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The Grenfell Firefighters; establishing a cohort
(short title: Grenfell Firefighters)

<version1.0; 17.04.2019>

This protocol was prepared with reference to HRA guidance. It describes the Grenfell Firefighters' Study, a cross-sectional survey without any medical intervention. While every care was taken in its drafting, corrections or amendments may be necessary; problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

Research reference numbers:

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ISRCTN: XX
Sponsor: Imperial College
Funder: The COLT Foundation (CF/01/19)

Imperial College London

Signatures:

The undersigned confirm that the following protocol has been agreed and accepted and that the Principle Investigator agrees to conduct the trial in compliance with the approved protocol, GCP guidelines and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:
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1. INTRODUCTION

1.1 Background

On the 14th June 2017 a fire broke out on the fourth floor of the 24-storey Grenfell Tower in west London, causing the deaths of over 70 occupants and becoming the worst residential fire in the United Kingdom since the second world war. The fire spread unusually rapidly and its extinction – which took 60 hours - required the labour of over 1000 firefighters from the London Fire Brigade (LFB). No firefighters died at the scene and none required emergency medical care for smoke inhalation. Because of the scale and nature of the fire, however, a sizeable proportion of them were subjected to unusually high exposures to fire smoke, in many cases without standard respiratory protection; we propose to establish a cohort of the Grenfell firefighters to study a range of potential adverse effects from these exposures.

Cardiorespiratory disease

The acute, non-burn, effects of exposure to fire smoke are reasonably well understood and are largely respiratory (1), but they include also systemic effects, such as those induced by exposure to products of pyrolysis such as hydrogen cyanide, benzene or acroleins, and – probably - cardiovascular effects (2). The evidence around longer-term, adverse outcomes of firefighting – and indeed smoke inhalation in general - is scanty, more complex and likely to be confounded by international and temporal differences in recruitment, retention, routine health surveillance and practice, including the use of personal protective equipment. These make generalisations very difficult.

A systematic review of the cumulative effects of firefighting on lung function has recently been published (3). It includes 22 studies whose findings are 'highly variable and provide an unclear picture of how the rate of change in lung function of firefighters relates to routine exposures; moreover the evidence for an 'exposure-response' relationship is not compelling'. The reasons for the discrepancies between studies probably embrace those listed above but will include also differences, and insensitivities, in the functional measures used and in the estimations of exposure to fire smoke which, with very few exceptions (4), are both crude and by self-report, and so likely to be open to misclassification and the obscuring of exposure-response relationships. Small airway damage is a plausible response to fire smoke inhalation (5), but most studies have relied on relatively crude spirometric measurements which may not detect obstructive changes in the smaller airways; in a survey of around 500 Australian firefighters, for example, the use of impulse oscillometry identified airways dysfunction even when spirometry values were normal (6) – although no relationship with exposure to fire smoke was evident. In the absence of sufficient longitudinal data, the prognostic significance of asymptomatic small airways disease is unclear but it is generally accepted that it presages more significant airflow obstruction in smokers (7); a recent editorial suggests that "differences in the small airways (even those that do not appreciably affect FEV_1) might also predict the development of asthma or COPD" (8). Moreover, acute exposure to inhaled irritants may give rise, in the conducting airways, to a complex interaction of inflammation, smooth muscle activation and neuronal inputs that create and perpetuate both fixed and reversible airflow obstruction. Bronchial hyperreactivity itself is another plausible outcome (9), but again has seldom been studied. An exception is a survey of 400 Dutch firefighters, most of them volunteers, in whom the dose–response slope to metacholine challenge was significantly and independently associated with the number of fires fought in the last year; limiting the analysis to firefighters without exposure within seven days of testing did not change the association (10). There have been just two studies of

lung function in UK firefighters (11, 12). Both were longitudinal, although one over just 12 months, and

both were undertaken over 30 years ago; neither showed any adverse effects attributable to firefighting.

