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**COPE- West Midlands: The contribution of occupational exposures to risk of COVID-19 and approaches to control among healthcare workers**

**Participant information leaflet**

**Who are we?**  We are a team of researchers from the University of Birmingham, working with several NHS Trusts across the West Midlands, undertaking a research study among healthcare workers linked to NHS Trusts.

**Why is this study being done?** Coronavirus 2019 (COVID-19) transmission is more likely to happen indoors than outdoors. For example, household members are advised to self-isolate alongside those with COVID-19, and hence, are more likely to be exposed to the infection. This is of particular importance for contacts of healthcare workers, as healthcare workers have a higher risk of getting COVID-19. We know some household members are more vulnerable to becoming more ill with COVID than others, e.g. those who are older and have a health condition. However, we know little about which factors are the most risky. Furthermore, although children seem to be at a lower risk of being infected, this remains unclear and we need to find out more. By learning more about who and what factors affect COVID-19 transmission within households, we can make recommendations for how the risk of infection among household members is minimised, and how healthcare workers can be supported by their workplace.

**Why have I been sent this information?** You are receiving this as, when completing your COPE-WM survey, you gave us your permission to contact you for the additional COPE study investigating COVID-19 transmission among household members.

We are keen to understand the impact on, and hear the views of, a **range** of household members, including those who have **and** have not had COVID-19. We plan to:

* Recruit 200 households of COPE-WM study participants who reported a positive COVID-19 swab test in their baseline survey. We will try to ensure that there is representation amongst those invited from various ethnic backgrounds (including Black, Asian and ethnic minorities and White backgrounds)
* Collect information from **all adult** members (aged 16 years and above) of recruited households using a questionnaire developed for this study
* Arrange dried blood spot tests to check for antibodies for past COVID infection for all members of recruited households, including where possible, children between 5 and 15 years
* Recruit 1 adult, from approximately 20 households, to take part in an interview to explore in more depth their experiences during the pandemic and their use of protective measures in and outside the home. We will only contact household members about an interview if they provide permission for us to do so when they complete the household member survey.

**What does taking part involve?** If you agree to take part, we will ask:

1. Each adult member of your household to complete an online consent form, and questionnaire about their health, lifestyle, home, work and experience of COVID-19 infection and testing. This should take approximately 20 minutes to complete. If you provide us with their email address we will send them a study invitation email directly otherwise we will do this by sending you an email containing a link for you to share with all adult household members living with you at the time you tested positive for COVID-19. This will provide them access to the household member participant information sheet, consent form and survey (for those who provide their consent)). If you have any questions about the process, please contact the study team.
2. All household members (including, if possible, children aged 5 years and above) to provide, using a finger prick, a few drops of blood for an antibody test. The antibody test kits will be sent to your household members after they have completed their questionnaire.

All blood test kits will be labelled, it is important to ensure that the appropriately labelled kit is used for each household member. We will provide a prepaid envelope to send each kit back to us. The blood samples will be tested for the presence and amount of COVID-19 antibodies. The samples will be confidentially processed, analysed and stored at the Clinical Immunology Service, which is a UKAS accredited laboratory in the University of Birmingham. The reason to store the sample is so that repeat or further testing can be performed. Adult members of your household will be given the option whether this sample can then be used in the future, in an anonymous way for other ethically approved research projects.

For children their main carer will be given the option whether this sample can then be used in the future, in an anonymous way for other ethically approved research projects.

 If they decide they do not want us to retain their and / or their children’s sample for future research, we will only use it/them for the purposes outlined in the research project, after which it/they will be destroyed.

To assist with accurate record linkage for your household members we will ask you to provide, with their permission, the name and age category for all members of your household, for children for whom you are not the main carer we will also ask you for the name of their main carer. The email address for adult members will be requested so that we can send them a study invitation email.

