COVID-19 Surveillance in Children attending preschool, primary and secondary schools

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Confidentiality Statement

Investigator Agreement

“I have read this protocol and agree to abide by all provisions set forth therein. I agree to comply with the International Conference on Harmonisation Tripartite Guideline on Good Clinical Practice”

Chief Investigator Name: Dr Shamez Ladhani

28 June 2020

Chief Investigator Signature

Date of Signature
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1.0 AMENDMENT HISTORY

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<tr>
<td>1</td>
<td>1.1</td>
<td>15/05/20</td>
<td>Shamez Ladhani</td>
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<td>2</td>
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<td>3</td>
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<td>Removing restrictions on document disclosure in the confidentiality statement; extending the number of participating schools across England and allowing more flexibility with swab, saliva and blood sampling in the different settings; anonymised reporting to the ONS; addition of insurance and indemnity arrangements</td>
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<td>Oral fluid testing for sKIDs swabs arm, questionnaires with last nasal swab in sKIDs swabs arm and for the second appointment for sKIDs bloods arm; removal of bleeding disorder as exclusion criteria for blood test</td>
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2.0 BACKGROUND AND RATIONALE

From December 2019, a novel infection "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) was identified in the Wuhan region of China. The infection was identified as the causal factor in a growing number of severe cases of pneumonia (1). This disease was subsequently named coronavirus disease 2019 (COVID-19). SARS-CoV-2 can cause severe disease similar to the previous SARS coronavirus from 2003. Severe disease is associated with pneumonia and damage to vital organs including lung, heart, liver, and kidney (1).

Very little is known about COVID-19 disease in children (1). In particular, we do not know if children attending preschool and educational settings might be asymptomatic carriers of SARS-CoV-2 and whether they develop immunity to the virus in the community. Understanding childhood carriage, transmission and immunity in children and the staff looking after them is critical for understanding how we can ease the lockdown for children and schools staff and support their safe return into preschool and educational settings.

We would like to approach families whose children continue to go to school and the school staff during the current lockdown in England. We have an opportunity to assess if they have developed COVID-19, whether they are carrying SARS-CoV-2 without any symptoms and whether they have already developed immunity against the virus. We will also be collecting oral fluid samples to validate antibody testing so that we can replace the need to have blood tests to test immunity in the future.

3.0 OBJECTIVES

3.1 Primary Objective
- To monitor SARS-CoV-2 infection and antibodies in children who are currently attending preschool, primary and secondary school and the school staff

3.2 Secondary Objectives
- To understand the role of children in the spread of SARS-CoV-2 in preschool and educational settings
- To validate oral fluid and capillary blood testing for SARS-CoV-2 antibodies in children and adults in some participating educational settings
- To evaluate the feasibility of more frequent swabbing in some participating educational settings

4.0 SITES, PARTICIPATION AND ELIGIBILITY

4.1 Sites
- We plan to recruit schools across England as the lockdown eases and more children return to school
Based on practical feasibility and accessibility, schools will be asked to participate in one of two arms of the study:

(a) sero-surveillance (three samples over 6 months) or
(b) weekly nasal swabbing until the end of the summer term

### 4.1 Participation

- Children who are currently attending preschool, primary and secondary school and staff will be invited to participate.
- Invitations will be sent via education settings (through email and/or letters) to staff and parents/guardians.
- In all instances, informed consent will be obtained from staff and parents/carers prior to participation.
- Staff and parents/guardians will be provided an information sheet, consent form and a short questionnaire.
- Staff and parents/guardians will have an opportunity to ask any questions by telephone, email or in person (on the day of testing).
- We will ask parents/guardians to involve their children by explaining why this surveillance is being undertaken and how the children can help by taking part.
- Children will receive age-appropriate information sheets and will be encouraged to co-sign the consent form with their parents/guardians.
- Completed consent forms will be stored securely at PHE.
- We will inform staff and parents/guardians that we may need to contact them again if additional information or sample(s) is/are required.

### 4.2 Subject Eligibility

- Children who are currently attending preschool, primary and secondary school and staff

#### 4.2.1 Inclusion Criteria

- Students whose parents/guardians sign a consent form
- School staff who sign a consent form
4.2.2 Exclusion criteria:
- Children whose parents/guardians do not provide a signed consent form.
- Staff who do not sign a consent form

4.3 Procedures

4.3.1 Unique participant identifier
- Following informed written consent, each participant will be allocated a unique participant number on enrolment to the study and a letter for the first visit (e.g. sKID 6001A).

4.3.2 Questionnaires and Tests

(a) Schools recruited for sero-surveillance
- Parents/guardians of all children attending school will be asked to participate in the sero-surveillance
- The parents will be asked to attend the appointment with their children when the samples are taken whenever possible
- Staff will also be asked to participate at the same time
- Where possible, this will take place on site in school or childcare facility, either at drop off or pick up time, or at the local Child Development Centre after school
- Where possible, testing will take place on a single day; alternatively, additional days may be agreed between the school and the investigators
- Parents/guardians and staff will be asked to sign a consent form and complete a short questionnaire
- Samples will be taken by experienced staff, wearing appropriate protective personal equipment as needed
- The samples taken at each visit will be decided with the individual schools when they agree to participate:
  - At a minimum, one nose swab (both nostrils) and one venous blood sample will be taken from all consenting participants
  - In some schools, an additional throat swab will be collected from all participants to assess whether one test is more sensitive than the other
  - In some schools, a capillary blood sample (finger-prick test) may also be collected in addition to the venous blood sample for validation of antibody testing – this could
potentially reduce the need for venous blood sampling to test for antibodies in the future

  o In some schools, an oral fluid sample may also be collected for validation of antibody testing – this could potentially reduce the need for blood tests to test for antibodies in the future

● To minimise distress to the children, we will offer local anaesthetic cream for the blood test

● Where a venous blood sample cannot be obtained either because venous sampling was difficult or unsuccessful or because the family refused the blood test, a finger prick test may be offered.

● All samples will be labelled with the participant’s unique identification number and sample date

● The samples will be appropriately packed and sent to PHE, where they will be processed and tested for SARS-CoV-2 infection and antibodies as appropriate

● Staff and parents/guardians will be asked to report any infectious illnesses in their children to the surveillance team by phone, text or email, and the results of any tests performed (e.g. SARS-CoV-2).

● Participants will have additional appointments for the same tests as follows:
  o Around 4-8 weeks after recruitment (around the end of the summer term, early to mid-July 2020)
  o 4-6 months later (around the end of the autumn half-term or the end of the autumn term)

● The study will seek to achieve high levels of follow up among those enrolled. Where necessary this will include making special arrangements to conduct subsequent appointments where children are not in school on follow-up study visit days

(b) Weekly nasal swabbing

● Where blood sampling for staff and/or students is not available or feasible, schools will be asked to take part in weekly nasal swabbing for SARS-CoV-2 infection

● Participating schools will have a co-ordinator appointed, ideally the school nurse.

● The co-ordinator will be provided with a copy of the protocol along with the instructions for taking nasal swabs

● The aim will be to ask staff will self-swab at school, ideally under supervision by the co-ordinator

● An adult will swab the students, ideally the school nurse, but this may be the parent of the child (under supervision) if needed
• The swabs will be dispatched by PHE to the school and delivered to the co-ordinator on an agreed day each week
• Ideally, all staff and students will be swabbed over two days and the samples returned to PHE, where they will be prioritised for testing
• Participants will be offered an oral fluid (saliva) test with the last nasal swab at the end of the summer term to test for SARS-CoV-2 antibodies.

4.3.3 Qualitative Research

A social science researcher will contact some of the participating schools, including those with and without multiple repeated swabbing, and conduct interviews with staff, students and parents to assess their views on the research in the context of the implementation of transmission control measures. The schools would ideally be a purposive sample of primary and secondary schools in a mixture of high and low incidence areas. Observations within each school will also include assessment of environmental measures for COVID-19 control. Some interviews may take place over the phone.

4.3.5 Testing samples

• The swabs will be tested in a PHE laboratory. Every attempt will be made to report the results of the swabs to individuals and schools as quickly as possible and no later than within 72 hours.
• The results of positive swabs will be provided to the participant and the school coordinator so that early and appropriate actions are taken to ensure the safety of students and staff
• Positive test results will also be reported to the track and trace team, and to the participants’ GP so that their medical records are appropriately updated
• National protocols will be followed if any participant tests positive, including self-isolation of the positive participant from school for 7 days
• Additional investigations of students and staff may be agreed between the investigators and the school following identification of a positive participant
• Participants with positive results and their household contacts may be approached for additional information and/or testing
• The blood samples from participating sites will be tested for SARS-CoV-2 antibodies using a validated assay at a PHE laboratory and reported back to the participants.
• The results of the blood tests may take 1-4 weeks to report depending on the numbers of tests received by the PHE laboratory.