Studies such as these are designed to reflect cumulative exposure(s) to repeated, relatively low-intensity events and their findings may not be applicable to those who fought the Grenfell fire. In a manner similar to that of the Grenfell firefighters, rescue and other workers at the World Trade Center (WTC) in 2001 experienced an abrupt and substantial, increase in exposure. While comparisons must be limited by the very different natures of the exposures (respectively, fire smoke *vs* dust of high alkalinity), increased rates of respiratory symptoms, airflow obstruction and bronchial hyperreactivity, and a stepwise fall in lung function, have been reported in WTC workers (13, 14). There has been only one other study of firefighters exposed to non-routine firefighting. Twenty (of 175) firefighters who extinguished an unusually intense chemical fire in Houston were followed over 18 months, during which they experienced, on average, declines in FEV1 and FVC of 122ml and 62ml respectively (15); the study is limited not only by its size but also by the lack of any pre-event spirometry.

The established relationships between exposure to fine particulate matter and cardiovascular diseases have led some to question whether the risks of the latter are increased in firefighters. Sudden cardiac death accounts for the largest share (c.40%) of on-duty cardiac deaths among firefighters – surpassing burns, trauma, asphyxiation and smoke inhalation. They most commonly coincide with active strenuous duties (16) suggesting that the physical and environmental hazards faced by firefighters acutely magnify their cardiovascular risk in the peri-emergency setting. Studies of US firefighters have reported increases in several adverse measures of arterial stiffness following three hours of firefighting activity (17) and decreased microvascular function and alterations in heart rate variability after fire training (18). A cross-sectional survey of US wildfire fighters reported a (tenuous) link between exposure and increased arterial stiffness (2). More broadly, a systematic review of prognostic studies concluded that central haemodynamic indices are independent predictors of future cardiovascular events and all-cause mortality; for example, a 10% increase in augmentation index was associated with a 26% increase in the risk of future coronary disease (19). Despite this, a recent analysis of a cohort of around 10,000 Danish firefighters (20) reported only a modest increase in the standardised incidence ratio of all cardiovascular diseases (SIR 1.10, 95%ci 1.05-1.15); the estimates and their precision, however, depended on whether reference was made to a general or military population.

Malignancy

Finally, there is concern that work as a firefighter increases the risk of malignant disease; the relevant literature is broad, and again somewhat inconsistent. The spectrum of toxic substances and metabolites produced by structural fires is wide and often unpredictable, but common components of fire smoke include several established human carcinogens such as benzene, polycyclic aromatic hydrocarbons, polychlorinated biphenyls, asbestos, arsenic, 1,3-butadiene, formaldehyde and cadmium (21). Exposures to fire smoke are, of course, intermittent and in many cases infrequent (see (21) but the routes of exposure for firefighters are not only respiratory but also dermal, including through the use of contaminated clothing and protective equipment (22), and perhaps more prolonged. The epidemiological evidence for cancer risks is, as above, likely to be confounded,

and further so by both lifestyle factors and by ascertainment bias. Two systematic reviews are available (21, 23) and suggest modest increases in risk for some non-solid organ cancers and for cancers of the testis and prostate and for melanoma. A more recent analysis of a cohort of around 10,000 Danish firefighters (20), however, reported no significant increase in the standardised incidence ratios of all

cancers (SIR 1.02, 95%ci 0.96-1.09). There have been no epidemiological studies of cancer in UK firefighters.

There have been several short-term molecular studies of cancer risk in firefighters; IARC (21) lists six, with varying results and none of more than about 50 subjects. A typical, more recent, example is of 53 Danish recruits undergoing fire-training (24); on the basis of an association between the level of DNA strand breaks with dermal exposure to pyrene and total PAHs, the authors conclude that firefighting activity is associated with cell genotoxicity. It is well accepted, too, that environmental exposures are associated with epigenetic change, ranging from alterations in DNA and RNA methylation patterns to changes in the expression of small non-coding RNAs. Although there are no studies examining changes to the epigenomes of firefighters following occupational smoke inhalation or through dermal routes, there are data to show that exposure leaves long term DNA methylation changes that can be detected in blood samples. For example, DNA methylation leaves a long-term signature of cigarette smoking that can be detected in blood samples more than 20-years after smoking has ceased (25, 26) and, similarly, occupational exposure to ionising radiation was found to leave a defined signature 2-4 years after a single exposure event (27). Therefore it should be possible to examine changes in, for example, the epigenome in blood of firefighters to obtain an exposure-related signature.