**Optional interview study**

For household members who provide their permission for us to do so when they complete the household member COPE-WM survey we may contact them to invite them to participate in a one-to-one interview to discuss their experiences during the pandemic. If they decide to take part, the interview will be arranged at a time convenient to them. The interview will be undertaken remotely either by telephone or using Zoom depending on their preference. We expect each interview will last approximately 30 minutes. The interviews will be audio recorded. They will be provided with a separate participant information sheet and consent form for this aspect of the household member study, which would be required to be completed prior to being interviewed.

**Do I have to take part?** No. Participation in this study is voluntary. If having read this information sheet you decide to take part, you will be asked to complete an online consent form; you will need to complete this before your household can take part in this study.

**Can I change my mind about taking part?** You may withdraw consent at any time, without giving a reason, and we will not collect any further information from you or your household members. Unless you request otherwise, any data or blood samples which have been collected whilst you have been in the study will be used for research as detailed in this information sheet. All your existing information will remain pseudo-anonymised, and neither you nor your household members will be identifiable. If you decide that you would like us to withdraw your data from the study, please let us know up to two weeks after collection of the data.

**Possible benefits of taking part** The information, views and experiences of members of your household will help us to provide recommendations to help reduce the risk of COVID-19 transmission within the households of healthcare workers. This information will be particularly helpful if there were further peaks in the pandemic here or in other countries. It will also inform NHS decisions in future epidemic and pandemic situations.

**Disadvantages of taking part** You/your household members will be required to invest time for the antibody tests (including helping others e.g. infants and children) and, for adult members, around 20 minutes for the survey. If your household member(s) agree to be contacted in relation to the household member interviews, should they decide to take part, the interview will be approximately 30 minutes, scheduled at a time that is convenient for them.

**Reimbursement for taking part**

As a thank you for taking part, all interview participants will receive a £20 high street voucher.

**Will my information be kept confidential?** Yes. We will follow ethical and legal practice and all information about you/your household members will be handled in confidence. The information you/your household members provide in this study will be subject to the General Data Protection Regulation (GDPR) and Data Protection Act 2018 for health and care research. The names of household members will be removed from the interview transcripts and they will be assigned a unique ID number to maintain confidentiality of their identity. Direct quotes may be used in publications, but these will be numbered and anything which could identify them will be removed.

Study information will be kept securely by The University of Birmingham for 10 years.

Further information on how your data or your family members’ data will be used can be found in **COPE additional information sheet** which can be accessed via a link on the study website. For more information on how we use your information please contact the study team, or visit: [www.birmingham.ac.uk/COPE-study](http://www.birmingham.ac.uk/COPE-study).

**How have patients and the public been involved in this study?**

This study arose partly from concerns and feedback from NHS Trust staff who want to understand how to avoid COVID-19. The questions addressed in the study are based on feedback from staff in relation to their concerns and needs. In planning the study, we consulted a panel of staff working in the Trusts and based on their feedback, amended aspects of the study. This panel will continue to advise us over the study period.

**What will happen to the results of the study?**

At the end of the study the information collected will be analysed and published in recognised medical journals, with summaries and briefing notes available on the study website and through the Trusts. The identity of participants in the study will remain confidential. We will also provide your family members with the result from their antibody test taken as part of this research study. However, please note: although the home-administered COVID-19 sample collection tests are approved and validated, no test is 100% reliable. Furthermore, the science on immunity from COVID-19 is still emerging and the implications of a positive antibody result are unknown. For example, we do not yet know if antibodies provide protection against further infections, if they are present at the time of testing, or how long these antibodies will last.

**Who is running the study?** This study is sponsored by the University of Birmingham and is being carried out by a research team led by Professors based at the University of Birmingham (Peymane Adab, Professor of Public Health; Alex Richter, Professor of Immunology; Elizabeth Sapey, Professor of Respiratory Medicine), together with other researchers with a range of expertise. The study is funded by the UK Medical Research Council (MRC), to support the country’s response to COVID-19.

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

**Further information or concerns?** If you have more questions, or if you have any concerns about the study or its conduct, please contact the COPE study research team at cope-wm@contacts.bham.ac.uk, or the research co-ordinator (Dr Emma Lancashire, email: e.r.lancashire@bham.ac.uk ; telephone: 0121 414 3151).