

Standard Operating Procedure for case and control recruitment and exposure assessment in the Idiopathic Pulmonary Fibrosis Job Exposure Study (IPF JES)

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1 Scope and applicability

The purpose of this SOP is to describe the instructions for the enrolment of cases and controls, exposure assessment, and genetic testing in the IPF JES.

2 Introduction

The objective of IPF JES is to characterize and measure job exposures as an occupational determinant of Idiopathic Pulmonary Fibrosis (IPF). This will be achieved through

a case-control study in which historic job exposures are measured using a validated semi-structured interview. A blood test will also be obtained to investigate interaction between job exposures and IPF genetic susceptibility factors.

3 Recruitment

3.1 Recruitment of cases

See figure 1

Cases will be recruited from male patients with a new diagnosis of IPF made during the study period within the research network.

From the time that recruitment opens at a centre the centre will write to all successive patients with an incident diagnosis of IPF inviting them to participate in the study and enclosing the patient information sheet, updating the central research team monthly. Patients will be enrolled into the study at their next outpatient department, blood will be drawn, and a telephone interview will be scheduled. Inclusion and exclusion criteria will be checked as part of enrolment.

Recruitment of cases from a centre stops when the agreed centre target is met or the agreed centre recruitment period ends.

3.2 Recruitment of controls

See figure 2

Controls will be recruited from male patients with a new outpatient department attendance at the same hospital or trust that the cases originate from. Controls will be frequency matched on age to 5-year bands (e.g 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85+). The overall ratio of cases to controls will be 1:1.

A control clinic will be randomly selected (from all clinics, not limited to respiratory) at each centre. Paediatric clinics and gynaecological clinics will be excluded.

The local research team will write to the lead clinician for the selected clinic to obtain permission to recruit patients to the study. If permission is refused then the process is repeated until a lead clinician agrees. Once agreement is obtained this clinic will be the source clinic for all controls at that centre for the duration of the study.

Potential controls will be invited to participate in the study and provided with a patient information sheet when they attend the outpatient department. Patients will be enrolled into the study, blood will be drawn, and a telephone interview will be scheduled. Inclusion and exclusion criteria will be checked as part of enrolment.

Recruitment of controls from a centre stops when recruitment of cases stops and one control for each case has been recruited or the agreed centre recruitment period ends.

4 Exposure assessment

The exposure assessment is carried out by the central research team by means of a computer-assisted telephone interview.

