Health Research Authority
East Midlands - Nottingham 1 Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

12 January 2017

Dr Carl Reynolds
National Heart and Lung Institute
Room 39, Emmanual 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**
IRAS project ID:	**203355**

The Proportionate Review Sub-Committee of the East Midlands - Nottingham 1 Research Ethics Committee reviewed the above application on 10 January 2017.

Provisional opinion

The Sub-Committee would be content to give a favourable ethical opinion of the research, subject to clarification of the following issues and/or the following changes being made to the documentation for study participants:

1. Please provide further information regarding the MUC5B rs35705950 gene as mentioned in A58 of the IRAS form and include information regarding this in the Participant Information Sheet.
2. Please include a definition of the abbreviation *'IPF'* in the Letter of Approach.
3. Please include a section of how the researcher got the contact details of the participant in the Letter of Approach.

4. Please implement the following amendments to the Participant Information Sheet;

    a) *Please add page numbers.*
    b) *Please include a sentence that states the study has been reviewed by the Nottingham 1 Research Ethics Committee.*
    c) *Please list the researchers name at the top of the sheet.*
    d) *Please include contact details for the researcher based in London.*
    e) *Please amend the opening bold paragraph as this is overly complicated and not user friendly.*
    f) *Please provide further information regarding the susceptibility gene. Please provide further information regarding what the implications of the discovery of a susceptibility gene are and further justification for investigating this. Further information is also required with regards to how this will affect the participant in the future and potentially other family members.*
    g) *Please provide further information on the role of compensation within the study and ensure that potential participants are not misled.*

h) Please provide contact details for support groups for claiming compensation.
i) Please include a Patient Liaison and Advisory Services (PALS) or equivalent.

5. Please amend the Consent Form to include a section for participant's to agree to the interview(s) to be recorded as stated in the IRAS form, in the form of a yes/no tick box.
6. Please amend the Consent Form to include a section for participants' *to agree to the storage and future use of samples*' in the form of a yes/no tick box.
7. Please amend the GP Letter to include the sentence *"inform your GP….with your permission."*
8. Please ensure that the participant is informed of any results as well as the GP.
9. Please confirm if the interview schedule incorporates questions from the validated exposure tool.
10. Please submit the validated exposure tool for review.
11. Please ensure the validated exposure tool is listed in the study protocol.
12. Please ensure that the interview schedule is inclusive of participant's who may not have knowledge of their family background.
13. Please ensure the questions in the interview schedule are made explicitly clear when querying about asbestos exposure.

When submitting a response to the Sub-Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

Authority to consider your response and to confirm the final opinion on behalf of the Committee has been delegated to Mrs Sarah Lennon.

Please contact REC Assistant Teagan Allen; nrescommittee.westmidlands@nhs.net if you need any further clarification or would find it helpful to discuss the changes required with the lead reviewer.

The Committee will confirm the final ethical opinion within 7 days of receiving a full response. A response should be submitted by no later than 11 February 2017.

Summary of discussion at the meeting

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity;

The PR Sub-Committee noted that the blood sample will be used for examining a gene; MUC5B rs35705950 and noted that this is not fully explained to the participant; further information is required in all study documentation. The relevance of this gene must also be explained further.

The PR Sub-Committee asked if the link between the MUC5B rs35705950 gene and asbestos exposure is proven. The PR Sub-Committee were in agreement that this information is not explicitly stated in the study documentation and would need to be added.

Informed consent process and the adequacy and completeness of participant information;

The PR Sub-Committee require the definition of the abbreviation *'IPF'* to be used in the Letter of Approach document.

The PR Sub-Committee require the addition of a section that details where and how the researcher's got the participants details in the Letter of Approach document.

The PR Sub-Committee require page numbers to be added to the Participant Information Sheet and include a sentence that states the study has been reviewed by the Nottingham 1 Research Ethics Committee.

The PR Sub-Committee require the researchers name to be listed at the top of the Participant Information Sheet.

