Facilitating A SARS CoV-2 TEst for Rapid triage (FASTER)
Consultee Information Leaflet and Declaration Form

We have decided that your patient has lost capacity to decide for himself/herself whether to continue participation in this research.
To help decide if he/she should continue in the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research, these should take precedence.
If you decide your patient would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your patient should be withdrawn.
If you decide that your patient would not wish to take part it will not affect the standard of care they receive in any way.
If you are unsure about taking the role of consultee you may seek independent advice.
We will understand if you do not want to take on this responsibility.
The following information is the same as what would have been provided to your patient.

What is the purpose of the study?

We are working in partnership with industry that has developed a new rapid test to detect the presence of Coronavirus (COVID-19). Currently the NHS uses the best test available to detect the virus using a nasal swab. The current test can take up to 4 days before the results are available which can lead to an extended amount of time in quarantine or a prolonged amount of time grouped with other patients that are suspected to have Coronavirus.
The new tests that we have available need to be validated against the current best practice. We need to use the tests with real samples to check if they are as accurate as the current test. If successful, this study may change practice and allow for early detection and appropriate isolation of patients.
In addition to this, we are working with Pfizer who have an existing vaccine which works against one cause of severe pneumonia but are working on a vaccine to prevent pneumonia specifically caused by COVID-19. The work funded by Pfizer will assess the immunologic response to COVID-19 and Pneumococcus and the relationship between the two

Does your patient have to take part?

No. Taking part in this study is voluntary.

Why have they been asked to take part?

We are looking for patients that are admitted to hospital with symptoms of COVID-19, these include any of the following
a new persistent cough and/or temperature above 37.8^0C and/or shortness of breath.
They will be eligible if:

- Adults aged 18 years and over

- Have symptoms of COVID-19: shortness of breath and/or temperature above 37.8^{0}C and/or new persistent cough OR Clinical/ X-ray evidence of pneumonia (chest infection)
- Fluent spoken English - to ensure a comprehensive understanding of the research project and their proposed involvement
- Capacity to give informed verbal consent

What happens if they take part?

If your patient takes part in this study and the research team agrees that they are suitable, you will be asked to sign the consultee declaration form. A copy of this information sheet will be given to you to keep and a copy of your consultee declaration will be filed where possible.
The study involves 4 visits over a minimum of 4-5 weeks. Samples and data will continue to be collected throughout your stay in hospital.

What samples do you take?

We collect nasal, saliva, blood and urine samples to look for the virus and the immune response to the virus in the nose, saliva and blood

Nasosorption: We put a small piece of blotting paper inside their nostril and hold it there for up to 3 minutes. This takes some concentrated secretions from inside their nose and will be repeated on each nostril.

Nasal & throat combined swabs: We take a cotton swab (similar to a cotton bud) and insert it into their mouth and wipe it over their throat. We then use the same swab, insert it into their nose and rotate it. This will take some cells so that we can look at bacteria and viruses. We may repeat this twice at each visit.

Throat swab: We take a cotton swab and insert it into their mouth and wipe it over their throat. This is repeated at each visit.

Blood samples: We take blood samples from a vein in their arm (using a needle) or from a centrally placed line. We will take up to 40 mL (~7 teaspoons) during this visit.

Saliva: We will take a saliva sample where possible to collect spit into a tube, up to 1ml.

Urine: We will take a 20ml urine sample.

Oral test: Some participants will be required to use an oral test to take some liquid and cells from their mouth, inside their cheek to test for COVID-19. These samples will be repeated at each time point.

Exhaled detection facemask: Some participants (those not requiring oxygen) will be asked to breathe into an exhaled detection mask. They will wear the face mask so it covers both nose and mouth for a duration of 30-60 minutes. There are no restrictions on talking or coughing while the mask is in situ.

They may be approached to take part in other research studies relating to COVID-19. They are able to take part in other research studies relating to COVID-19. Participants may also be approached to take part in a future research study, this would be discussed with them at the day 28 visit if appropriate. The participant would be consented separately for this under a separate study protocol.

What will happen at each visit?

Screening Period	
Witnessed Verbal Consent Visit: Day 0 Baseline samples	A member of the research team will discuss the study involvement with your patient. They will have the opportunity to ask questions and discuss the study directly with the researcher. If they are happy to take part in the study, they will have been asked to give verbal consent. This will have been witnessed and documented by a member of the clinical team. We will have asked them some questions about their medical history, medications, social contacts and their symptoms. We will also have reviewed their medical records. A blood sample (up to 40ml/ approx seven teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test. A selected group will undergo the Exhaled detection Facemask
At any point in which the patient loses capacity due to a deterioration in their condition, a member of the clinical team will be approached to act as the nominated consultee.	
Visit 2: Day 2 * +/- 1day	A blood sample (up to 40ml/ approx 7 teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
Visit 3: Day 7 * +/- 2days	A blood sample (up to 40ml/ approx. 7 teaspoons) along with saliva, throat swab, 2 nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
Visit 4: Day 28* +/- 15days	A blood sample (up to 40ml/ approx. 7 teaspoons) along with saliva, nasosorption, up to 2 nasal/throat swabs and a urine sample will be taken during this visit. A selected group of participants will undergo the oral test.
End of study	

At each visit, the research team will access your patient's medical records including their clinical results and they will ask about your symptoms.

* A group of participants selected by the research team

If day 28 occurs following hospital discharge, the participant may be invited to attend this visit in a clinic, this will be arranged directly with the participant. If the participant is unable to attend clinic, it may be possible for a home visit by a research nurse to be arranged

What are the benefits in taking part?