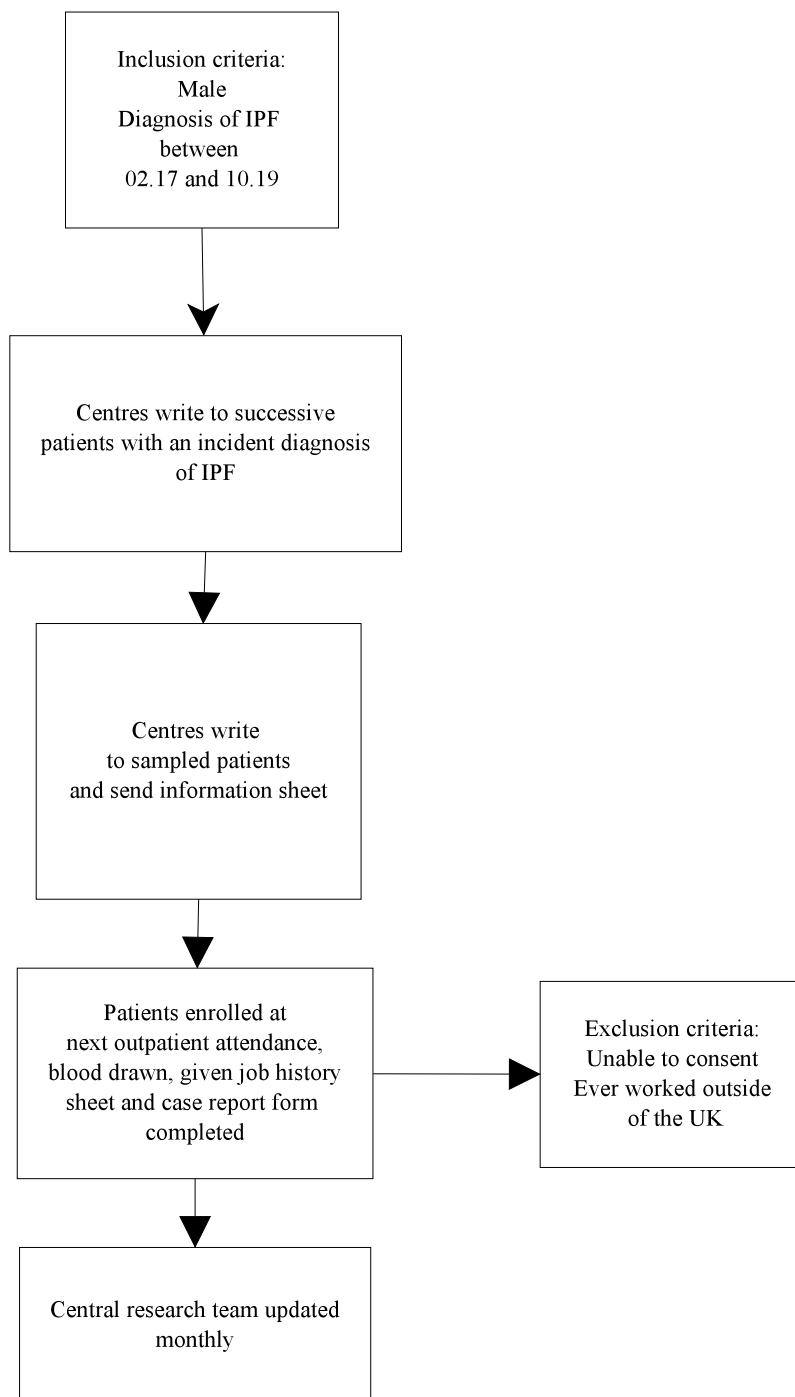


Figure 1: Case recruitment

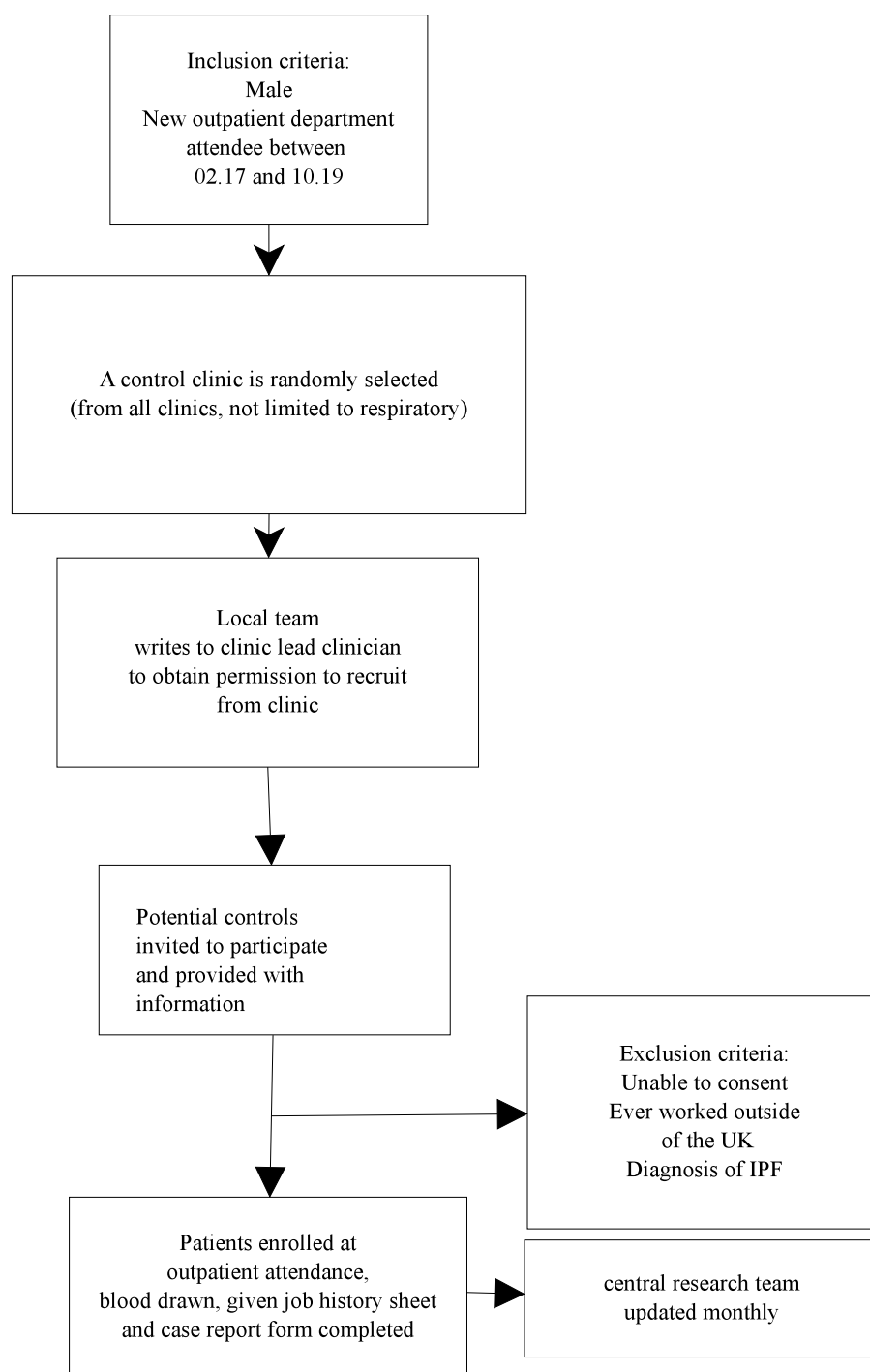


Figure 2: Control recruitment

5 Introduction

Hello, my name is **name of researcher**. I am a doctor/nurse/research assistant calling as part of the IPF Job Exposure Study. Is this **name of participant**?

I would like to ask you some questions about the jobs you have had, where you have lived, and smoking. I would also like to record this call for our research if that's ok with you.

Your answers will help us to understand the causes of IPF, make sure people get the right treatment, and ensure that controls of exposures at work are right so that we protect workers and prevent disease in the future.

The interview should take about 30 minutes. Is now a good time to talk?

6 Occupational history

I want you to think about all of the jobs you've had. I know this can be hard, we'll try one at a time.

Do you remember the first job that you had after school?

1. What was the name of your job? (we record SOC2000 job title and map SOC90)
2. What did you do in this job? (we record free text but also have a drop down of activities associated with asbestos exposure)
3. What was the name of the company (if applicable)? (we record name and SIC code, we possibly link to open corporates company house record)
4. What did the company make (if applicable)? (we record free text but also have a drop down of asbestos containing products)
5. In what sort of working area did you spend most of your time? e.g Office, In the Open, Workshop, Construction Site, Factory (Light Industry), Heavy Industry (eg. Power Station), Hospital, School/University, Warehouse, On Location, various buildings, Shop, At Home, Ship/Ship yard, Other (specify)