• The oral fluid swabs will be tested over the summer and the results reported back to the individual participants.

• Any remaining serum sample at the end of the survey will be anonymised (only labelled with age and sex) and stored for future tests that might help us better understand virus infections and immunity in educational settings.

• The surveillance will be co-ordinated by PHE Colindale.

4.3.6 Data entry, analysis and presentation

The primary analysis in the sero-surveillance arm will be to estimate the rate at which enrolled participants seroconvert from antibody negative to antibody positive between the enrolment visit and subsequent visits. The primary aim of the weekly nasal swabs will be to estimate the rate of infection over time during the summer term.

The results of the surveillance will be reported to relevant authorities in PHE and the Department of Health and Social Care. A paper containing the overall results of the tests may be submitted for publication in a peer-reviewed journal. An anonymised copy of the dataset will be placed in the Office for National Statistics Secure Research Service for the purposes of wider re-use for statistics and research purposes, subject to all relevant legal, statutory and policy requirements and safeguards.

4.3.7 Withdrawal of Participants

Staff and parents/guardians are free to withdraw consent at any time without providing a reason and without any resulting detriment. The rights and welfare of the staff and families will be protected, and their medical and work/educational care will not be affected in any way.

5.0 NUMBER OF SUBJECTS

The aim is to recruit as many schools as possible across England, initially focussing on preschool and primary schools and, potentially extending to secondary schools. The number of subjects available for analysis will be dependent on several factors including: the number of enrolled schools, participation rates and attendance at school within participating schools, and follow up rates. The precision of estimates generated by the study will be dependent on the number of subjects included, the follow up time, the level of seroincidence and the design effect given how schools are sampled/enrolled.

6.0 COMPLIANCE WITH GUIDELINES

As a public health body, PHE data collection role is strictly governed. All data will be collected and handled in accordance with PHE guidelines and policy:

- recommendations of the PHE Caldicott committee
7.0 ETHICAL APPROVAL

This surveillance is being performed as part of PHE’s responsibility to investigate the risk and transmission of SARS-CoV2 among children in educational settings. This information is critical for supporting national recommendations on easing the current COVID-19 lockdown and allowing children back to school safely. This work has been identified as a public health priority and is being undertaken as part of the Public Health England’s response to the national outbreak of COVID-19 in England. The results will be used to provide an evidence base to inform national guidance and public health policy to help protect children and staff in educational settings. As such, this work falls outside of the Health Research Authority remit for ethical review. This is in accordance with the revised guidance in the Governance Arrangements for Research Ethics Committees (GAfREC) that was released in September 2011. This protocol been subject to an internal ethical review by the PHE Research Ethics and Governance Group, to ensure that it is fully compliant with all regulatory requirements.

For completeness, and as part of our duty of care, we are providing all participants a voluntary option to participate, a detailed information leaflet so that they are fully aware of what they are signing up for and a signed consent form to ensure that they have all the information they need to participate. PHE has legal permission, provided by Regulation 3 of The Health Service (Control of Patient Information) Regulations 2002, to undertake this surveillance (http://www.legislation.gov.uk/uksi/2002/1438/regulation/3/made). Regulation 3 states:

**Communicable disease and other risks to public health**

3. (1) Subject to paragraphs (2) and (3) and regulation 7, confidential patient information may be processed with a view to

(a) diagnosing communicable diseases and other risks to public health;

(b) recognising trends in such diseases and risks;

(c) controlling and preventing the spread of such diseases and risks;

(d) monitoring and managing

   (i) outbreaks of communicable disease;

   (ii) incidents of exposure to communicable disease;

   (iii) the delivery, efficacy and safety of immunisation programmes;

   (iv) adverse reactions to vaccines and medicines;

   (v) risks of infection acquired from food or the environment (including water supplies);
(vi) the giving of information to persons about the diagnosis of communicable disease and risks of acquiring such disease.

(2) For the purposes of this regulation, “processing” includes any operations, or set of operations set out in regulation 2(2) which are undertaken for the purposes set out in paragraph (1).

(3) The processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by—

(a) the Public Health Laboratory Service;

(b) persons employed or engaged for the purposes of the health service;

(c) other persons employed or engaged by a Government Department or other public authority in communicable disease surveillance.

PHE Research and Development and the Sponsors were consulted and confirmed that the work would be covered by Regulation 3 and hence does not require external research ethics approval.

PHE will indemnify all volunteers for any clinical negligence claims arising out of acting in accordance with the Study Protocol and under the direction of PHE, to the extent that the volunteer is not already covered by existing insurances which are either personal or through their employer.

7.1 Participant Confidentiality

Personal data collected for the purposes of this surveillance may include name, date of birth, age and any relevant medical information required to assess testing for SARS-CoV-2 and antibody responses. The only people with access to this information will be the surveillance staff, or regulatory authorities who may wish to check the surveillance is being carried out according to appropriate guidelines. Every effort will be made to protect the participants’ identity. The samples will identified only by a unique identification number. Data will only be used for the purposes of this study, stored in secure PHE facilities with restricted access. Identifiable data will be destroyed at the end of the study. An anonymised (i.e. no individual can be identified) copy of the dataset may be placed in the Office for National Statistics Secure Research Service for the purposes of wider re-use for statistics and research purposes, subject to all relevant legal, statutory and policy requirements and safeguards. Anonymised data will be destroyed three years after the end of the project.

8.0 TARGET DATES

- Recruitment to commence: 18 May 2020
- Completion of recruitment: at the end of the outbreak
- Completion of surveillance: when the last participant has their blood sample taken
APPENDIX 1

Sero-prevalence: Email for parents/guardians

Dear X,

We are contacting you because your child is currently attending preschool/school in England. Your school has given us permission to conduct this surveillance and to contact you. We are working with Public Health England to find out if children attending preschool/school might be infected with the coronavirus, SARS-CoV-2. We also want to find out if the children have developed antibodies against the virus. This information is important to decide how we can open the lockdown and allow children safely back to preschool/school.

Please find attached an information leaflet that provides more information for you and your child(ren).

You can attend the tests with your child when you drop them or when you pick them up from school.

We hope that you will be interested in helping us understand more about how this new virus affects children and those around them. If you are interested in your child taking part, then please call/text/email us. The school will inform you when the testing will take place.

Many thanks in advance,

Weekly Swab: email for parents/guardians

Dear X,

We are contacting you because your child is currently attending preschool/school in England. Your school has given us permission to conduct this surveillance and to contact you. We are working with Public Health England to find out if children attending preschool/school might be infected with the coronavirus, SARS-CoV-2. This information is important to decide how we can open the lockdown and allow children safely back to preschool/school.

Please find attached an information leaflet that provides more information for you and your child(ren).

You can attend the test with your child when you drop them or when you pick them up from school. We hope that you will be interested in helping us understand more about how this new virus affects children and those around them. If you are interested in your child taking part, then please call/text/email us. The school will inform you when the testing will take place.
APPENDIX 2

Sero-surveillance: Parent/Guardian Information Leaflet

We are working with Public Health England to understand how the new coronavirus, SARS-CoV-2, affects children who go to preschool, primary or secondary schools. We also want to know whether children can be infected with the virus without developing any symptoms and whether they develop immunity against the virus. This information is important because it will help us decide how to bring all the children and staff safely back to school.

We are writing to you because your child is currently attending preschool/school. Your school has given us permission to conduct this surveillance and to contact you. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you and your child. Please ask us if there is anything that is not clear.

1) Why are we doing this?

We know very little about how SARS-CoV-2 affects children, whether children can be infected with the virus without becoming unwell and what part children play in passing the virus to others.

2) What will happen if I agree for my child/children to take part?

We will ask you to sign a consent form and complete a short questionnaire about your child’s health.

We will take the following samples:

- Nose swab – this will involve rubbing a soft cotton bud on the inside of each of your child’s nostrils to test for the virus
- Blood sample – we will use local anaesthetic cream to numb the skin on the elbow or the back of your child’s hand before we take a small blood sample (5-10 mls, a teaspoonful). The blood sample will be used to check if your child has antibodies against the virus
- <<In some schools: Throat swab - this will involve gently rubbing a soft cotton bud on the back of your child’s throat to test for the virus>>
- <<In some schools: Saliva swab – this will involve collecting some saliva (spit) from your child using a small sponge on a stick that looks like a lollipop. The saliva swab will be used to test if we can...>>
measure your child’s antibodies against SARS-CoV-2 in the saliva by comparing the saliva results with the blood test results

- <<In some schools: A finger-prick test – this will allow us to collect very small blood samples to check if we can measure your child’s antibodies against SARS-CoV-2 by comparing the results with the blood test results>>

All samples will be taken by trained staff. Where possible, we will maintain physical distancing and staff will be wearing aprons, gloves and face masks when taking the samples.

3) What will happen next?

