



East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048016

09 September 2019

Dr Carl Reynolds
National Heart and Lung Institute
Room 39, Emmanuel Kaye Building
1b Manresa Road, London
SW3 6LR

Dear Dr Reynolds

Study title:	Idiopathic Pulmonary Fibrosis Job Exposures Study (IPF JES)
REC reference:	17/EM/0021
Amendment number:	2
Amendment date:	06 February 2019
IRAS project ID:	203355

The above amendment was appealed and re-reviewed at the meeting of the Sub-Committee held on 18 June 2019 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review decided that they could not give a favourable ethical opinion of the amendment, for the following reasons:

The Committee stated that the Amendment was not acceptable for approval as submitted, as there is insufficient justification and independent scientific review provided regarding the addition of two new control groups, which the Committee reported to be inadequately specified. In addition, the Committee noted that the documentation requires general revision to adequately cover the new groups, and to update the genetic analysis information particularly for future research.

The Committee did not consider this to require resubmission as a New Study, although the Committee agreed that because this was originally approved under PR, and has now been substantially extended, it would be appropriate for it to be reviewed by a Full Committee.

Additional points: *The Committee did not consider there to be adequate documentation of the process of identification, invitation and informed consent process for the new control*

groups, and the informed consent documentation should be revised to provide each Participant with a 'tailored' version.

The Committee did not consider the PIS adequately informs the new control Participants about the potential use of their samples and data in future research, and incidentally although approved, this also applies to the original groups. The Committee added, given the rapidity of advances in genetic analyses, it would be appropriate to revise this aspect, add a clear statement on the limits and boundaries for such future research, and expand the options in the consent form, e.g. to whole-genome, or to wider genes relevant to respiratory disease.

I regret to inform you that the amendment is therefore not approved. The study should continue in accordance with the documentation previously approved by the Committee.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact: nrescommittee.eastmidlands-nottingham1@nhs.net .

Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter Of Intention To Appeal		10 July 2019
Notice of Substantial Amendment (non-CTIMP)	2	06 February 2019
Other [ipfjes-sop-diff]	0.7	06 February 2019
Participant consent form [ipfjes-consent-diff]	0.7	06 February 2019
Participant information sheet (PIS) [IPF JESParticipant Information Sheet]	0.7	06 February 2019
Research protocol or project proposal	0.7	06 February 2019

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

17/EM/0021:	Please quote this number on all correspondence
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Yours sincerely

A handwritten signature in black ink, appearing to read 'A. Lamont', with a small 'P.P.' written above it.

Dr Alan Lamont
Chair

E-mail: NRESCCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Carl Reynolds

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Attendance at Sub-Committee of the REC meeting on 26 March 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Alan Lamont	Retired Consultant Oncologist	Yes	Chair of Cambridge EAST REC.
Mrs Victoria Hollamby	Assistant Research Governance Advisor	Yes	

Also, in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Noorisha Rahman	Approvals Officer