As above, much of the research into the long–term effects of smoke inhalation has been undertaken in firefighters; studies of surviving fire victims are very few and very limited in scope. Two years after the event, small airways damage was detected in 14 passengers caught in the King's Cross fire in London (5), selected from those with reported 'smoke inhalation' during the incident suggesting that damage may accrue in those most intensely exposed. Airway hyper-reactivity and bronchial inflammation were identified in a small sample of survivors of the Inchon bar fire in South Korea, 1999 (28). There appears to be no published evidence relating to cardiovascular or cancer outcomes in non-professional populations.

Hence, with the exception of the WTC event, the available evidence on respiratory damage following an unusually intense firefighting operation is limited to a single, small study undertaken almost 40 years ago. While its findings suggest an accelerated rate of lung function decline, its relevance to those involved in the Grenfell Tower fire is doubtful. Similarly, there is no large-scale evidence relating to medium-term cardiovascular outcomes or to epi(genetic) DNA damage after intense firesmoke exposure.

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1.2 Study Rationale

The Grenfell firefighter population offers a rare opportunity to study the effects of intense fire smoke inhalation on a range of mid- and long-term outcomes. The population is readily defined and enumerated and can, through contemporary records, be subdivided into descending categories of exposure at the Grenfell fire, allowing internal comparisons in the assessment of cause and effect.

Importantly, and uniquely, detailed records held by the LFB will provide an objective, semi-quantitative estimate of professional exposure to fire smoke before and after the Grenfell incident; moreover, periodic, three-yearly health surveillance, undertaken as a condition of active employment at LFB, will provide pre-incident information on lung health including spirometry.

2. STUDY OBJECTIVES

We aim to establish a **Grenfell Firefighters cohort** with the purpose of identifying and measuring any adverse cardio-respiratory outcomes incurred through occupational exposure to fire smoke at the Grenfell fire. In addition and by accounting for prior and subsequent exposures to fire smoke, the cohort will provide unique information on the frequency and nature of the mid- and long-term adverse effects of active firefighting and smoke-inhalation in general.

This protocol is to establish the cohort. To do this we aim to:

1. identify the exposed population, together with a smaller, referent sample of eligible but unexposed firefighters
2. invite each member of the cohort to enrol in a long-term, prospective study and to obtain individual permissions for long-term linkage to routinely collected health data
3. obtain semi-quantitative measures of exposure to firesmoke at Grenfell and at other fires
4. undertake a baseline survey of respiratory and cardiac physiology and to link these to Grenfell firesmoke exposure estimates, to inform our mechanistic understanding of any subsequently identified long-term outcomes
5. collect biosamples for future use in 'omic analyses of outcomes (such as malignancy), probably within nested case-control studies.
   Dependent on our findings in the baseline survey, subsequent follow-up of the cohort may require further face-to-face study but may be more efficiently undertaken by data linkage alone.

3. STUDY DESIGN AND METHODS

3.1 Design and procedures

On our behalf, to satisfy the requirements of GDRP, LFB will identify the names and contact details of all firefighters who directly attended the Grenfell Tower fire in June 2017; every effort will be made to include those who have left service since the fire, estimated to number no more than a dozen. In addition we will ask LFB to identify a random sample (n=100) of firefighters from stations close to Grenfell Tower who would have been eligible to attend the fire but did not do so because of annual leave.

Each of the above will be invited, by the Brigade, to contact us with regard to enrolling in a long-term, prospective study.

Those who do so make contact will be invited to:

1. provide consent to, and the necessary information (name, date of birth, sex, NHS number and contact details) for prospective linkage to national registers including those of mortality, cancer incidence, hospital admission and A/E attendance, and GP consultations.
2. provide consent for their individual histories of employment and firesmoke exposure at and other than Grenfell to be released to Imperial College by LFB, and for this information to be periodically updated; and to provider similar consent for access to their past and subsequent lung function measurements made in the normal course of their employment by LFB.