After the first appointment, we will ask you and your child to attend two more appointments where we will ask you to complete another short questionnaire and take the same samples again:

- 4-8 weeks after the first appointment (at the end of the school term)
- 4-6 months later (either the beginning and end of the next school term)

<<In some schools: we are also asking your permission to take nose swabs from your child every week to help understand the risk and transmission of the virus in school settings>>

We will contact you to arrange all your appointments.

If your child becomes unwell during the term, you should record their symptoms in the diary card provided. This will be collected with the final swab at the end of the term. This will help us understand the results of samples we take from you.

4) Will you tell me my child’s results?

We will tell you your child’s swab results as quickly as possible, but this may take a few days. Children rarely carry the virus and we expect very few children in the school (if any) to be infected the virus. If your child is infected with the virus, the school and the track and trace programme will be informed so that appropriate actions can be taken to protect the other students, staff and other contacts your child may have had. We will also inform your child’s GP so that your child’s medical records are appropriately updated. The school will ask you to keep your child at home for 7 days to stop the virus spreading to others. If your child develops any symptoms during those 7 days, then you should keep them at home for 7 days from the day of the first symptoms. Your child can then return to school as long as they are not unwell. We may contact your family for additional information and testing.
With regards to the blood tests, we will report the results to you as soon as we can, but it may take a few weeks. The results will tell you if your child has antibodies against the virus, which means that your child has been exposed to the virus before. Antibodies are proteins made by the immune system that help fight against infections, but this is not certain for SARS-CoV-2.

<<If taken: The results of the saliva/finger-prick test will take a few months, but they should be same as the swabs test and the blood test, so we will not give the same results from the saliva/finger-prick tests to you again>>.

5) What will happen to any remaining blood sample?

With your permission, we would like to store any remaining blood sample at Public Health England so that we may use it in the future for research on virus infections. The samples will be stored anonymously and it will not be possible to link the sample back to your child. You can choose what happens to any remaining samples on the consent form. Your child can still take part even if you ask us to have the samples destroyed after the tests are complete.

6) What are the benefits and risks of taking part?

We will report the results of your child’s tests to you so that you will know if your child is infected with the virus or has antibodies against the virus. The overall results will help us make important decisions about how to ease the lockdown and allow all the children and staff back to school safely.

For some, having the swab and the blood test may cause temporary discomfort. The blood test may cause a little pain, bruising, redness, and swelling around the site, bleeding at the site, and rarely, an infection at the site of the blood draw. The local anaesthetic cream will help numb the skin where the blood sample will be taken from and all the samples will be taken by very experienced staff who work with children.

7) Do I have to take part?

Participation is completely voluntary and if you choose not to take part this will not affect the care or education that your child receives.

8) Will taking part in this study be confidential?

We will need to collect some personal information, including names, date of birth, contact details some health information about your child and other household members. We need this information to
understand the results of the tests that we perform and to contact you during the surveillance. Only those involved with this surveillance will have access to this information. Your child’s questionnaire and samples will only be labelled with a unique code number and not with a name or date of birth. We will keep all information about you and your family safe and secure. We will write our reports in a way that no one can work out that your child took part in the study. All personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. An anonymised (i.e. no individual can be identified) copy of the information may be placed in the Office for National Statistics Secure Research Service for additional analysis and statistics, subject to all relevant legal, statutory and policy requirements and safeguards.

Can we change our mind?

You can decide to withdraw your child at any time, without giving a reason. We would like to keep the information and results that we might already have collected unless you tell us not to.

9) What if there is a problem?

If you have any concerns, please talk to a member of our team.

If you are still unhappy, you can contact the Public Health England Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG or email:

complaints@phe.gov.uk

Thank you for your time

sKID Surveillance Team: Name, Email, Telephone
APPENDIX 3

Sero-Surveillance: Consent Form For Parents/guardians

COVID-19 Surveillance in KIDs (code: sKID)

1. I confirm that I have read and understand the Parent/Guardian Information Sheet. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my child’s participation is voluntary. I am free to withdraw my child at any time without giving a reason and without my child’s care or education being affected.

3. I understand that the information I provide, and my child’s samples, will be labelled with a unique reference number and will not have my child’s name or any personal details recorded.

4. I understand that the samples collected will be used to test for coronavirus, SARS-CoV-2, and for immunity against the virus.

5. I understand that my and my child’s personal data will be stored in accordance with the Data Protection Act 2018 and the GDPR.

6. I agree for my child to have the nose swab taken <<In some schools: throat swab, saliva swab>>.

7. I agree for my child to have a blood test <<In some schools: finger-prick test>>.

8. I understand that if my child’s swab is positive, the results will be reported to the school to ensure the safety of students and staff, my child’s GP and the track and trace team.

The following are optional. You can still take part even if you do not consent to the two options below.

8. I agree for any remaining blood sample from my child to be stored for future research on virus infections.

9. I would like to be informed of my child’s test results.

Name of child: __________________________
Name of Parent/Guardian: _______________________
Signature: __________________________
Date: ______________
Child’s signature (optional): _______________________

Initial
APPENDIX 4

Sero-Surveillance: Short questionnaire for parents/guardian

Date:  
Participant ref:  

INFORMATION FROM PARENT/GUARDIAN  
1. Parent/guardian name: 
2. Contact email address: 
3. Contact phone number: 
4. What are parent/guardian jobs: 
5. How many children are there in your household and what are their ages? 
6. Has any household member been tested positive for COVID-19? Yes / No  
   • If yes, date: 
   • If yes, was the test positive or negative: 

INFORMATION ABOUT PARTICIPANT  
1. Name of child: 
2. Date of Birth of child: 
3. Gender: 
4. Ethnicity (please tick): 

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<td>☐ Any other Mixed / Multiple ethnic background</td>
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5. Has your child got any medical conditions? Yes / No  
   • If yes, please specify: 
6. Has your child been unwell with COVID-like symptoms since March 2020? Yes / No  
   • If yes, approximate date of symptoms: 
   • If yes, what were the symptoms: 

7. Has your child tested positive for COVID-19? Yes / No  
   • If yes, date: 
   • If yes, was the test positive or negative:
8. During the lockdown, how often did your child go to school?
   - Every day
   - Not every day but more than half the week
   - Less than half the week but more than one day
   - One day or less per week

**ADDITIONAL FEASIBILITY QUESTIONS**

We are trying to assess the practicalities of testing school children more regularly

1. **How frequently would you agree for your child to have a nose swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

2. **How frequently would you agree for your child to have a throat swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

3. **How frequently would you agree for your child to have a saliva swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

4. **How frequently would you agree for your child to have a blood test? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

5. **Any further comments:**

**BEFORE YOU LEAVE**

Please remember to keep a record of any illness and any test results done between now and your next appointment

Thank you for taking part in sKID
APPENDIX 5

Information leaflet for children under 10 years

COVID-19 Sero-surveillance in KIDs (code: sKID)

Information Leaflet

For children under 10 years of age
Background

You might have heard lots of people talking about something called the “coronavirus.” Coronavirus is a type of virus that can make you feel unwell.
What do we do?

Doctors, nurses and scientists are working very hard to find out how children are fighting the virus and we need your help.

How you can help us

We will ask you and your parents some questions about how you have been feeling. We will also ask for a small blood sample (teaspoonful). We will use a numbing cream to make sure it isn’t too sore. We will also need a test from your nose and throat called a “swab”. The swab test may be a little uncomfortable but it doesn’t hurt. Taking a swab involves wiping the inside or your nose and the back of your throat with a cotton bud. This is what a swab looks like
Do I have to take part?
You do not have to take part and, even if you say yes, you can change your mind at any time.

Who will do the tests?
The tests will be performed by nurses and doctors looking after children all the time. We are friendly but we might look a bit different than usual. To make sure we don’t pass the coronavirus around we might have to wear special clothes for protection. Below you can see how we look with and without the special clothes on.
APPENDIX 6

COVID-19 Sero-surveillance in KIDs (code: sKID)

Information Leaflet

For children aged 10 years and older
How do children fight against the Coronavirus and COVID-19?
We are asking for your help with a study to better understand coronavirus and how it affects children.

**The sKID Study**

**PROTEIN SPIKES**
These make me look like I have a *corona*, which means crown.

**GENETIC INFORMATION (RNA)**
My RNA is what makes me different from other viruses.

**ENVELOPE**
This is my outer layer.

**DID YOU KNOW?**
Washing your hands for 20 seconds using soap and water helps break down my envelope so I don’t make you sick.
Coronavirus and Covid-19 disease represents a global public health emergency. There is an urgent need for research to understand the disease process in children.

It's also called COVID-19, which stands for Coronavirus Disease 2019.

There are other types of coronavirus, but the virus that causes COVID-19 is a new type.

You also might hear it being called “novel coronavirus” because it is a new virus.

The sKID Study

is a virus that can spread easily from person to person.

The sKID Study
Background

You might have heard lots of people talking about something called the “coronavirus.” Coronavirus is a type of virus that can make you feel unwell.

