[insert NHS Trust logo when localised]

Participant Information Sheet (Patient or Accompanying Person)

Study Title: Assessing effectiveness of **A**rtificial **I**ntelligence air **Sa**fety **Tool** (**AISaT)** recommendations in outpatient, day-case rooms, and wards to reduce risks of airborne disease transmission

Invitation and Brief Summary

We invite you to take part in a study testing the value of Artificial Intelligence air Safety Tool (AISaT).

- Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and family if you wish.
- You are free to decide whether to take part. If you choose not to take part, this will not affect the clinical care you receive.
- Please ask us if there is anything that is unclear, or you would like more information.

In this research study we will use information from you and your medical records (please note that medical records will not be accessed if you are an 'accompanying person' participant). We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.

Why have you been invited?

You have been invited to participate in this study as you are either a patient, or a person accompanying a patient, at one of our study sites. Our research team have developed a computer software called 'Artificial Intelligence air Safety Tool' (AISaT) and we would like to test its value for reducing risk of transmitting airborne diseases in different clinical settings as well as its acceptability to patients.

---

1. What is 'AISaT'?

Artificial Intelligence air Safety Tool' (AISaT) is an AI system that uses artificial intelligence techniques to suggest to users the best place to put air filters or other devices, such as screens, fans etc., to clean the air in the room or ward bay. This is difficult to work out as the best place for each device depends on the type of room (e.g. room size, existing ventilation,

number of people etc.) and what it is being used for. Our researchers are developing this tool to be used by staff in hospitals with the aim of reducing the risk of transmitting airborne infections.

2. Why are we doing this study?

Inadequate ventilation in hospitals drove disease transmission during the COVID-19 pandemic. When people breathe, speak, or cough, they release tiny droplets of saliva into the air. The smallest of these droplets, called aerosols, are so light that they can stay suspended in the air for hours and spread widely, especially in indoor spaces. If these droplets contain viruses, they become infective respiratory particles which can infect others who breathe them in.

Good ventilation can help by clearing the air, preventing infective respiratory particles from building up indoors. Other mitigations include devices such as air filters, that can reduce the number of infective respiratory particles in the air; screens or curtains create physical barriers between people; and fans can change the direction of airflows.

Research has shown that the location of mitigation devices such as air filters, screens and fans in a room or ward bay plays a crucial role in how clean the air will be. We are testing the effectiveness of AISaT to advise hospital staff (usually estates or infection prevention and control staff) how to place these mitigation devices. By optimising the placement of air filters, screens and fans, we aim to improve their ability to prevent the spread of airborne diseases.

Preparing for future airborne transmitted diseases with an easily deployable technology is a critical NHS need. We need to test our AISaT tool in different areas of the hospital with different layouts, to see if it works to reduce the risk of the spread of infections in the air.

3. What is the study's purpose?

We aim to find out how well the AISaT software tool reduces the number of aerosol droplets in the air over time when its recommendations for mitigation device placement are followed.

Our research will test how effective AISaT is in hospital settings, such as outpatient clinics, rooms where aerosol-generating procedures take place (such as endoscopy and Ear, Nose and Throat assessments), and inpatient wards. To do this, we will use a small aerosol generator to produce tiny, safe salt-water particles in the air and measure the number of these particles in the air with particle counters in each setting.

We will compare the results in three scenarios:

1. **No AISaT tool or airborne transmitted disease mitigation devices:** Neither the AISaT tool, nor mitigation devices will be used.

2. **Clinician-placed mitigation devices:** Devices including air filters, screens and fans will be offered, and the clinician can decide whether and where to place them. The AISaT tool will remain off.
3. **AISaT-guided location of airborne transmitted disease mitigation devices:** The AISaT tool will guide hospital staff on where to place the air filters.

In all these scenarios, your appointment/procedure will take place as usual.

4. How many participants are we planning to involve in the study?

We plan to involve around 4,848 participants, in a series of pilots and staged randomised clinical trials. This means that we will do a series of trials in turn. The first will be in hospital consulting rooms. The second will be in rooms where procedures such as endoscopy take place and the third will be on hospital wards.

5. What would taking part involve?

Informed consent

You will be given this information sheet prior to your appointment, and you will be provided the opportunity to ask any questions about the study. On the day of the study, a member of the research team who is working on the study at the hospital will talk to you about the study and answer any questions you have. If you agree to take part, you will be asked to sign a form to give your consent. The research team is separate to your clinical care team and are not involved in your clinical care.

Mental capacity means being able to understand information, think about it clearly, and make your own decisions. Our study team will not be monitoring mental capacity and so following the consent process, continued capacity will be assumed.

What will I have to do?

After completing the consent forms, we will first ask you a few basic questions, such as your age range, sex, ethnicity, height, weight, and history of breathing difficulties. We need this information as these factors can affect the number of tiny droplets you produce when you breathe and speak.

By consenting to take part in the study, you are agreeing that the clinical area you are visiting (consultation room, procedure room or ward bay) is randomly assigned into one of three conditions for the duration of the consultation/procedure. If this is taking part in a ward bay, the duration will be for one day using each condition. If you move out of the ward bay during the time of the study, the study will still carry on.