3. participate in an independent and confidential survey of (cardio)respiratory health, to take place in the clinical research facility of Royal Brompton hospital in London. For those who choose to take part, we will collect the consents and information in 1 and 2 above at the time of survey; for the remainder we will communicate by post, and include the questionnaire outlined below.

   For the baseline survey, we have elected to use investigative methods which are well-established and which can be completed fairly rapidly; moreover, our tests need to be minimally invasive since it will be essential that participation in the project will not impede an immediate return to active work.

   The information we propose to collect is listed below:

   A. Demographics and confounding exposures

   Through self-completed questionnaire, the collection of some simple demographic and lifestyle information, to include:

   - age/sex
   - duration of employment as a firefighter
   - smoking: detailed (pack years; age of starting/quitting)
   - other, relevant occupational and non-occupational exposures
   - other relevant ill-health and medications

   Participants will be invited to complete the questionnaire using a web-based tool designed specifically for this study.

   B. Respiratory health assessment

   - a respiratory symptoms questionnaire incorporating standardised questions that focus on breathlessness and cough, modified from the Dyspnoea 12 instrument; to include also an enquiry into prior respiratory health, diagnoses and relevant treatments
   - small airways function; we will measure resistance of the respiratory tract at 5 and 20 Hz (R5 and R20) using impulse oscillometry (Master Screen Spirometry-IOS System, Jaeger, Germany). Participants will be seated and will undertake a minimum of three trials, each lasting 30s, during tidal breathing while firmly supporting their cheeks with their hands.
   - spirometry: following oscillometry and using a standard, electronic spirometer (Vitalograph, Buckingham, UK) in accordance with internationally accepted guidelines (29), we will measure FEV_1, FVC and small airway flows.
   - bronchodilator reversibility: the above measurements of lung function will be repeated 15 minutes after the administration of a bronchodilator (400µg inhaled salbutamol through a 'spacer' device).

   C. Cardiovascular health assessment

   - arterial stiffness: we will measure pulse wave velocity and augmentation index using a Vicorder (Skidmore Medical, Bristol, UK). Central aortic pulse wave velocity will be defined as the

ratio of pulse wave transit time and distance between the carotid and femoral arteries and augmentation index by the enhancement of central aortic pressure by a reflected pulse wave.

D. Biosampling: we do not plan to undertake analyses of these samples within this project but will retain them for future work to examine – at a later date - epigenetic and other 'omic changes

- a venous blood sample (serum and plasma)
- a urine sample

After collection and processing, the samples will be stored in a dedicated freezer at -80^{o}C.

Firesmoke exposure assessment:

Grenfell

- we will, with experts from LFB and with the use of contemporaneous records, develop a tool which will provide semi-quantitative estimates, for all consenting cohort members, of individual exposure to fire smoke during the Grenfell fire.

pre- and post-Grenfell

- we will, for each consenting member of the cohort, use the detailed information, held by LFB, on individual incidents of smoke inhalation documented as a 'safety event/injury' supplemented by station-specific 'operational experience' linked to employment records for each firefighter; see box. This will provide an unprecedented, objective measure of the non-Grenfell fire experience for each participant.

3.2 Data and sample handling and analysis

We will not be using any paper records. Demographic, contact and questionnaire data will be collected using bespoke software (Microsoft ODK) on tablets and automatically uploaded to a secure, password protected Imperial server. The physiological measurements are automatically stored on their linked laptops and will be regularly transferred to the same server. We will retain records of all participants sufficient to link their crfs, questionnaires, measurements and samples; and all original signed informed consent forms.