What do we do?

Doctors, nurses and scientists are trying to understand how children are fighting against the coronavirus and we need your help.

How you can help us

If you agree to help us we will ask you and your parents some questions about how you have been feeling. We will also ask for a small blood sample (teaspoonful). We will use a numbing cream to make sure it isn’t too sore. We will also need a test from your nose and throat called a “swab”. The swab test may be a little uncomfortable but it doesn’t hurt. Taking a swab involves wiping
the inside or your nose and the back of your throat with a cotton bud. A picture of the swab can be seen below.
Do I have to take part?
You do not have to take part and, even if you say yes, you can change your mind at any time.

Who will do the tests?
The tests will be performed by nurses and doctors with lots of experience of looking after children. We are friendly but we might look a bit different than usual. To make sure we don’t pass the coronavirus around we might have to wear special equipment. Below you can see how we look with and without this special equipment on.
APPENDIX 7

Sero-surveillance: Staff Information Sheet

We are working with Public Health England to understand how the new coronavirus, SARS-CoV-2, is transmitted in preschool, primary and secondary schools. We also want to know whether students and staff can the virus without developing any symptoms and whether they have developed immunity against the virus. This information is important because it will help us decide how to bring all the children and staff safely back to school after the lockdown.

We are writing to you because you are a member of staff in the preschool/school. Your school has given us permission to conduct this surveillance and to contact you. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you. Please ask us if there is anything that is not clear.

1) Why are we doing this?

We know very little about how the new coronavirus affects staff and children in preschool, primary and secondary schools. We do not know whether staff or children carry the virus without becoming unwell or how the virus is transmitted in these settings.

2) What will happen if I agree to take part?

If you agree to take part, we will ask you to attend an appointment at your preschool/school. For some preschool/schools, we may ask you to attend the local Child Development Centre.

We will ask you to sign a consent form and complete a short questionnaire about your health.

We will take the following samples:

- Nose swab – this will involve rubbing a soft cotton bud on the inside of each of your nostrils to test for the virus
- Throat swab - this will involve gently rubbing a soft cotton bud on the back of your throat to test for the virus

<<In some schools:
• <<In some schools: Saliva swab – this will involve collecting some saliva (spit) using a small sponge on a stick that looks like a lollipop. The saliva swab will be used to test if we can measure antibodies against SARS-CoV-2 in the saliva by comparing the saliva results with the blood test results>>

• <<In some schools: A finger-prick test – this will allow us to collect very small blood samples to check if we can measure any antibodies against SARS-CoV-2 by comparing the results with the blood test results>>

• Blood sample – we take a small amount of blood (5-10 mls, a teaspoonful) to test for antibodies against SARS-CoV-2

All samples will be taken by trained staff. We will maintain physical distancing where possible and all staff will be wearing aprons, gloves and face masks when taking the samples.

3) What will happen next?

After you attend the first appointment, we will ask you to attend three more appointments where we will ask you to complete another short questionnaire and take the same samples again:

• Around 4-8 weeks after the first appointment, around the end of the school term
• Around the beginning and end of the next school term

<<In some schools: we are also asking your permission to take nose swabs every week to help understand the risk and transmission of the virus in school settings>>

We will contact you to arrange all your appointments.

We will also ask you to email us if you become unwell during this time so that we can keep a record of your illness. This will help us understand the results of samples we take from you.

4) Will you tell me my results?

We will tell you your swab results as soon as possible, but this may take a few days. If you are infected with the virus, the school and the track and trace programme will be informed so that appropriate actions can be taken to protect the other students, staff and other contacts you may have had. We will also inform your GP so that your medical records are appropriately updated. The school will ask you to self-isolate at home for 7 days to stop the virus spreading to others. If you develop any symptoms during those 7 days, then you should stay at home for 7 days from the day of the first symptoms. You can then
return to school as long as you are not unwell. We may contact you for additional information and testing.

We will report the results of the blood tests to you after a few weeks. The results will tell you if you have antibodies against the virus, which means that you have been exposed to the virus before.

<<If taken: The results of the saliva/finger-prick test will take a few months, but they should be same as the swabs test and the blood test, so we will not give the same results from the saliva/finger-prick tests to you again>>.

5) What will happen to any remaining blood sample?

With your permission, we would like to store any remaining blood sample at Public Health England so that we may use it in the future for research on virus infections. The samples will be stored anonymously, and it will not be possible to link the sample back to you. You can choose what happens to any remaining samples on the consent form. You can still take part even if you decide to have the samples destroyed after the tests are complete.

6) What are the benefits and risks of taking part?

We will report your results back to you, so you will know if you have antibodies against the virus. The overall results will help answer important questions and make decisions about how to ease the lockdown and allow all staff and children back to preschool/school safely.

Having the nose and throat swabs and the blood test may cause temporary discomfort. The blood test may cause a little pain, bruising, redness, and swelling around the site, bleeding at the site, and rarely, an infection at the site of the blood draw. However, the samples will be taken by very experienced staff.

7) Do I have to take part?

Participation is completely voluntary, and you can choose to take part or not.

8) Will taking part in this study be confidential?

We will need to collect some personal information about you, including your name, date of birth, contact details, some health information about you and other household members. We need this information to understand the results of the tests that we perform and to contact you during the surveillance. Only those involved with this surveillance will have access to this information. Your questionnaire and samples will only be labelled with a unique code number and not with a name or date.
of birth. We will keep all information about you and your family safe and secure. We will write our reports in a way that no one can work out that you took part. Your personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. An anonymised (i.e. no individual can be identified) copy of the information may be placed in the Office for National Statistics Secure Research Service for additional analysis and statistics, subject to all relevant legal, statutory and policy requirements and safeguards.

9) Can we change our mind?

You can decide to withdraw at any time, without giving a reason. We would like to keep the information and results that we might already have collected unless you tell us not to.

10) What if there is a problem?

If you have any concerns, please talk to a member of our team.

If you are still unhappy, you can contact the Public Health England Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG or email: complaints@phe.gov.uk

Thank you for your time

sKID Surveillance Team: Name, Email, Telephone
APPENDIX 8

CONSENT FORM FOR STAFF

COVID-19 Surveillance in KIDs (code: sKID)

1. I confirm that I have read and understand the Staff Information Sheet. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary. I am free to withdraw at any time without giving a reason.

3. I understand that the information I provide, and my samples will be labelled with a unique reference number and will not have my name or any personal details recorded on the samples.

4. I understand that the samples collected will be used to test for SARS-CoV-2 and for antibodies against the virus.

5. I understand that my personal data will be stored in accordance with the Data Protection Act 2018 and the GDPR.

6. I agree to have a nose swab taken <<In some schools: throat swab, saliva swab>>.

7. I agree to have a blood test <<In some schools: finger-prick test>>.

8. I understand that if my swab is positive, the results will be reported to the school to ensure the safety of students and staff, my GP and the track and trace team.

*The following are optional. You can still take part even if you do not consent to the two options below*

9. I agree for any remaining blood sample to be stored for future research on virus infections.

10. I would like to be informed of my test results.

<<In some schools>>

11. I agree to have a nose swab taken every week during the school term.

Name of Staff: __________________________

Signature: ________________________________________

Date: _____________
APPENDIX 9

Short questionnaire for School Staff

1. Date:  
2. Name:  
3. Contact email address:  
4. Contact phone number:  
5. Have you been unwell with symptoms that might have been due to COVID-19:  
   • If yes, approximate date of symptoms:  
   • If yes, what were your symptoms:  
6. Has any household member been tested positive for COVID-19?  
7. If any other household members are working, what work do they do (e.g. nurse working in hospital)?  
8. During the lockdown, were you working (tick the correct box):  
   ☐ Full time at the school  
   ☐ Mainly at the school  
   ☐ Equally at school and at home  
   ☐ Mainly at home  
   ☐ Only at home  
9. During the lockdown, how much physical contact did you have with students (e.g. teaching in class)  
   ☐ Regular contact  
   ☐ Occasional contact  
   ☐ No contact  
10. What is your ethnicity?  

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<td>☐ English / Welsh / Scottish / Northern Irish / British</td>
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<tr>
<td>☐ Any other White background</td>
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<td>☐ Any other Black / African / Caribbean</td>
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</tbody>
</table>
ADDITIONAL FEASIBILITY QUESTIONS

We are trying to assess the practicalities of testing school staff more regularly.