The PR Sub-Committee noted that no contact details are provided for the researcher based in London in the Participant Information Sheet.

The PR Sub-Committee agreed that the opening bold paragraph of the Participant Information Sheet was overly complicated and not user friendly and recommended that this is simplified to help aid recruitment.

The PR Sub-Committee discussed the use of the terminology…."*susceptibility gene*" in the Participant Information Sheet and were in agreement that further information about this was required. The PR Sub-Committee discussed what the implications of the discovery of a *susceptibility gene* were and agreed that further justification for investigating this is required and further information provided with regards to how this will affect the participant in the future and potentially other family members.

The PR Sub-Committee discussed the role of "*compensation*" as stated in the Participant Information Sheet and agreed that the study must not be construed as misleading regarding claiming compensation. The PR Sub-Committee asked who on the study will make the link to asbestos exposure and asked how this will be managed. The PR Sub-Committee were in agreement that clarification regarding compensation is required and that relevant support groups must be included as a point of reference for participants.

The PR Sub-Committee noted that there was no Patient Liaison and Advisory Services (PALS) or equivalent listed in the Participant Information Sheet.

The PR Sub-Committee require the Consent Form to include a section for participant's to agree to the interview(s) to be recorded as stated in the IRAS form, in the form of a yes/no tick box.

The PR Sub-Committee require the Consent Form to include a section for participants' to agree to the storage and future use of samples in the form of a yes/no tick box.

The PR Sub-Committee require the GP Letter to be amended to state include the sentence "*inform your GP….with your permission*."

The PR Sub-Committee noted that the GP will be informed of any results and questioned why the participant themselves would not also be informed of any results. The PR Sub-Committee acknowledged that the participant will already have a diagnosis but recognised that asbestos exposure will have further health implications

that will require further exploration and require this to be altered and the participant informed alongside their GP.

The PR Sub-Committee discussed the use of a validated exposure tool and asked if this was incorporated into the interview schedule. The PR Sub-Committee require confirmation if this is the case. Sight of the validated exposure tool is also required for review. The validated exposure tool must also be listed in the study protocol.

The PR Sub-Committee noted that the interview schedule included questions regarding a participant's family background and agreed that not every participant will have this information if they have been fostered or adopted for example; there are also no prompts in the tool on how to address this. The PR Sub-Committee agreed that this needs to be considered to be inclusive of all potential participants and not cause unnecessary upset or distress.

The PR Sub-Committee discussed how asbestos exposure can be from a range of different scenarios such as a partner who is exposed to asbestos and brings this into the family home on work clothes for example; and agreed that questions regarding exposure need to be made clearer.

Documents reviewed

The documents reviewed were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters	0.3	19 December 2016
Interview schedules or topic guides for participants	0.3	19 December 2016
IRAS Application Form [IRAS_Form_20122016]		20 December 2016
Letter from funder		
Letter from sponsor		
Letters of invitation to participant	0.3	19 December 2016
Participant consent form	0.3	19 December 2016
Participant information sheet (PIS)	0.3	19 December 2016
Referee's report or other scientific critique report		
Research protocol or project proposal	0.3	19 December 2016
Summary CV for Chief Investigator (CI)		
Summary CV for student		
Summary CV for supervisor (student research)		
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	0.3	19 December 2016

Membership of the Committee

The members of the Committee who were present at the meeting 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.

17/EM/0021	**Please quote this number on all correspondence**

Yours sincerely

P.P

Mr John Aldridge
Chair

Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net

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

Copy to: *Mrs Ruth Nicholson, Imperial College London and Imperial College Healthcare NHS Trust*

East Midlands - Nottingham 1 Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 10 January 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr John Aldridge (Chair)	Retired Senior Lecturer in Nursing	Yes	
Mrs Sarah Lennon	Ex-Surgical Registrar (GMC registration maintained)	Yes	
Ms Ellen Milazzo	Development and Change Management Consultant	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Teagan Allen	REC Assistant
Miss Daniella Sarno	REC Assistant