Periodically, through the course of the prospective study, we will estimate the associations between semi-quantitative estimates of Grenfell exposure and incident respiratory, cardiovascular and cancer outcomes obtained through data linkage, after controlling for potentially confounding exposures such as other firesmoke exposures and smoking. Similarly, we will examine associations between the physiological measurements made at survey and subsequent incidents of cardiac and respiratory disease. Our sample size is, necessarily, constrained and because of the unique nature of the Grenfell fire we cannot make meaningful estimates of the statistical power of the prospective study.

We can, however, estimate the power of relating exposure at the Grenfell fire to the physiological measurements made at the baseline survey. There will be, we anticipate, sufficient variation between firefighters in their exposures at Grenfell to allow 'internal' comparisons of the above measures between exposure groups but we will include also an unexposed reference group of 'eligible but unexposed' LFB firefighters.

In this respect, our primary hypothesis is that intense exposure at Grenfell will have given rise to deficits in small airways function as measured through impulse oscillometry. Measurements in almost 500 Australian firefighters (*Schermer T et al. Respirology (2010) 15, 975–985*) suggest that R5 distributes Normally with a mean of 0.27kPa/L/s and a standard deviation of 0.08. On the assumption that there were 100 heavily exposed firefighters and 900 with lesser exposures and that 80% of each group participate in the survey, we will have, on internal comparison, 90% power to detect a minimum between-group difference of 0.027kPa/L/s (α=0.05). This estimate depends on their being an equal distribution of potential confounders between the two groups which we think is a reasonable

assumption. There is not yet an established minimal clinically important difference for R5 (or other oscillometry values) but it will almost certainly be >0.02; our intent, however, would be simply to compare values across exposure strata to establish cause/effect.

The primary statistical analysis will be of the relationship between R5 and 'Grenfell exposure', an independent, ordinal variable with several levels including nil. Secondary analyses will be of other, continuous and categorical measures of respiratory function and symptoms and of arterial stiffness. Univariable analyses will be through ANOVA or Kruskall Wallis (as appropriate) with a non-parametric test of trend, an extension of the Wilcoxon rank-sum test. We will subsequently undertake linear regression analyses adjusting for non-Grenfell firesmoke exposures (likely a continuous measure) and other potential confounders including age, sex, ethnicity, BMI, smoking and other non-firefighting occupational exposures (Yes/No).

3.3 Biosample storage

We do not plan to undertake analyses of the biosamples within this project but will retain them for unspecified, future work to examine epigenetic and other 'omic changes in relation to firesmoke exposure. After collection and immediate processing, whole blood, serum and urine samples will be held in long-term storage in a dedicated freezer at -80^{o} +/- 10^{o}C, located in an HTA-compliant facility at Imperial.

4. PARTICIPANT RECRUITMENT

4.1 Recruitment strategy and pre-recruitment evaluations

On our behalf, to satisfy the requirements of GDPR, London Fire Brigade (LFB) will identify the names and contact details of all firefighters (c.1000) who directly attended the Grenfell Tower fire in June 2017; every effort will be made to include those who have left service since the fire, estimated to number no more than a dozen. We will also recruit, a sample (n=100) from a 'referent' group, those who were eligible to attend the fire but did not do so because of annual leave and the like. In order to conform to CONSORT, we will ask LFB to provide a breakdown, by age and sex, of all eligible to take part.

We will not undertake any pre-recruitment evaluations. Each potential participant will be invited, by the Brigade, to take part in an independent and confidential survey of (cardio) respiratory health, to

take place in the clinical research facility of Royal Brompton hospital in London; a proposed letter of invitation is attached. Up to two follow-up letters of invitation will be sent to those who do not respond to earlier invitations.

LFB have agreed to bear the costs of 'cover' at work for participants and of travel for those in current service. We will cover any travel costs for the small number of participants who have left service. We will not offer any other inducement. LFB will be aware of who has taken part in the study as they will need to ensure their work shifts are covered whilst they attend the study visits.

4.2 Inclusion Criteria

Attendance (or eligibility to attend) Grenfell fire as a firefighter

4.3 Exclusion Criteria

Unwillingness or inability to provide informed consent

4.4 Withdrawal Criteria

Participants will be free to withdraw at any stage without giving reason; they can do so prior to or at any time during the survey. Any data collected from them up the time of withdrawal will be used, as with fully participating individuals, only after (pseudo-)anonymization.