1. **How frequently would you agree to have a nose swab in the future? (tick one)**
   - ☐ Daily
   - ☐ Twice a week
   - ☐ Once a week
   - ☐ Once a month
   - □ At the beginning and end of each half-term
   - □ At the beginning and end of each term
   - □ The frequency of swabbing does not bother me
   - □ I wouldn’t agree to have any more swabs done

7. **How frequently would you agree to have a throat swab in the future? (tick one)**
   - ☐ Daily
   - ☐ Twice a week
   - ☐ Once a week
   - ☐ Once a month
   - □ At the beginning and end of each half-term
   - □ At the beginning and end of each term
   - □ The frequency of swabbing does not bother me
   - □ I wouldn’t agree to have any more swabs done

8. **How frequently would you agree to have a saliva swab in the future? (tick one)**
   - ☐ Daily
   - ☐ Twice a week
   - ☐ Once a week
   - ☐ Once a month
   - □ At the beginning and end of each half-term
   - □ At the beginning and end of each term
   - □ The frequency of swabbing does not bother me
   - □ I wouldn’t agree to have any more swabs done

9. **How frequently would you agree to have a blood in the future? (tick one)**
   - ☐ Daily
   - ☐ Twice a week
   - ☐ Once a week
   - ☐ Once a month
   - □ At the beginning and end of each half-term
   - □ At the beginning and end of each term
   - □ The frequency of swabbing does not bother me
   - □ I wouldn’t agree to have any more swabs done

10. **How would you rate your overall experience today?**
    - A. Very dissatisfied
    - B. Dissatisfied
    - C. Neutral
    - D. Satisfied
    - E. Very satisfied

11. **Any further comments:**

**BEFORE YOU LEAVE**

Please remember to keep a record of any illness and any test results done between now and your next appointment.

Thank you for taking part in sKID
APPENDIX 10

Report of swab results

Dear <<name>>

Your/your child’s nose/throat swab was positive for the coronavirus, SARS-CoV-2. We would advise you to stay/keep your child at home for 7 days starting from the day that the swab was taken.

If you/your child develop/s any symptoms during those 7 days, then please stay/keep your child at home for 7 days starting from the first day of the symptoms.

You/your child can return to school after 7 days if you/your child is well and has no symptoms. Otherwise, please wait until after the symptoms have gone before returning to school.

Report a positive antibody result

Dear <<name>>,

Many thanks for taking part in the sKID study, I would like to thank you once again for your support. <<Your/your child’s>> continued participation is essential to allow us to answer important questions about the spread of COVID in the community, what does the presence or absence of antibodies mean and how long do these last for. We are currently testing the serum samples with the Abbott assay (https://www.abbott.com/coronavirus.html).

Your Visit XX antibody level is positive. This result implies that <<you have/your child has>> been infected with or exposed to SARS-CoV-2. The PHE evaluation of this test suggests that this result is likely to be true. It is however still possible to have a false positive result. At this time, it is not known if this result means that <<you/your child>> cannot be re-infected with SARS-CoV-2, and if <<you/your child>> gets re-infected, then <<you/your child>> may still be infectious to others.
APPENDIX 11

Weekly Nasal Swabs: email for parents/guardians

Dear X

We are contacting you because your child(ren) is/are currently attending preschool/school in England. Your school has given us permission to conduct this surveillance and to contact you. We are working with Public Health England to find out whether students and staff might be infected with the coronavirus, SARS-CoV-2, during the summer term. This information is important to decide how we open the lockdown and allow children safely back to preschool/school.

Please find attached an information leaflet that provides more information for you and your child(ren). The nasal swabs will be performed at your child’s school and you will have the opportunity to be present when the swab is taken. We hope that you will be interested in helping us understand more about how this new virus affects children and those around them. If you are interested in your child(ren) taking part, then please return the signed consent form with your child or by email. We will let you know when the testing will take place so that you can attend with them.

Many thanks in advance,

XXX
APPENDIX 12

Weekly Nasal Swabs: parent/guardian information leaflet

We are working with Public Health England to understand how the new coronavirus, SARS-CoV-2, affects children, teachers and other study in preschool, primary or secondary schools. We also want to know whether children can be infected with the virus without developing any symptoms. This information is important because it will help us decide how to bring all the children and staff safely back to school.

We are writing to you because your child is currently attending preschool/school. Your school has given us permission to conduct this surveillance and to contact you. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you and your child. Please ask us if there is anything that is not clear.

10) Why are we doing this?

We know very little about how SARS-CoV-2 affects children, whether children can be infected with the virus without becoming unwell and what part children might play in passing the virus to others.

11) What will happen if I agree for my child/children to take part?

If you agree for your child to take part, we will ask you to sign a consent form and complete a short questionnaire about your family and your child’s health. We will arrange for your child to have a nose swab once a week until the end of the summer term. This will involve rubbing a soft cotton bud on the inside of each of your child’s nostrils to test for the virus. Taking a nose swab is very simple and safe. The swab will be taken by the school nurse or equivalent. You will have the opportunity to attend the session with your child if you wish. If your child is anxious or concerned, we may ask your help in taking the nose swab. Where possible, physical distancing will be maintained, and aprons, gloves and face masks will be worn when taking the nasal swab.

12) What will happen next?

The nasal swabs will be taken around the same day every week. If your child becomes unwell during the term, you should record their symptoms in the diary card provided. This will be collected with the final swab at the end of the term. This will help us understand the results of samples we take from you.
13) Will you tell me my child’s results?

We will tell you your child’s nose swab results as quickly as possible, but this may take a few days. Children rarely carry the virus and we expect very few children in the school (if any) to be infected with the virus. If your child is infected with the virus, the school and the track and trace programme will be informed so that appropriate actions can be taken to protect the other students, staff and other contacts your child may have had. We will also inform your child’s GP so that your child’s medical records are appropriately updated. The school will ask you to keep your child at home for 7 days to stop the virus spreading to others. If your child develops any symptoms during those 7 days, then you should keep them at home for 7 days from the day of the first symptoms. Your child can then return to school as long as they are not unwell. We may contact your family for additional information and testing.

14) What are the benefits and risks of taking part?

We will report the results of your child’s tests to you so that you will know if your child is infected with the virus. The overall results will help us make important decisions about how to ease the lockdown and allow all the children and staff back to school safely. For some, having the swab may cause temporary discomfort but this should last only a few seconds. A nasal swab involves inserting the tip of the cotton bud into each nostril. This is not the same as a nasopharyngeal swab, which involves inserting the swab deeper into the nasal passage and can be more painful.

15) Do I have to take part?

Participation is completely voluntary and if you choose not to take part this will not affect the care or education that your child receives.

16) Will taking part in this study be confidential?

We will need to collect some personal information, including names, date of birth, contact details some health information about your child and other household members. We need this information to understand the results of the tests that we perform and to contact you during the surveillance. Only those involved with this surveillance will have access to this information. Your child’s questionnaire and samples will only be labelled with a unique code number and not with a name or date of birth. We will keep all information about you and your family safe and secure. We will write our reports in a way that no one can work out that your child took part in the study. All personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. An anonymised
(i.e. no individual can be identified) copy of the information may be placed in the Office for National Statistics Secure Research Service for additional analysis and statistics, subject to all relevant legal, statutory and policy requirements and safeguards.

17) Can we change our mind?

You can decide to withdraw your child at any time, without giving a reason. We would like to keep the information and results that we might already have collected unless you tell us not to.

18) What if there is a problem?

If you have any concerns, please talk to a member of our team.

If you are still unhappy, you can contact the Public Health England Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG or email: complaints@phe.gov.uk

Thank you for your time

sKID Surveillance Team: Name, Email, Telephone
APPENDIX 13

Weekly Nasal Swabs: Consent Form For Parents/Guardians

COVID-19 Surveillance in KIDs (code: sKID)

1. I confirm that I have read and understand the Parent/Guardian Information Sheet. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my child’s participation is voluntary. I am free to withdraw my child at any time without giving a reason and without my child’s care or education being affected.

3. I understand that the information I provide, and my child’s samples, will be labelled with a unique reference number and will not have my child’s name or any personal details recorded.

4. I understand that the samples collected will be used to test for coronavirus, SARS-CoV-2.

5. I understand that my and my child’s personal data will be stored in accordance with the Data Protection Act 2018 and the GDPR.

6. I agree for my child to have a nose swab taken every week during the school term.

7. I understand that if my child’s swab is positive, the results will be reported to the school to ensure the safety of students and staff, my child’s GP and the track and trace team.

