study (IPF JES)
IRAS Project ID:	17/EM/0021
Sponsor Amendment Notification number:	1
Sponsor Amendment Notification date:	11/7/17
Details of Chief Investigator:	
Name [first name and surname]	Carl Reynolds
Address:	National Heart and Lung Institute, Room G39 Emmanual Kaye Building, 1b Manresa Road, London, SW3 6LR
Postcode:	SW3 6LR
Contact telephone number:	07737 904 807
Email address:	Carl.reynolds@imperial.ac.uk
Details of Lead Sponsor:	

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

Name:	Ruth Nicholson
Contact email address:	r.nicholson@imperial.ac.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	Yes
Name of lead R&D office:	North West London

2. Summary of amendment(s)

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Brief description of amendment *(please enter each separate amendment in a new row)*	**Amendment applies to** *(delete/ list as appropriate)*		**List relevant supporting document(s), including version numbers** *(please ensure all referenced supporting documents are submitted with this form)*		**R&D category of amendment** *(category A, B, C) For office use only*
	Nation	**Sites**	**Document**	**Version**	
Residential history removed Drug history simplified (prev asked about drugs generally, now ask specifically only about drugs know to call pulmonary fibrosis) Family history simplified (prev asked generally, now specifically ask if blood relative with pulmonary fibrosis) Add asbestos screening question Add thank-you and capture information regarding communication preference Add clinicaltrials.gov reference	England Scotland Wales	All sites All sites All sites	Interview schedules or topic guides for participants	0.5	
Remove previous medical history section from CRF Remove previous drug history section from CRF Add GP contact details to CRF Add detail to clarify exclusion criteria Simplify randomisation procedures for random selction of cases and controls Add qualifier to exclusion criteria (would not exclude men in armed services or merchant navy) Add guidance on posting blood samples Add guidance on generating research Ids Add guidance of age bands for frequency matching Add clinicaltrials.gov reference	England Scotland Wales	All sites All sites All sites	Research protocol or project proposal	0.5	
Add Portsmouth Hospital as a participating centre Add Queen Elizabeth Hospital Birmingham as a participating centre Add Worcester Hospital as a participating centre	England Scotland	All sites All sites	N/A	N/A	

Remove Ashford and St Peters Hospital as a participating centre	Wales	All sites			
Remove line "– Where you have lived" from What will happen to me section of participant information sheet because we will no longer be asking about this. Add clinicaltrials.gov reference	England	All sites	Participant Information Sheet	0.5	
	Scotland	All sites			
	Wales	All sites			

[Add further rows as required]

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: .....

Print name: .....CARL REYNOLDS.....

Date: .....11/7/17.....

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: .....

Print name:.....Ruth Nicholson.....

Post: .....Research Governance Manager.....

Organisation:.....Imperial College London.....

Date: 11/07/17.....