5. ADVERSE EVENTS

5.1 Definitions

Adverse Event (AE): any untoward occurrence in a participant.
Serious Adverse Event (SAE): any untoward and unexpected occurrence or effect that:

- **results in death**
- **is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **requires hospitalisation**
- **results in persistent or significant disability or incapacity**

5.2. Reporting Procedures

All adverse events will be reported. Any questions concerning adverse event reporting will be directed to the Principal Investigator in the first instance.

5.2.1 Non serious AEs

All such events, whether expected or not, will be recorded.

5.2.2 Serious AEs

An SAE form will be completed and emailed to the Principal Investigator within 24 hours. All SAEs will be reported to the Ethics and Research Governance Coordinator at Imperial where, in the opinion of the Principal Investigator, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and

- ‘unexpected’, i.e. an event that is not listed in the protocol as an expected occurrence

6. ASSESMENT AND FOLLOW UP

At this stage we are not planning any face-to-face follow up. However:

a. we will seek permission to contact participants for follow up should that be scientifically justified.

b. we are seeking permission to link, at any future date, participants’ NHS numbers to routinely collected health data such as those collected on hospital admission, on cancer identification and on death; this too will require further funding and additional approval from an ethics committee but we would not seek further permission to do so from individual participants.

c. we are asking permission to analyse their biosamples at a future date; this will require further funding and additional approval from an ethics committee but, again, we would not seek further permission to do so from individual participants.

7. REGULATORY ISSUES

7.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and will do so from the Joint Research Compliance Office (JRCO) at Imperial and from a national Research Ethics Committee (IRAS). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2 Consent

Signed consent to take part in the study will be sought from each participant only after an information leaflet (attached) has been offered, a full explanation has been given, and time allowed for consideration. The right of the participant to refuse to participate without giving reasons will be respected; all participants will be free to withdraw at any time. We do not anticipate that there will be any participants without a good understanding of spoken and written English or with other special communication needs

7.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study.

7.4 Indemnity

Imperial College London holds negligent harm insurance policies which apply to this study.

7.5 Sponsor

Imperial College London will act as the main Sponsor for this study

7.6 Funding

The funding for the initial stage of this study is provided by the COLT Foundation. Neither participants nor investigators will receive direct payment for the study.

7.7 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Johanna Feary. She will liaise regularly and frequently with Paul Cullinan.

9. PUBLICATION POLICY

The goal of the study's publication policy is to disseminate accurate and informative results of the research to the scientific community and to other interested stakeholders; these results include those of primary study outcomes, secondary analyses, and ancillary studies. Priorities in selecting forums for publication will be given to peer-reviewed journals as well as presentations and publications of abstracts at national and international scientific meetings. The PIs will work with the study statistician to identify potential scientific papers related to both the study's primary and secondary aims, establish writing teams and manuscript authorship, and prioritize manuscript development. The PIs will write the scientific manuscripts related to the study's primary aims as lead/senior author(s). The lead author will be responsible for assuring production of the draft of the paper within three months of availability of the data. This time period should allow for review and comment of the draft by all co-authors and input from other members of the study team. For protocols that have secondary research aims, investigators other than the PIs may be assigned lead authorship of manuscripts. Investigators who accept lead authorship of manuscripts related to secondary aims will be expected to produce a manuscript of publishable quality following the principles outlined above. Abstracts reporting the preliminary or highlighted results of the research will not negate the necessity of preparing a full manuscript for publication. All papers and abstracts will be submitted to LFB for their (timely) comment prior to submission; Imperial College retains the right to publish material without requiring the permission of LFB or any other external parties.

Material – written or audiovisual – that is intended for non-scientific audiences will be prepared by the PIs in conjunction with the study statistician and in consultation with LFB and, if deemed appropriate by them, the FBU; all such material must be agreed by all parties before its use.

No publications/presentations/press releases etc arising from this research will be produced in a manner that could identify any individual participant(s).

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