8. I would like to be informed of my child's test results.

Name of child: ____________________________________
Name of Parent/Guardian: __________________________
Signature: _________________________________________
Date: _________________
Child’s signature (optional): _________________________
APPENDIX 14

Short questionnaire for parents/guardian

Date: 
Participant ref: 

INFORMATION FROM PARENT/GUARDIAN
9. Parent/guardian name: 
10. Contact email address: 
11. Contact phone number: 
12. What are parent/guardian jobs: 
13. How many children are there in your household and what are their ages? 
14. Has any household member been tested positive for COVID-19? Yes / No 
   • If yes, date: 
   • If yes, was the test positive or negative: 

INFORMATION ABOUT PARTICIPANT
15. Name of child: 
16. Date of Birth of child: 
17. Gender: 
18. Ethnicity (please tick): 

White
☐ English / Welsh / Scottish / Northern Irish / British 
☐ Irish 
☐ Gypsy or Irish Traveller 
☐ Any other White background 

Mixed / Multiple ethnic groups
☐ White and Black Caribbean 
☐ White and Black African 
☐ White and Asian 
☐ Any other Mixed / Multiple ethnic background 

Black / African / Caribbean / Black British
☐ African 
☐ Caribbean 
☐ Any other Black / African / Caribbean 

Asian / Asian British
Indian ☐ 
Pakistani ☐ 
Bangladeshi ☐ 
Chinese ☐ 
Any other Asian background ☐ 

Other ethnic group
☐ Arab 
☐ Any other ethnic group (state below): 

19. Has your child got any medical conditions? Yes / No 
   • If yes, please specify: 
20. Has your child been unwell with COVID-like symptoms since March 2020? Yes / No 
   • If yes, approximate date of symptoms: 
   • If yes, what were the symptoms: 

21. Has your child tested positive for COVID-19? Yes / No 
   • If yes, date: 
   • If yes, was the test positive or negative: 

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22. During the lockdown, how often did your child go to school?
   - Every day
   - Not every day but more than half the week
   - Less than half the week but more than one day
   - One day or less per week

23. After the lockdown, how often is your child going to school?
   - Every day
   - Not every day but more than half the week
   - Less than half the week but more than one day
   - One day or less per week

**ADDITIONAL FEASIBILITY QUESTIONS**

We are trying to assess the practicalities of testing school children more regularly

1. **How frequently would you agree for your child to have a nose swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

13. **How frequently would you agree for your child to have a throat swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

14. **How frequently would you agree for your child to have a saliva swab? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

15. **How frequently would you agree for your child to have a blood test? (tick one)**
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

16. **Any further comments:**
BEFORE YOU LEAVE
Please remember to keep a record of any illness and any test results done between now and your next appointment

Thank you for taking part in sKID
APPENDIX 15

Information leaflet for children under 10 years

COVID-19 Surveillance in KIDs (code: sKID)

Information Leaflet

For children under 10 years of age
Background

You might have heard lots of people talking about something called the “coronavirus.” Coronavirus is a type of virus that can make you feel unwell.

Some people also call me

**COVID-19**

It is the sickness I cause.

COVID is short for coronavirus disease.
What do we do?
Doctors, nurses and scientists are working very hard to find out how children are fighting the virus and we need your help.

How you can help us
We will ask you and your parents some questions about how you have been feeling. We need a test from your nose called a “swab”. The swab test may be a little uncomfortable but it doesn’t hurt. Taking a swab involves wiping the inside of your nose with a cotton bud. This is what a swab looks like
Do I have to take part?
You do not have to take part and, even if you say yes, you can change your mind at any time.

Who will do the tests?
The tests will usually be done by a nurse. To make sure they don’t pass the coronavirus around, they might have to wear special clothes for protection. Below you can see how they might look like with and without the special clothes on.
APPENDIX 16

COVID-19 Surveillance in KIDs (code: sKID)

Information Leaflet

For children aged 10 years and older
How do children fight against the Coronavirus and COVID-19?
PROTEIN SPIKES
These make me look like I have a corona, which means crown.

GENETIC INFORMATION (RNA)
My RNA is what makes me different from other viruses.

ENVELOPE
This is my outer layer.

The sKID Study
We are asking for your help with a study to better understand coronavirus and how it affects children.

DID YOU KNOW?
Washing your hands for 20 seconds using soap and water helps break down my envelope so I don’t make you sick.
The sKID Study

is a virus that can spread easily from person to person.

It’s also called COVID-19, which stands for Coronavirus Disease 2019.

There are other types of coronavirus, but the virus that causes COVID-19 is a new type.

You also might hear it being called “novel coronavirus” because it is a new virus.

Corona virus and Covid-19 disease represents a global public health emergency. There is an urgent need for research to understand the disease process in children.
Background
You might have heard lots of people talking about something called the “coronavirus.” Coronavirus is a type of virus that can make you feel unwell.

What do we do?
Doctors, nurses and scientists are trying to understand how children are fighting against the coronavirus and we need your help.

How you can help us
If you agree to help us we will ask you and your parents some questions about how you have been feeling. We will also need a test from your nose called a “swab”. The swab test may be a little uncomfortable but it doesn’t hurt. Taking a swab involves wiping the inside of your nose with a cotton bud. A picture of the swab can be seen below.
ACROSS
3. Cover your ______ and sneezes
5. A new virus
8. Staying away from people in your community
9. Body temperature above normal
10. Something you wear to keep from spreading germs

DOWN
1. ______ your hands
2. Staying home if you have symptoms
4. The virus that causes COVID-19
6. Where coronavirus gets its name
7. A disease that has spread across the world
Do I have to take part?
You do not have to take part and, even if you say yes, you can change your mind at any time.

Who will do the tests?
The tests will usually be done by a nurse. To make sure they don’t pass the coronavirus around, they might have to wear special clothes for protection. Below you can see how they might look like with and without the special clothes on.
APPENDIX 17

Staff Information Sheet

We are working with Public Health England to understand how the new coronavirus, SARS-CoV-2, might be transmitted in preschool, primary and secondary schools. We also want to know whether students and staff can the virus without developing any symptoms. This information is important because it will help us decide how to bring all the children and staff safely back to school after the lockdown.

We are writing to you because are a member of staff in the preschool/school. Your school has given us permission to conduct this surveillance and to contact you. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you. Please ask us if there is anything that is not clear.

11) Why are we doing this?

We know very little about how the new coronavirus affects staff and children in preschool, primary and secondary schools. We do not know whether staff or children carry the virus without becoming unwell or how the virus is transmitted in these settings.

12) What will happen if I agree to take part?

If you agree to take part, you will be asked to attend an appointment at your preschool/school. We will ask you to sign a consent form and complete a short questionnaire about your health.

A nurse will show you how to take your own nasal swab. This involves rubbing a soft cotton bud on the inside of each of your nostrils to test for the virus and takes a few seconds only. Physical distancing will be maintained where possible and, if needed, the nurse will wear aprons, gloves and face masks.

13) What will happen next?

After you the first swab, you will be asked to provide a weekly swab around the same time every week until the end of the summer term. If you feel unwell during the term, you should record your symptoms in the diary card provided. This will be collected with the final swab at the end of the term. This will help us understand the results of samples we take from you.
14) Will you tell me my results?

We will tell you your swab results as soon as possible, but this may take a few days. If you are infected with the virus, the school and the track and trace programme will be informed so that appropriate actions can be taken to protect the other students, staff and other contacts you may have had. We will also inform your GP so that your medical records are appropriately updated. The school will ask you to self-isolate at home for 7 days to stop the virus spreading to others. If you develop any symptoms during those 7 days, then you should stay at home for 7 days from the day of the first symptoms. You can then return to school as long as you are not unwell. We may contact you for additional information and testing.

15) What are the benefits and risks of taking part?

We will report the results of your tests to you so that you will know if you are infected with the virus. The overall results will help us make important decisions about how to ease the lockdown and allow all the children and staff back to school safely. For some, having the swab may cause temporary discomfort but this should last only a few seconds. A nasal swab involves inserting the tip of the cotton bud into each nostril. This is not the same as a nasopharyngeal swab, which involves inserting the swab deeper into the nasal passage and can be more painful.

16) Do I have to take part?

Participation is completely voluntary and you can choose to take part or not.

17) Will taking part in this study be confidential?

We will need to collect some personal information about you, including your name, date of birth, contact details, some health information about you and other household members. We need this information to understand the results of the tests that we perform and to contact you during the surveillance. Only those involved with this surveillance will have access to this information. Your questionnaire and samples will only be labelled with a unique code number and not with a name or date of birth. We will keep all information about you and your family safe and secure. We will write our reports in a way that no one can work out that you took part. Your personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. An anonymised (i.e. no individual can be identified) copy of the information may be placed in the Office for
18) Can we change our mind?

You can decide to withdraw at any time, without giving a reason. We would like to keep the information and results that we might already have collected unless you tell us not to.

19) What if there is a problem?

If you have any concerns, please talk to a member of our team.

If you are still unhappy, you can contact the Public Health England Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG or email:

complaints@phe.gov.uk

Thank you for your time

sKID Surveillance Team: Name, Email, Telephone
CONSENT FORM FOR STAFF

COVID-19 Surveillance in KiDs (code: sKID)

1. I confirm that I have read and understand the Staff Information Sheet. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary. I am free to withdraw at any time without giving a reason.

3. I understand that the information I provide and my samples will be labelled with a unique reference number and will not have my name or any personal details recorded on the samples.