6. Did you work full time? (if not specify average hours per week)
7. Did you work all year round (if not specify months of the year)
8. Do you remember how old you were or what year you started the job?
9. Do you remember how old you were or what year you finished the job?
10. Do you remember what job you had next?

(1 through 10 repeats until lifetime occupational history is complete. Standard occupational classification is used to code occupations)

Any reported contact with asbestos or 'trigger' products (HSE list), industries (construction, factory work, power station work, other heavy industry, ships or ship yards), jobs (see Table 1), and job processes prompts an asbestos exposure history (see later) to be taken.

SOC90	Occupation	PMR
541	Coach & vehicle body builders	528.18
534	Metal plate workers, shipwrights, riveters	416.64
532	Plumbers, heating & ventilating engineers	388.67
570	Carpenters & joiners	382.34
896	Construction & related operatives	359.23
311	Building inspectors	317.83
520	Production fitters (electrical/electronic)	300.15
521	Electricians, electrical maintenance fitters	264.12
893	Electrical, energy, boiler & related	252.09
533	Sheet metal workers	245.71
301	Engineering technicians	232.22
506	Floorers, floor coverers, carpet fitters	232.05
913	Mates to metal/electrical & related fitters	230.89
211	Mechanical engineers	217.44
571	Cabinet makers	215.36

Table 1: Standard Occupational Classification 1990 code, Occupation, and Mesothelioma Proportional Mortality Ratio (PMR) for the top 15 significant (95% CI does not include 100) PMRs. HSE data.