There are no direct benefits in taking part in the study and the participant will not receive payment. The study may lead to the approval of a new diagnostic test for COVID-19 that is faster than the current test used in the NHS. This could lead to appropriate isolation and rapid results thereby reducing the risk to the wider community.

What are the risks of being in the study?

The risks that you and the participant should consider *before* participation in this study are the risks associated with venepuncture, nasal and urine sampling.

Blood sampling: The risks associated with blood sampling (venepuncture) are minimal, but this may cause temporary pain, bruising and/or bleeding to the arm. The blood sampling will be performed by trained medical professionals.

Nasal sampling: There are limited risks associated with these samples. The nasal swab can be a little uncomfortable (this passes very quickly) and may cause a small amount of bleeding but this is uncommon. The nasosorption can tickle the nose a little.

Throat swab: This may make the participant gag a little.

Saliva sampling: There is no risk involved in saliva sampling.

Nasosorption sampling: There is no risk involved in the nasosorption sampling, it may just tickle.

Urine sampling: There is no risk involved in urine sampling.

Exhaled Detection Facemask: participants may feel claustrophobic while wearing the facemask

During the study, if the participant has any adverse events that they feel should be notified to the research team, they must self-report these using the contact below.

What if there is a problem?

You or the participant can contact the research team by phone, they will answer any questions. Any medical care they need will be provided by the NHS.

What if I wish to complain?

If you or the participant wish to complain about any aspect of the study, you can contact the study doctor or nurse. They can also contact the sponsor by email on lstmgov@lstmed.ac.uk Complaining will not affect the medical care the participant receives now or in the future.

The study is sponsored by the Liverpool School of Tropical Medicine (LSTM) and is covered by Clinical Trial Insurance.

What if I change my mind, or want to stop?

Even if they do start in the study, they are free to stop at any time and without giving a reason. If they decide not to take part, or to withdraw from the study, this will have no effect on their future health care.

If they decide to stop or you decide they should not continue in the study, we will continue to use the samples and information that we have already collected unless they tell us not to.

Will their details be kept confidential?

Yes. For safety, we collect information about their medical history and contact details before they take part. The research team use this information to check they are healthy, and to contact them when needed.

We will also collect information which allows us to understand more about the samples, for example, their age or sex. However, those outside of the clinical team are never given information that can identify you. their samples are given a unique number, and their name is not used. We will request information from their GP such as vaccination history, medical and medication history. We will send a GP questionnaire for completion retrospectively.

We do not expect to find anything which would affect their health care. If we do, we will let them and their GP know about it.
All data will be collected and stored at the LUHFT and the LSTM. It will be stored for a minimum period of 15 years. Their medical notes and research data are may be looked at by those who monitor the research.

What will happen to their samples?

The samples taken during this study will be processed and stored in the LSTM. These samples will be gifted for future use in ethically approved research.
At the end of the study, remaining samples will be transferred to a research tissue bank held at the LSTM. All samples will be anonymised at the point of sampling. Stored samples will be analysed as and when new technology becomes available, when new scientific questions arise relating to protection and susceptibility of respiratory disease. Samples will be sent to Pfizer Inc for development of lab assays which may be used in vaccine development Samples may be sent to national and international collaborating laboratories for their expertise however all identifiable information will be removed.

Contact details

General questions and self-reported adverse events: please contact the research team on 07740 410 290 or 0151 702 9424 during normal working hours.

*The Chief Investigator for this study is **Dr Andrea Collins**. You may contact her at the LSTM, Liverpool Life Sciences Accelerator Building, 1 Daulby Street, Liverpool, L7 8XZ, UK. Telephone: 0151 702 9439. This research is sponsored by the LSTM. It is funded by LSTM and Pfizer Inc. The research has been reviewed for scientific content by an external panel. The National Research Ethics Service Committee has reviewed the study and given approval for it to take place.*
LSTM is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. LSTM will keep identifiable information about you 10 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information by contacting dataprotection@lstmed.ac.uk.
LSTM will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from LSTM and regulatory organisations may look at your medical and research records to check the accuracy of the research study. LSTM (research site) will pass these details to LSTM (sponsor) along with the information collected from you and your medical records. The only people in LSTM who will have access to information that identifies you will be people who need to contact you to regarding your participation in the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.
LSTM (research site) will keep identifiable information about you from this study for 10 years after the study has finished.

LSTM will collect information about you for this research study from you and/or your GP records. Your GP will not provide any identifying information about you to LSTM. We will use this information to confirm your eligibility

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care.

Liverpool University Hospitals NHS Foundation Trust

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Consultee Declaration Form

Participant Study number

Please read the following statements and initial each box. Then, print and sign and date below.

Please initial box

I [name of consultee] have been consulted about [name of potential participant]'s participation in this research project. I have had the opportunity to ask questions about the study and understand what is involved.	☐
In my opinion he/she would have no objection to taking part in the above study.	☐
I understand that I can request he/she is withdrawn from the study at any time, without giving any reason and without his/her care or legal rights being affected.	☐
I understand that relevant sections of his/her care record and data collected during the study may be looked at by responsible individuals from [name of sponsor and/or host organisation] or from regulatory authorities, where it is relevant to their taking part in this research	☐
I agree to their GP or other care professional being contacted to provide relevant medical history	☐
I agree to their continued participation in this study.	☐

Name of Consultee	Date	Signature
Relationship to participant:		

Person undertaking consultation (if different from researcher):

Name of Researcher	Date	Signature

Copies: 1 for participant, original for site file and one scanned or filed in hospital medical notes