4. I understand that the samples collected will be used to test for SARs-CoV-2.

5. I understand that my personal data will be stored in accordance with the Data Protection Act 2018 and the GDPR.

6. I agree to have a nose swab taken every week during the school term.

7. I would like to be informed of my test results.

8. I understand that if my swab is positive, the results will be reported to the school to ensure the safety of students and staff, my GP and the track and trace team.

Name of Staff: __________________________

Signature: ________________________________

Date: ______________
APPENDIX 19

Short questionnaire for School Staff

11. Date: 
12. Name: 
13. Contact email address: 
14. Contact phone number: 
15. Have you been unwell with symptoms that might have been due to COVID-19? Yes / No  
   • If yes, approximate date of symptoms: 
   • If yes, what were your symptoms: 
16. Has any household member been tested positive for COVID-19? Yes / No 
17. If any other household members are working, what work do they do (e.g. nurse working in hospital)? 
18. During the lockdown, were you working (tick the correct box):  
   ☐ Full time at the school 
   ☐ Mainly at the school 
   ☐ Equally at school and at home 
   ☐ Mainly at home 
   ☐ Only at home 
19. During the lockdown, how much physical contact did you have with students (e.g. teaching in class)  
   ☐ Regular contact 
   ☐ Occasional contact 
   ☐ No contact 
20. Currently, were you working (tick the correct box):  
   ☐ Full time at the school 
   ☐ Mainly at the school 
   ☐ Equally at school and at home 
   ☐ Mainly at home 
   ☐ Only at home 
21. Currently, how much physical contact did you have with students (e.g. teaching in class)  
   ☐ Regular contact 
   ☐ Occasional contact 
   ☐ No contact 
22. What is your ethnicity? 

<table>
<thead>
<tr>
<th>Ethnicity Category</th>
<th>Possible Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>English / Welsh / Scottish / Northern Irish / British ☐  Irish ☐  Gypsy or Irish Traveller ☐  Any other White background</td>
</tr>
<tr>
<td>Mixed / Multiple ethnic groups</td>
<td>White and Black Caribbean ☐  White and Black African ☐  White and Asian ☐  Any other Mixed / Multiple ethnic background</td>
</tr>
<tr>
<td>Asian / Asian British</td>
<td>Indian ☐  Pakistani ☐  Bangladeshi ☐  Chinese ☐  Any other Asian background ☐</td>
</tr>
<tr>
<td>Other ethnic group</td>
<td>Arab ☐  Any other ethnic group (state below):</td>
</tr>
</tbody>
</table>

PLEASE TURN PAGE
ADDITIONAL FEASIBILITY QUESTIONS

We are trying to assess the practicalities of testing school staff more regularly

1. How frequently would you agree to have a nose swab in the future? (tick one)
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

18. How frequently would you agree to have a throat swab in the future? (tick one)
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

19. How frequently would you agree to have a saliva swab in the future? (tick one)
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

20. How frequently would you agree to have a blood in the future? (tick one)
   - Daily
   - Twice a week
   - Once a week
   - Once a month
   - At the beginning and end of each half-term
   - At the beginning and end of each term
   - The frequency of swabbing does not bother me
   - I wouldn’t agree to have any more swabs done

21. How would you rate your overall experience today?
   - A. Very dissatisfied
   - B. Dissatisfied
   - C. Neutral
   - D. Satisfied
   - E. Very satisfied

22. Any further comments:
Thank you for taking part in sKID

BEFORE YOU LEAVE
Please remember to keep a record of any illness and any test results done between now and your next appointment.
## APPENDIX 20

### Symptom Diary

Staff: Please complete this form for every episode of illness you had during the school term  
Parents/guardians: Please complete this form for every episode of illness your child had during the school term

Please shade the boxes for the days you were off school because you were ill and if you had any of the following symptoms:

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<td>Shortness of breath/difficulty breathing</td>
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<td>Nausea (feel like vomiting)</td>
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Please provide more information (e.g. test results, anyone else unwell at home, hospitalisation):
APPENDIX 21

sKIDs Bloods: email to headteacher about second appointment

Dear head teacher,

We are now approaching the end of the summer term and the staff and students participating in the sKIDs study will be having their second appointment for their tests. We would be grateful if you could send the attached questionnaires to the staff and students, respectively, to be completed and brought back to school on/before the day of testing. The amended protocol (version 1.4) including the attached questionnaire is available online at: https://www.gov.uk/guidance/covid-19-paediatric-surveillance. We will report the results of the tests back to the individual participants, but it may take a few weeks before the results become available.

Please note that we will only be testing those who had consented to take part in the first round of the tests because we have been monitoring this group throughout the summer term. We will not be recruiting any new participants at the second appointment.

Thank you once again for taking part in the sKIDs study

The sKIDs Team
Dear parent/guardian of sKID Participant,

In anticipation of your next appointment as part of our COVID Surveillance in schools, we would be grateful if you would complete a very short questionnaire and ask your child to return it to school on/before their next appointment.

To remind you, we will be taking samples from your nose and throat to see if you are infected with SARS-CoV-2. We will also be taking a blood sample to test for SARS-CoV-2 antibodies. Regardless of your previous test results, this repeat test in crucial for us to have a better understanding of the role of schools in SARS-CoV-2 infection and transmission. We are working hard to gather as much data as possible to ensure the safety of staff and students in educational settings.

Many thanks for your time

The sKID Team
sKIDs sero-surveillance: Second Questionnaire for Parents

Thank you for taking part in the sKIDs COVID-19 surveillance in schools. We are now reaching the end of the term and the second round of testing is very important to monitor changes in SARS-CoV-2 infection and antibody positivity rate in students. In order to better understand the test results, please complete the questionnaire and return it to the school on/before the day of testing.

1. Name of School:
2. Name of Parent/guardian:
3. Email address of parent/guardian:
4. Name of child:
5. Date of birth of child:
6. Since our first visit, has your child been unwell with symptoms that might have been due to COVID-19? Yes / No
   □ If yes, approximate date of symptoms:
   □ If yes, what were your child’s symptoms:
7. Since our first visit, has your child tested positive for COVID-19? Yes / No
   □ If yes, was that on: nose swab / antibody test
   □ If yes, what was the date of the test?
8. Since our first visit, has any other household member been unwell with COVID-19 symptoms? Yes / No
   □ If yes, approximate date of symptoms:
   □ If yes, what were your symptoms:
9. Since our first visit, has any household member tested positive for COVID-19? Yes / No
   □ If yes, was that on: nose swab / antibody test
   □ If yes, date of test:
10. Since our first visit, on average, has your child been going to school (tick the correct box):
    □ Everyday
    □ 3-4 days a week
    □ 1-2 days a week
    □ 1 day or less a week
    □ My child has not gone to school
11. Since our first visit, how many days has your child been off school? _______ days (write 0 if full attendance)
    If your child has been off school, the reason was (tick one)
    □ My child was unwell and had to take time off school
    □ Another student in my child’s bubble was unwell with possible COVID-19 symptoms
☐ Another student in my child’s bubble was unwell with confirmed COVID-19
☐ A staff member in my child’s bubble was unwell with possible COVID-19 symptoms
☐ A staff member in my child’s bubble was unwell with confirmed COVID-19
☐ Other (please give details):

Thank you once again for taking part in sKID
If you have any questions, please email us: sKIDs@phe.gov.uk
APPENDIX 24

**sKIDs Bloods: email to school staff about second appointment**

Dear school staff participating in the sKIDs Study,

In anticipation of your next appointment as part of our COVID Surveillance in schools, we would be grateful if you would complete a very short questionnaire and bring it with you at the next appointment.

To remind you, we will be taking samples from your nose and throat to see if you are infected with SARS-CoV-2. We will also be taking a blood sample to test for SARS-CoV-2 antibodies. Regardless of your previous test results, this repeat test is crucial for us to have a better understanding of the role of schools in SARS-CoV-2 infection and transmission. We are working hard to gather as much data as possible to ensure the safety of staff and students in educational settings.

Many thanks for your time

The sKID Team
APPENDIX 25

sKIDs sero-surveillance: Second Questionnaire for Staff

Thank you for taking part in the sKIDs COVID-19 surveillance in schools. We are now reaching the end of the term and the second round of testing is very important to monitor changes in SARS-CoV-2 infection and antibody positivity rate among staff. In order to interpret the test results, please complete the questionnaire and bring it with you on the day of testing.