7 Residential history

I'm going to ask you about places that you've lived now. I know it might be difficult to remember, don't worry.

1. What country were you born in?
2. What place were you born in?
3. Do you remember the places you lived when you were growing up? (until you finished school)
4. Where did you live at first?
5. How long did you live there for? (record year moved in and out if recalls else just duration)
6. Then where did you live?

8 Cohabitation history

I'm going to ask you about people who have lived with you now. I'm specifically interested in people that lived at home with you who went out to work.

1. When you were growing up did anyone who went out to work live at home with you?
2. What was the name of the person?
3. How long did they live with you?
4. Do you remember what their job was?

9 Smoking history

1. Have you ever smoked?
2. What old were you when you started smoking?
3. Do you still smoke?
4. How old were you, or when, did you stop smoking?
5. How many, on average, a day do you/did you smoke?
6. What do you/did you smoke?

10 mMRC dyspnoea questions

I would like to ask you some questions about being short of breath.

Are you:

1. Not troubled by breathless except on strenuous exercise?
2. Short of breath when hurrying on a level or when walking up a slight hill?

Are you someone who:

3. Walks slower than most people on the level, stops after a mile or so, or stops after 15 minutes walking at own pace?
4. Stops for breath after walking about 100 yds or after a few minutes on level ground?

Are you:

5. Too breathless to leave the house, or breathless when dressing/undressing?

11 Drug and medical history

1. Have you ever taken any heart medications such as amiodarone or flecainade, antibiotics such as nitrofurantoin, or immunosuppressants and chemotherapy drugs such as, azathioprine, gefitinib, ifosfamide, melphalan, and rituximab?
2. Do you take any regular medications currently?
3. What do you take these for?
4. Do you have any other serious illnesses?

12 Family history

1. Does anyone in your family have scarring of their lungs or pulmonary fibrosis?
2. Do you have any brothers or sisters? Are they well?
3. How about your mother and father?
4. How about your children?

13 Asbestos exposure history

1. Did you, or anyone close to you, ever work with or disturb material you suspected to be made from asbestos? This might include materials such as asbestos lagging, asbestos sprayed coatings, AIB(asbestos insulation board - e.g asbesolux, marinite, shipboard, LDR, turnasbestos etc) or corrugated roofing? (Yes, record what using free text, which job(s) associated with and John Cherrie item/No/Not known)
2. What was done with it? (free text and John Cherrie item)
3. How long did the task take and how often did you do it? (Record % work time on task)
4. Where was the task completed? (free text and drop down e.g inside small room, inside large room, outside)
5. Did you wear a mask? (free text and drop down)

14 (for cases only) how were you diagnosed

1. What took you to the doctor at the beginning of the illness? (e.g cough, breathlessness, incidental finding, other)

15 Ethnicity

For the blood test that we have taken it would be helpful for us to know what ethnicity you are.

To which of the following ethnic groups do you consider you belong?

1. White
2. Black or Black British
3. Mixed
4. Chinese
5. Asian or Asian British
6. Other ethnic group (please specify)

16 Thank-you and updates

Thank-you very much for participating today. Is there anything you'd like to ask us? Would you like to be kept updated on the study? How would you prefer to be updated? (Post or email, capture email if prefers email).

17 Venepuncture, sample storage, transportation, and processing

Venepuncture will be performed by a qualified practitioner. The number of blood tubes to be drawn depends on the volume of the tubes used. A total of 14mls of blood will be obtained using purple top EDTA tubes and a total of 10mls of blood using gold top SST tubes for each participant. Samples will be labelled with the participants unique research ID and posted using Royal Mail Safebox to a secure lab storage facility at NHLI where they will be kept in a -80 degree centigrade freezer. The sender will record the day of delivery and the research team will record receipt of the sample and keep an accurate record of its location. Analysis of samples will include DNA isolation and quantitative PCR taqman assay to investigate pre-defined SNPs of interest.