1. **No AISaT tool or air filters:** Neither the AISaT tool, nor air filters, will be used.

2. **Clinician-placed air filters:** Devices including air filters, screens and fans will be offered, and the clinician can decide whether and where to place them. The AISaT tool will remain off.
3. **AISaT-guided air filters:** The AISaT tool will guide hospital staff on where to place the air filters.

The research team will set up the room or ward bay in the relevant assigned way. During the clinic, procedure session or day on the ward, the only other changes in the room will be the presence of a particle counter, which counts the particles in the air and a small aerosol generating device. The aerosol it produces is saline (salt water), which is completely safe.

The study will compare how many of these small air particles are measured in each of the three settings listed above.

There may also be an infrared camera in the room to count how many people are in the room at the time, their location and movement. It will not be possible to identify people from the infrared images recorded on the camera.

As part of the consent form, we will also ask you if you would be happy to be invited to a follow up part of the study (which involves further questionnaire(s) after the date of your initial visit from our research team). Consenting to this does not confirm your involvement, it just allows us to contact you to send you the information about it and offer you the opportunity to take part.

Whether you take part in the study or not will not affect your care.

What would exclude me from being able to take part?

We will not do this study in obstetric, psychiatric or paediatric clinical areas.

People under 18 years old will not be eligible to participate.

What are the possible benefits of taking part?

There are no definite benefits of taking part, although you might benefit from the clinical space you are in having a lower risk of airborne disease transmission.

What are the possible disadvantages and risks of taking part?

Due to the low impact of this study, the known risks of taking part are very unlikely.

The known and potential risks include trip hazards in all study stages when air safety mitigation devices are placed in unsuitable places when following the AISaT guidance, for example in the middle of the floor, with leading wires left uncovered.

There is a risk, if involved in a ward setting, of portable filters and similar devices falling over, inpatients throwing them, not having enough plug sockets to plug devices into and getting in the way of emergency procedures. There is a risk that mitigation devices may make too

much noise which could interfere with patients hearing doctors or with sleep. Salt water does not cause any risks to humans.

6. How will we process your data will in line with General Data Protection Regulation (GDPR)?

The data controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, please visit this weblink for further information:

https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The lawful basis that will be used to process your personal data is: 'public task' and 'research purposes' will be the lawful basis for processing special category data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data, you provide we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk

How will we use information about you?

We will need to use information from you for this research project. We will also access medical records only to find basic demographic information

This information will include your sex, age, height, weight, history of respiratory illness. People will use this information to do the research or to check your records to make sure that the research is being done properly. If you consent to an optional follow-up questionnaire, our research team will contact you following your appointment to complete this online.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

UCL is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by pseudo-anonymising your data. Only our internal research team will have access to your data. Your data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

After the study has ended, we will store your data for a minimum of 10 years in the first instance. This may be renewed with a further ethical application**.**

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information, by contacting our team.

You can contact the research team via email by contacting the Clinical Trial Coordinator (Sharon Cheung sharon.cheung@ucl.ac.uk). UCL Data Protection Officer is data-protection@ucl.ac.uk.

For further information about your data in our research: www.hra.nhs.uk/patientdataandresearch

7. **What will happen if I don't want to carry on with the study?** If you decide you no longer wish to take part, you will be withdrawn from the study and your data will not be used. Your decision to take part in research is entirely voluntary, and you can change your mind at any time. Any decision you may make to withdraw (or to decline the invitation to be involved in the first place) will not affect the care you receive from the NHS.

What will happen to the results of this study? The results of the study will be analysed by our internal research team. The results may feed into research papers/outputs and will hopefully help to create a system producing cleaner air in health systems in future. There will be no individual or patient identifiable data at any point.

8. **Who is organising and funding this study?**

This research is part of the Air Safety programme which is funded by National Institute for Healthcare Research (NIHR). University College London (UCL) is the sponsor and data controller for this study. The Chief Investigator is Professor Laurence Lovat (UCL).

Who has reviewed this study?

This study is sponsored by the Joint Research Office (JRO) at UCL and has received prior ethics approval. We have a Patient Advisory Group who have supported this study.

We will not inform your GP of taking part in this study as there is no impact on your health.

9. What if something goes wrong?

Every care will be taken throughout the course of the study. In the unlikely event that you experience any issues related to your participation, please discuss them with a member of the study team in the first instance.

If you wish to make a complaint or have any concerns about how you have been approached or treated, you may also contact the Patient Advice and Liaison Service (PALS) at the hospital where this study is being conducted, or the local complaints office:

PALS: [insert details of local PALS here]

Local complaints office: [insert details of local complaints office here]

Further information and contact details:

You will be offered lay summary results of the study if you opt in to this. Results will be sent only by e-mail.

Study team / clinical trial coordinator (Sharon Cheung): dsis.airfilters@ucl.ac.uk

UCL is the data controller; the UCL Data Protection Officer is data-protection@ucl.ac.uk. The data processor is University College London.