1. Name of School:
2. Name of Staff:
3. Email address:
4. Age:
5. Sex: Male / Female
6. Since our first visit, have you been unwell with symptoms that might have been due to COVID-19? Yes/ No
   - If yes, approximate date of symptoms:
   - If yes, what were your symptoms:
7. Since our first visit, have you tested positive for COVID-19? Yes/ No
   - If yes, was that on: nose swab / antibody test
   - If yes, what was the date of the test?
8. Since our first visit, has any household member been tested positive for COVID-19? Yes/ No
   - If yes, was that on: nose swab / antibody tests
   - If yes, which household member (partner, child, etc):
9. Since our first visit, on average, how often have you been working in the school premises (tick one):
   - Every day
   - 3-4 days a week
   - 1-2 days a week
   - 1 day or less a week
   - I have not attended the school premises
10. Since our first visit, how much contact do you have with students (e.g. teaching in class) (tick one)
    - Regular contact /mainly student facing
    - Occasional contact /some student facing
    - No contact
11. Since our first visit, how many days have you taken off work? ________ days
    If you took time off work, the reason was (tick one)
Thank you once again for taking part in sKID

If you have any questions, please email us: sKIDs@phe.gov.uk

☐ I was unwell with possible COVID-19 symptoms
☐ Another staff member in my bubble was unwell with possible COVID-19 symptoms
☐ Another staff member in my bubble was unwell with confirmed COVID-19
☐ A student in my bubble was unwell with possible COVID-19 symptoms
☐ A student in my bubble was unwell with confirmed COVID-19
☐ Other (give details):
APPENDIX 26

sKIDs Swabs: email to headteacher about second questionnaire and oral test

Dear head teacher,

RE: 1. Questionnaires to be completed by the staff and student participants
2. SARS-CoV-2 antibody testing using oral fluid (saliva)

We are now approaching the end of the summer term and the staff and students participating in the sKIDs study will be having their final swabs. We would be grateful if you could send the attached questionnaires to the staff and students respectively to be completed and brought back to school on the day of the final swabbing. These forms can be returned with the swabs by courier. You may or may not wish to photocopy the forms for your records.

Additionally, at Public Health England, we have developed an oral fluid (saliva) test to measure antibodies against the novel coronavirus SARS-CoV-2 and can be done at the same time as the last nose swab. The amended protocol (version 1.4) is available online at: https://www.gov.uk/guidance/covid-19-paediatric-surveillance. We would like to offer the test to the thousands of staff and students taking part in the sKIDs study across the country and we will be reporting the results back to the individual participants, but it may take a few weeks before the results become available.

The attached document provides the participating staff and students with more information about the oral fluid (saliva) tests and an option to consent for the test on the questionnaire page. Please note that the saliva test is only being offered to those who took part in the nose swab surveillance because we have been monitoring this group throughout the summer term.

We will be sending out instructions with a video link on how to take an oral fluid (saliva) swab with the next pack of saliva swabs. Both the samples need to have the same unique participant number (e.g. AXW1) for each participant with the date of sample and placed in the same bag. All other processes will remain the same. We will pick up all the samples at the end of the swabbing session as previously arranged.

We thank you once again for taking part in this important Public Health England study

The sKIDs team
Dear parent/guardian,

RE: 1. Questionnaires to be completed by the staff and student participants
    2. SARS-CoV-2 antibody testing using oral fluid (saliva)

Thank you for taking part in the sKIDs study. We are now approaching the end of the summer term and the last nose swab will be due soon. In order to better understand the results of the tests, we would be grateful if you could please complete the attached questionnaire and send it back to school with your child. It is important that your child has the complete form for the final nose swab.

We have also developed an oral fluid (saliva) test to measure SARS-CoV-2 antibodies at the national reference laboratory at Public Health England. The test involves placing and rotating a small sponge into the mouth for two minutes, similarly to the motion and timing of toothbrushing. We are offering the test to thousands of staff and students taking part in the sKIDs study and we will be reporting the results of the antibody test to all those who agree to take part, but it may take a few weeks before the results become available. If you would like to take part in the saliva antibody test, please sign the top of the questionnaire and hand it to the team taking final nose swab at the school. We will email you with the results as soon as they become available. If you have any questions, please email us at skids@phe.gov.uk. Thank you once again for taking part in this important Public Health England study

The sKIDs Team
APPENDIX 28

sKIDs swabs: Second Questionnaire for Parents

Please complete the questionnaire and return the completed questionnaire to school on the day of testing.

If you would like your child to have the oral fluid (saliva) test for antibodies against the novel coronavirus SARS-CoV-2, please sign and date here:

Signature: ___________________________________________ Date: ____ / ____ / ________

1. Name of School:
2. Name of Parent/guardian:
3. Email address of parent/guardian:
4. Name of child:
5. Date of birth of child:
6. Since the first swab, has your child been unwell with symptoms that might have been due to COVID-19? Yes / No
   - ☐ If yes, approximate date of symptoms:
   - ☐ If yes, what were your child’s symptoms:
7. Since the first swab, has your child tested positive for COVID-19? Yes / No
   - ☐ If yes, was that on: nose swab / antibody test
   - ☐ If yes, what was the date of the test?
8. Since the first swab, has any other household member been unwell with COVID-19 symptoms? Yes / No
   - ☐ If yes, approximate date of symptoms:
   - ☐ If yes, what were your symptoms:
9. Since the first swab, has any household member tested positive for COVID-19? Yes / No
   - ☐ If yes, was that on: nose swab / antibody test
   - ☐ If yes, date of test:
10. Since the first swab, on average, has your child been going to school (tick the correct box):
    - ☐ Everyday
    - ☐ 3-4 days a week
    - ☐ 1-2 days a week
    - ☐ 1 day or less a week
    - ☐ My child has not gone to school
11. Since the first swab, how many days has your child been off school? _______ days (write 0 if full attendance)
    - If your child has been off school, the reason was (tick one)
      - ☐ My child was unwell and had to take time off school
      - ☐ Another student in my child’s bubble was unwell with possible COVID-19 symptoms
☐ Another student in my child’s bubble was unwell with confirmed COVID-19
☐ A staff member in my child’s bubble was unwell with possible COVID-19 symptoms
☐ A staff member in my child’s bubble was unwell with confirmed COVID-19
☐ Other (please give details):
APPENDIX 29

sKIDs Swabs: Email to School Staff about second questionnaire & oral fluid test

Dear staff member

RE: 1. Questionnaires to be completed by the staff and student participants
     2. SARS-CoV-2 antibody testing using oral fluid (saliva)

Thank you for taking part in the sKIDs study. We are now approaching the end of the summer term and the last nose swab will be due soon. In order to better understand the results of the tests, we would be grateful if you could please complete the attached questionnaire and hand it in to the team when you have your final nose swab.

We have also developed an oral fluid (saliva) test to measure SARS-CoV-2 antibodies against the novel coronavirus SARS-CoV-2 at the national reference laboratory at Public Health England. The test involves placing a small sponge into the mouth for two minutes and can be done at the same time as the nose swab. We are offering the test to thousands of staff and students taking part in the sKIDs study and we will be reporting the results of the antibody test to all those who agree to take part, but it may take a few weeks before the results become available. If you would like to take part in the saliva antibody test, please sign the top of the questionnaire and hand it to the team taking final nose swab at the school. We will email you with the results as soon as they become available. If you have any questions, please email us at skids@phe.gov.uk. Thank you once again for taking part in this important Public Health England study

The sKIDs Team
APPENDIX 30

sKIDs swabs: Second Questionnaire for Staff

Please complete the questionnaire and bring it with you on the day of the last swab

If you would like to have the oral fluid (saliva) test for antibodies against the novel coronavirus SARS-CoV-2, please sign and date here:

Signature: ____________________________  Date: ____ / ____ / ________

1. Name of School:
2. Name of Staff:
3. Email address:
4. Age:
5. Sex: Male / Female
6. Since the first swab, have you been unwell COVID-19 like symptoms? Yes/ No
   □ If yes, approximate date of symptoms:
   □ If yes, what were your symptoms:

7. Since the first swab, have you tested positive for COVID-19? Yes/ No
   □ If yes, was that on: nose swab / antibody test
   □ If yes, what was the date of the test?

8. Since the first swab, has any household member been unwell with COVID-19 like symptoms? Yes/ No
   □ If yes, was that on: nose swab / antibody tests
   □ If yes, which household member (partner, child, etc):

9. Since the first swab, has any household member been tested positive for COVID-19? Yes/ No
   □ If yes, was that on: nose swab / antibody tests
   □ If yes, which household member (partner, child, etc):

10. Since the first swab, on average, how often have you been working in the school premises (tick one):
    □ Every day   □ 3-4 days a week   □ 1-2 days a week   □ 1 day or less a week
    □ I have not attended the school premises

11. Since the first swab, how much contact do you have with students (e.g. teaching in class) (tick one)
    □ Regular contact /mainly student facing
    □ Occasional contact /some student facing
☐ No contact

12. **Since the first swab**, how many days have you taken off work? _______ days

   *If you took time off work, the reason was (tick one)*

   ☐ I was unwell with possible COVID-19 symptoms

   ☐ Another staff member in my bubble was unwell with possible COVID-19 symptoms

   ☐ Another staff member in my bubble was unwell with confirmed COVID-19

   ☐ A student in my bubble was unwell with possible COVID-19 symptoms

   ☐ A student in my bubble was unwell with confirmed COVID-19

   ☐ Other (give details):